Study Title: A Pilot Sensor-controlled Digital Gaming Intervention With Real-time Behavior Tracking to Motivate Self-management Behaviors in Older Adults With Heart Failure

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Document Title: Study Protocol

Background:
There remains a great need for in-home, scalable and resource-conservative approaches to support and motivate older adults especially in heart failure self-management behaviors with the poorest adherence: weight monitoring and physical activity.[8,9] One promising approach is the use of sensor-controlled[10] digital games (SCDGs), which offer an accessible learning and habit-forming medium that can make heart failure self-management more engaging and immersive while objectively measuring heart failure self-management behaviors.

Objective
To compare trends in the primary outcome of engagement in the heart failure self-management behavior of daily weight-monitoring and secondary outcomes of physical activity engagement, quality of life, functional status, heart failure self-management knowledge, self-efficacy, and heart failure hospitalization at baseline and weeks 6, 12, and 24, in a SCDG playing group (Intervention Group: IG) versus a control group (CG) that receives sensors and app tracking weight monitoring and activity only.

Study Protocol:
Study Design: Prospective feasibility randomized controlled trial (1:1) with 2 parallel groups (sensors alone or sensors plus SCDG app)

Study Population and Recruitment
Before COVID-19, we identified potential participants through chart review at a cardiac rehabilitation center as well as through referrals by clinical case managers at an inpatient cardiac floor in central Texas. Research staff provided information on the study to adults who were age 55 years or older, English-speaking diagnosed with HF, and classified in the New York Heart Association's HF classification II to III [32] during their inpatient stay or outpatient visit to the cardiac center. Other eligibility criteria included smartphone ownership as a proxy measure to indicate prior familiarity with smartphone usage, ability to independently walk without a walker or human assistance, and score of 4 or above on the Mini-cog [33] cognitive screen. Exclusion criteria included severe visual or tactile impairments (e.g., legal blindness or severe arthritis), which would adversely prevent the use of a smartphone, or end-stage renal failure or terminal illness (e.g., cancer), both of which adversely affect HF prognosis [34].

To continue the trial during the COVID19 pandemic, all in-person interactions were converted to remote interactions. We used a secure, HIPAA-compliant email system to continue receiving referrals from clinical case managers at the inpatient HF center. In addition, we contracted with the participant recruitment company Trialfacts [35] to recruit participants online from the states of Texas and Oklahoma. The eligibility criteria remained the same, but the formal screening process then requested a narrative description of HF history or confirmation from the potential participant's healthcare provider to confirm the individual's HF diagnosis.

Intervention Procedures
CONSORT guidelines [40] informed this parallel-group RCT and reporting of outcomes. The SCDG intervention group (IG) received sensors tracking weight-monitoring and physical activity and played the SCDG app on a mobile smartphone; the control group (CG) received sensors tracking weight-monitoring and physical activity only. Both IG and CG participants were given

the Withings Go activity tracker [41], Body smart weight scale [42], and Health Mate app [43] to record, store, and transmit daily weight and physical activity data, but the CG did not receive the SCDG app. Also, whereas the IG received standardized HF education [6,38] embedded within the SCDG, the CG received the same information in written format. Thus, the difference between the IG and CG as receipt of the SCGD gaming elements. The SCDG app transmitted IG participants' game playing and the Health Mate app transmitted all participants' sensor data to the research team via cellular data service or home Wi-Fi. Before the COVID19 pandemic, an intervention nursing research assistant installed the apps on IG and CG participants' smartphones and trained participants to use the sensor devices and apps at either the participants' homes or a location of their convenience. During the COVID19 pandemic, in-person interactions were converted to remote interactions. Contactless delivery of study equipment, video-conferencing on smartphones, and printed pictorial and video instructions allowed remote support for installation, training, and troubleshooting of the devices and apps. The study team members' experience with the devices and apps during in-person interactions with the older adults in their homes helped inform the training materials that were provided to the participants during the pandemic. Installation and training times by the research team member varied widely during the remote phase from 0 (participant self-installation) to 180 minutes as compared to 45 to 120 minutes during in-person phase.

Randomization

Participants were assigned into CG and IG with a 1:1 randomization ratio, such that the 2 groups were equivalent in terms of gender. Randomization was done after informed consent and the baseline survey were obtained. The allocation sequence list for block randomization was generated by an independent researcher at the Sealed Envelope Ltd website [44] with random block sizes of 2 and 4 and concealed in sequentially numbered, opaque, sealed, stapled envelopes until the trial group was assigned. To ensure blinding during assessment of the outcomes, the research assistant who delivered the intervention to the 2 groups was different from the research assistant who collected the baseline and follow-up surveys from the 2 groups. The researcher who performed the data analysis was blinded to the participant groups. The participants were also blinded to the IG

Ethical Considerations

The University of Texas at Austin Institutional Review Board approved this study on July 30, 2018 (number 2017-12-0042).