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TITLE: The Effect of Interactive Simulations on Exercise Adherence with Overweight and Obese Adults

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14. ABSTRACT This clinical research protocol was designed to test exercise adherence between two groups riding a stationary bicycle: one while watching television and the other one while playing video games. Related variables tested were exercise motivation and self-efficacy in overweight and obese adults. Unique software was written to integrate the exercise equipment/video game components, and to capture and transfer data from the exercise bicycle ergometer to the study database computer. This protocol was submitted to the local Institutional Review Board (IRB) which required revisions to be made. During the reporting period MAJ Melba C. Stetz replaced Dr. Sarah D. Miyahira as the Principal Investigator and submitted the required changes both to the local IRB and the 2nd-level reviewers at Medical Research and Materiel Command in Fort Detrick, Maryland. The Start Letter was received on Dec 20, 2010 and recruitment of participants commenced in Feb 2011.						
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INTRODUCTION:

This study examines the effects of interactivity with video game play on exercise adherence, exercise motivation, and self-efficacy in overweight and obese Army personnel. Despite being younger, less obese, and more physically fit than the average American adult, many active duty personnel are challenged by being overweight and obese. These conditions adversely impact military readiness and mission-related success. While increased activity level has proven to be a critical element in weight loss and improved health, adherence to physical exercise programs have been problematic. Two important mediators in this relationship are self-efficacy and motivation to exercise. Interactive simulations such as video games are highly engaging and provide positive visual and auditory stimulation that may allow participants to enhance and maintain positive exercise behaviors. The project randomizes 60 active duty military participants into 2 exercise groups---one using video game-enhanced exercise bicycles and the other using non-enhanced exercise bicycles. A repeated measures experimental design is used to evaluate group differences in exercise adherence, self-efficacy, and exercise motivation. Secondary variables include cardiovascular fitness, exercise behavior indicators, physiologic changes, health perceptions, and quality of life. The longer-term goal of this effort is to improve the readiness of military personnel and the health status of the general public through the study of innovative applications of new and emerging technologies to treat behavioral health disorders.

BODY:

Task 1: Submit protocol for IRB and second level review approval

The protocol was submitted to the local Institutional Review Board (IRB). The IRB reviewers required the following changes: addition of a Medical Monitor (MM), additions to the Consent form so that females must undergo an urinalysis (UA) for pregnancy screening. In addition, the IRB reviewers required only to asking for the last four of numbers of a participant's Social Security Number (unless there is a health concern brought up by the MM), removing CIRO's mention in the protocol, and allowing participants to skip any question that they do not want to answer. There was also a change of Principal Investigator (PI); MAJ Melba C. Stetz replaced Dr. Sarah D. Miyahira as the PI. Once MAJ Stetz took over (informally in OCT and formally in DEC) she submitted the required changes on Nov 16, 2010 to both the local IRB and the 2nd-level reviewers at the Medical Research and Materiel Command (MRMC), in Fort Detrick, Maryland. The start Letter was received on Dec 20, 2010.

Task 2: Evaluate, purchase, setup equipment and physiologic monitors

The software was further refined and modified and new equipment was purchased to test the system. The new items purchased include: a multi-port serial connector, another television, and an infrared device to control the television. See Task 3 for more details. Additionally, as space for the project was identified and allocated, the PI purchased a 2nd and a 3rd set of equipment including: bicycles, computers, videogame systems, videogames, monitors, etc.

Task 3: Develop, install, test software to capture exercise data

While the prototype was fully functional with the software that communicates between the heart sensor and the monitor, it required the exercise monitor to be reconfigured for each participant prior to beginning each session. Therefore, another option was tested. This option was the use of an infrared unit that interfaces with the PC while it is attached to the television. This process replicated the signal sent by the television remote control device.

Task 4: Hire & train research staff on equipment and protocol procedures

Due to the delay of IRBs, UCERA, USAMRAA, and TATRC process, the hiring of the Research Coordinator did not take place until Jan 2011. Additionally, three Research Assistants were hired in Feb 2011.

Task 5: Pilot test procedure & equipment on 5 volunteers (no data collection)

Final testing of connectivity and functionality was completed using the existing project team staff.

Task 6: Recruit & identify participants

Recruitment has commenced and 10 volunteers have been identified as possible participants.

