## **Medical devices**

## Research and development of innovative remote cardiac rehabilitation system

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## Project Outline

The number of patients with heart failure (HF) in Japan is estimated as over 1.2 million, and further increase is expected in future as HF is prevalent in the elderly. The biggest issue of HF is its high rehospitalization rate. In Japan, two in five patients experience re-hospitalization within one year after discharge. It is reported that cardiac rehabilitation improves cardiopulmonary function of the patients and effective in lowering rehospitalization rate. However, only <10% eligible patients are receiving cardiac rehabilitation program in Japan. The main reason for this is that it is difficult for those elderly patients to visit hospitals frequently.

In this research and development, we will develop a system that can provide home-based cardiac rehabilitation under remote supervision from medical facilities at remote site. By establishing this system, patients will be able to have effective and efficient rehabilitation at home. In results, the extension of healthy life expectancy, improvement in quality of life and decrease in rehospitalization rate will be given to the patients.

This project was launched after clinical observation and needs finding in medical institutions, evaluation and screening of the needs, concept creation and business model verification through the Japan Biodesign fellowship program at Osaka University which is an educational program for entrepreneurs to develop medical equipment. After the program, we added further investigation from the viewpoint of medical practice flow and business implementation, iterative prototyping, and the first system was developed. We have already completed feasibility study proving the usability of the system, safety for remotely-supervised cardiac rehabilitation at home and high participation rate.

Clinical trials for the regulatory application have started since this trial was adopted by AMED in 2019, and preparations to get the approval for the medical device is ongoing.



Several Patents already applied

Target disease: Chronic heart failure

Intellectual property: 2 applications

Market: HF patients is estimated as >1.2 million and still increasing. The market size is 442 billion yen. The number of patients in the US and the market size are about five times that of Japan. Other diseases where exercise has been proved to be clinically efficient such as dialysis (0.3million), hypertension (10million), diabetes (3.1 million), chronic obstructive pulmonary disease (5.3 million) and depression (1.1 million) will be the next target market.

Coopration with enterprises: We are promoting joint research and development with Remohab. Inc.