Unique Protocol ID:	Motiview Project
Brief Title:	Motivating Videos to Encourage Cycling for Geriatric Rehabilitation
NCT ID:	Not yet assigned.
DATE:	January 3rd, 2018

BACKGROUND

As the Canadian population continues to age with life expectancy being prolonged, creative ways to encourage activity of older adults is vital. Aging is associated with a reduced motivation for physical activities (Etnier et al., 2017), a decline in motor skills, mobility impairment resulting in a higher risk of falls. These complications are compounded when the older adult sustains an injury (e.g. hip fracture) and must undertake rehabilitation. According the World Health Organization, the aim of rehabilitation is to maximize function and minimize limitation of activity and restriction of participation resulting from an underlying impairment or disease. In order to reach these aims, modalities must optimize effectiveness through optimal engagement of the participant. Aerobic exercise activity has been recommended for older adults as it has been shown to reduce age-related decline and improve functional capacity (Lemura, von Duvillard, & Mookerjee, 2000). It has also been shown to enhance cognitive function (Colcombe & Kramer, 2003).

Motiview, the solution by Motitech, provides a possible solution for elderly reducing unnecessary emergency department visits, preventing falls/fall-injuries, improving management of complex health conditions, and improving brain health/cognitive fitness. Motiview was developed in 2013 and has been rolled out to more than 60 Nordic municipalities. Motiview is a motivational tool that stimulates elderly to increase their physical activity and cognitive training. By using videos, music and sound displayed on a TV screen, the user can take a cycle trip through familiar surroundings and memories. Motiview is coupled to a mobile user-adapted cycle-trainer (TheraTrainer (Figure 1)) that elicits activity as the individual pedals the virtual trip. TheraTrainer facilitates activity for numerous populations by allowing motor-operated (passive), motor-assisted or active movement training (using your own muscle power) from the safety of a chair, armchair or wheelchair. Motiview is a large and continuously growing video- and music-library with the ability to create new cycle trips according to the users' wishes and memories. Incorporating appropriate music into activity programs adds interest and serves to facilitate participation and adherence. By lessening the perceptions of difficulty, monotony, and discomforts associated with physical activity, participation and the experience is enhanced.

Figure 1: TheraTrainer

Additionally, since the virtual cycle trip is displayed on the TV screen, observers (family members, other residents, staff, etc.) may receive secondary benefits of reminiscence which may in-turn facilitate continued conversation of past experiences. Reminiscence, defined as inducing a vocal or silent recall of past activities, events, and experiences in the life of a person by using tangible prompts (Huang, Chen, & Chen, 2015), has been shown to be effective in improving cognitive functions while reducing depressive symptoms. While Motiview is a large and continuously growing video- and music-library, the ability to create new cycle trips according to the users' wishes and memories increases reminiscence for that individual.

Therefore, the research protocol of this project is designed to document the added value of Motiview for achieving activity participation. Qualitative data will be gathered on the social aspects and reminiscence observed with the video/audit overlay in order to capture user satisfaction and staff and caregiver perceptions.

DESIGN & METHODS

Implementation will be conducted in two settings (Geriatric Day Hospital (GDH) (Elisabeth Bruyere Hospital and the Day Treatment Centre (DTC) Baycrest Health Sciences)). The settings selected have similar client profiles in terms of age, frailty, cognition, etc. Three subject groups will be included to obtain a holistic understanding of the use of this technology: geriatric program clients (clients) and their carers (carer) and staff (staff). All subjects (clients, carers and staff) will consent to participate prior to continuing with study involvement as documented below.

Recruitment & Consent Procedures:

- Baycrest –

Clients

DTC clients will undergo their usual intake assessment conducted by the DTC clinical team. Any clients who are determined to be medically unstable based on this assessment will not be recruited for this study. At the end of this assessment, any clients who are eligible for the study will be introduced to the study by the intake team. If they verbally consent to finding out more details about the project, their contact information will be provided to a research assistant (RA) who will then call the client with more information. If the client agrees to participate, they will be scheduled to meet the RA when they attend their regular DTC session during a time that does not conflict with treatment interventions or regular programming. At this point, the clients may choose to take part in a consenting session with the RA, followed by baseline testing. As a risk management strategy, the DTC clinical team will inform the research staff if a client is determined to be unable to continue participation at any point in the study.

