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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 project was designed to evaluate the effect of video game play on exercise motivation, self-efficacy, and adherence in overweight and obese adults. Unanticipated events required modifications to the project schedule and delayed data collection. Exercise equipment and software that met the study requirements were not available. Therefore, the project team opted to develop a prototype stationary exercise bicycle that integrated video game play capabilities, and to create software that integrated the components and transferred data from the exercise bicycle ergometer to the study database. Available commercial components, e.g., stationary exercise bicycle and video game console, were used to develop the prototype exercise bicycle which allows a participant to continue video game play contingent upon maintaining his or her target heart rate zone while pedaling. If the heart rate falls below the target zone, game play stops. Unique software had to be developed to create a functioning unit and to transfer the data. The software allows performance data to be automatically transferred to the database during the exercise session, and eliminates the need for a separate television controller. In addition, the software requires minimal re-configuration for each participant, and provides simultaneous heart rate level monitoring displays for up to 8 cyclists. A no-cost extension was obtained to support data collection in the subsequent performance period.					
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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 overweight and obesity. 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 has been problematic. Two important mediators of 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

Several events occurred during the previous award period that resulted in unanticipated postponements of the protocol submission. The local military administrative principal investigator (PI-A) was frequently away at job-required training and travel during the 2007 award period, which resulted in a substantial delay in the preparation and IRB submission of the protocol. Early in the 1st quarter of the award period, the PI-A received a new posting to the East Coast. Unfortunately a replacement PI-A was not identified prior to her departure. About the same time a change in the base command occurred, and the new commander required that the project be re-reviewed by the base ethics board, and that a replacement PI-A be identified prior to approval of the protocol application for submission to the Navy IRB. The ethics board approved the protocol for submission, and a replacement PI-A was identified during the first quarter of the performance period. However, before the protocol was submitted to the IRB, the new PI-A left on a training assignment, and did not return until early in the 2nd quarter. Upon his return, he learned that the local base Federal Wide Assurance had lapsed. The protocol could not be submitted to the IRB until the assurance was reinstated, which took several months. In the 3rd quarter, the new PI-A was notified that he was being deployed for eight months, and began a search for a replacement PI-A. Early in the 4th quarter a new PI-A returning from deployment arrived on the base. However, she indicated that the workload at the base clinic had increased and would not be able to serve as the PI-A. The project was subsequently transferred to Tripler Army Medical Center where there is greater stability in staffing, and adequate facilities to support the project. A no-cost extension was obtained to enable data collection during the next performance period. The protocol is expected to be submitted to the local IRB in the 1st quarter of the new performance period. It is anticipated that submission to the second-level review authority will occur during the 2nd quarter upon receipt of local IRB approval.

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

Substantial development on a prototype exercise bicycle for use in the study was completed during the first year of the award. As there was no commercially available stationary exercise bicycle with the capabilities required for the study, the project developed exercise equipment with an interactive video game unit. Unique software was written to integrate the components into a functioning unit that met protocol specifications. An additional 10 months, not included in the original projected project schedule, were required to develop and test the prototype exercise unit and software. During the performance period, the software was further refined and modified. During this performance period, the project

purchased a multi-port serial connector, another television, and an infrared device to control the television. See Task 3 for more details.

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

During the first year, an exercise bicycle, television controller, computer, TV monitor and video game console was purchased to create the prototype. During this period a database and user interface was also developed. While the prototype was fully functional, it required the exercise monitor to reconfigure the TV controller for each participant prior to beginning exercise. Although the configuration was not complex, an error at any of the several steps would not control the television in accordance with the protocol. As a result, manual configuration caused a concern about the reliability of the study data obtained. Therefore, two new alternatives were considered. The first solution tested a television with a serial port connection to the PC, which was the most economical. Unfortunately, the program codes provided by the television manufacturer were not reliably responsive when submitted from the personal computer. Some features worked occasionally, other required actions did not work at all. The television manufacturer was unwilling to assist with troubleshooting so this alternative was considered unworkable.