Task 7: Assess, randomize, run study

Participant assessments, randomization, and exercise protocol implementations are planned for the next performance period.

Task 8: Analyze data and complete final report

This task will be done close to the ending of this study.

RESEARCH ACCOMPLISHMENTS:

- Submission of modification to the protocol to both IRBs (local and 2nd-level MRMC).
- Modification of software to capture and record real time physiological and other exercise-related study variables.
- Refinement of software to enable exercise performance data transfer from the bicycle ergometer to a personal computer database while the participant is exercising.
- Refinement of software to create unique user codes that allow the heart rate levels of as many as 8 participants to be monitored simultaneously on a single screen.

REPORTABLE OUTCOMES:

Submission of the modified protocol to both IRBs (local and 2nd-level MRMC). Also, a request for a final no-cost extension has been submitted.

CONCLUSION:

It is expected that after the data has been collected and analyzed during the next performance period, a summary of the results and their impact will be discussed.

REFERENCES:

Not applicable at this time.

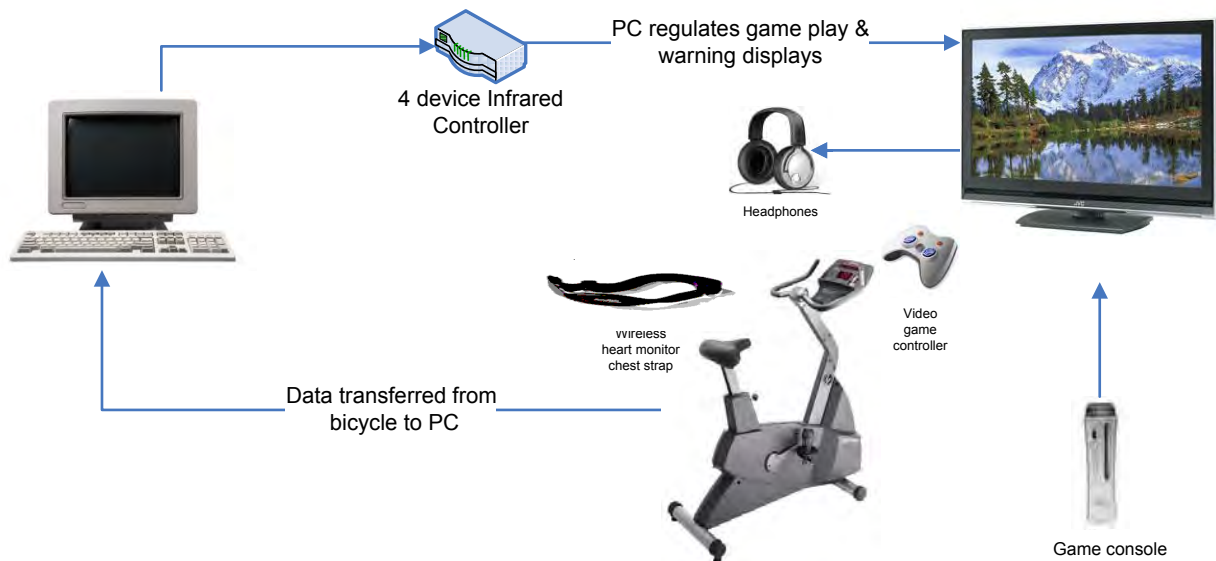
APPENDICES:

Appendix A: Diagram of Integrated Exercise Bicycle-Video Game Prototype and Related Procedures.

SUPPORTING DATA:

Not applicable at this time.

Appendix A: Diagram of Integrated Exercise Bicycle – Video Game Prototype and Related Procedures



- Participant assigned unique identifier and physical data (height, weight, age, gender, blood pressure) recorded and stored in computer database.
- Wireless heart monitor chest strap transfers heart rate data to bicycle ergometer
- Software determines target heart rate zone based on stored participant data
- Wireless game controller interfaces with video game
- Game play continues while in target heart rate zone
 - Warning displayed on television screen if heart rate is under or over target zone
 - Television shuts off ending video game play if heart rate does not return to target zone
- Heart rates of up to 8 participants concurrently displayed and monitored on the computer
- Four separate channels are regulated through infrared controller (study group)
- Headphones are provided to avoid disrupting other participants