The second alternative was an infrared unit interfaced with the PC and attached to the television, which replicated the signal sent by the television remote control device. This solution proved to be fully effective, and programming was performed to include remote infrared signals to automatically turn the television on and off at the start and ending of the exercise activity. Additional programming and configuration will be necessary to ensure there is no cross communication between exercise units while multiple users are actively exercising. However, no problems are anticipated as the infrared transmitter is taped directly to the infrared receiver on the television. Final testing will be performed after IRB protocol approval is received, and additional equipment is purchased.

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

Hiring of the research coordinator and research assistants was deferred as a result of the protocol submission delays and the development of the exercise equipment prototype and related software. These positions will be filled after IRB approval of the study protocol is received. It is anticipated that personnel training on the equipment and protocol procedures will be completed in 2 weeks.

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

Initial testing of connectivity and functionality was completed using the existing project team staff. Testing with the volunteers will be finalized following assembly, installation, and testing of all of the exercise equipment units at the study site.

Task 6: Recruit & identify participants

Participant recruitment will begin when protocol approval is received from the local IRB and the second-level review authority.

Task 7: Assess, randomize, run study

Participant assessments, randomization, and exercise protocol implementation will begin upon receipt of local IRB and the second-level review authority approvals.

Task 8: Analyze data and complete final report

Data analysis and completion of the project final report are anticipated to occur in the last quarter of the no-cost extension year.

RESEARCH ACCOMPLISHMENTS:

- Modification of software to capture and record real time physiologic 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 and allow the heart rate levels of as many as 4 participants to be monitored simultaneously on a single screen.

REPORTABLE OUTCOMES:

Due to unanticipated delays in the submission of the study protocol for IRB approval (see Body-Task 1), and modifications to the software to automatically capture and transfer the data to the study database computer (see Body-Task 3), the implementation of the protocol was deferred until local and second-level IRB approvals are obtained. A no-cost extension was requested and approved for a third year of the project.

CONCLUSION:

It is premature to discuss any conclusions at this time. It is expected that after the data has been collected and analyzed later in the next performance period, a summary of the results and their impact will be discussed.

REFERENCES:

Not applicable at this time.

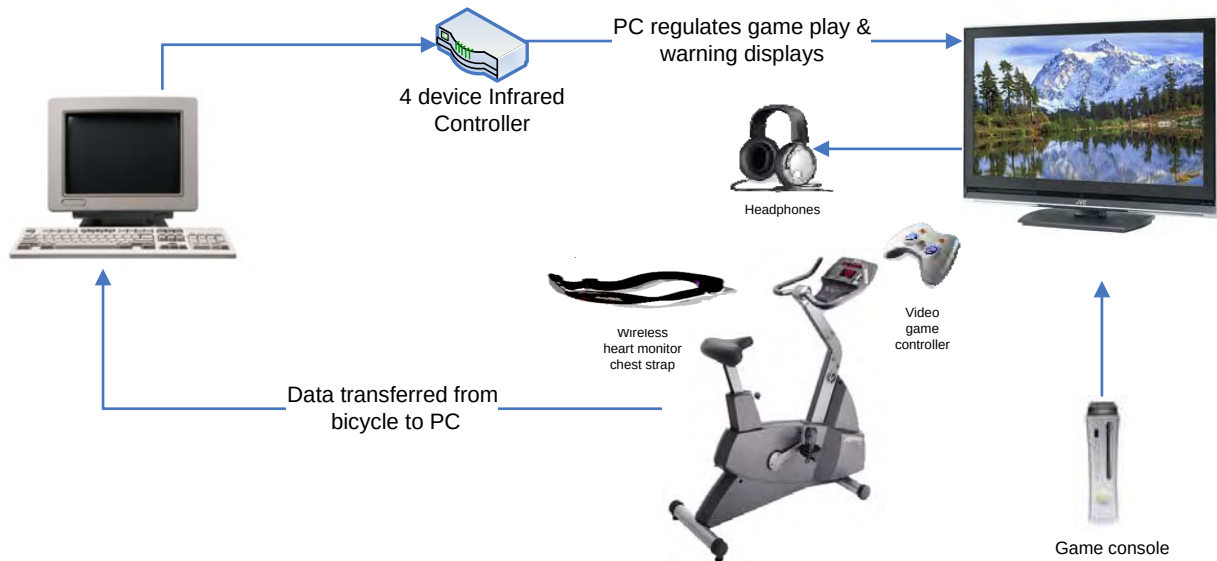
APPENDICES:

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