Consent: Carers will be asked to contact the RA if they have any questions regarding the research project or if they would like to participate. On this call, the RA will confirm their understanding of their involvement in the research project. If the carers agree to participate, they will attend a session at Baycrest. During this session, the details of participation will be explained and the carers will be asked to repeat the information that has just been discussed, in order to ensure that they understand the consent form. Once they are fully informed, they will sign the consent form.

Staff

Following an informational session, consent forms will be left with the staff for them to read on their own. They will be told to contact the RA if they have any questions regarding the research project or if they decide to participate. The RA will then go to them at the DTC to collect the consent form and will ensure understanding of their participation at this time.

- Bruyere –

Clients

On the initial intake call by the GDH staff, all clients will be informed that there are research projects at the GDH that they may be eligible for. A verbal consent to contact will be obtained over the phone during this initial call. Contact information will then be sent to a recruitment coordinator who will then obtain consent for chart review to assess for eligibility for the research projects. Provided the client meets the inclusion criteria for the research project, the recruitment coordinator will then call back to inform them that they are eligible for participation and asked for verbal consent to be contacted by a member of the research team. If the client agrees to participate, they will be then invited to Bruyere prior to their GDH program to provide written consent and for baseline testing.

Carers

Following consenting and baseline testing with the client, the client will be told that the project is also interested in the perceptions of carers (family, informal carers). Clients will be asked to inform their carers of the study and to provide the RA's contact information so the carer can call with any questions. The carer will be subsequently invited to attend the baseline testing to provide written consent and to complete a semi-structured interview.

Staff

An informational session regarding Motiview will be provided to inform staff about the research project. Consent forms will be left at the end of the meeting for staff to read through on their own. If they decide to participate, they can leave their signed forms with the DTC (Baycrest) or GDH (Bruyere) reception for the research assistant in sealed envelopes that will be provided to them.

Study Methods

- Baycrest –

Clients

Participation: After the consenting and initial (baseline) testing session (which will be held at a time convenient to the client attending the DTC program, and which does not interfere with their regular programming/treatment intervention), the client will attend their day treatment program as usual (i.e., 3 hours a day, twice a week on either Monday & Wednesday or Tuesday & Thursday, for a duration of approximately 12 weeks). At Baycrest, assignment to the experimental or control group will be determined by their day treatment program schedule. If clients are scheduled for their program on Monday and Wednesday, they will be provided with the opportunity to use the TheraTrainer with Motiview (Experimental group). If they are scheduled for the program on Tuesday and Thursday, they will be provided with the opportunity to use the TheraTrainer without Motiview (allocated to the control group). Both groups will be informed that they have the option to use the TheraTrainer during any free time between their scheduled treatment appointments, for the duration of their day treatment program. Free time was selected so as to not disrupt a client's regularly scheduled treatment plans.

Every time a participant chooses to use the TheraTrainer, an occupational/physical therapy assistant hired for this project will assist the participant with his/her safe transfer onto and from the TheraTrainer. The assistant will set up the TheraTrainer (and Motiview system, if applicable). The assistant will record any field notes that are relevant for the study. After the completion of a cycling session, participants will be asked micro-interview questions once per week to collect qualitative data about their cycling session. In addition, the participants will be continuously observed by the occupational/physical therapy assistant for the duration of each cycling session in the event that any participant experiences adverse responses to the physical activity. If any concerns arise related to the participants' ability to safely continue the cycling session, the session will be ended.

Follow-up outcomes: At the end of the study, participants will be asked to participate in a post-participation semi-structured interview.

Carers

Participation: After consent is obtained, the carers will be taken through a semi-structured interview to gain feedback about their opinions about their study partner's involvement with the TheraTrainer and/or Motiview. Also, they will be asked about their general characteristics.

Follow-up: None for this group.

Staff

Participation: Following the study period, the staff will be taken through a semi-structured interview to gain feedback about their opinions about the client's involvement with the TheraTrainer and/or Motiview. Also, staff will be asked about their general characteristics.

Follow-up: None for this group.

- Bruyere –

Client

Participation: If they agree to participate, they will be invited, along with their caregiver to Bruyere for one visit of approximately 30 minutes prior to their participation in the GDH. During this session, they will be told again of their involvement requirements for this study and signed written consent will be obtained. Subsequently, baseline outcome measure testing will be done.

They will then attend the rehabilitation program as usual and will be encouraged by the staff as part of their regular GDH program to use the TheraTrainer (one group with Motiview, one group without Motiview). At certain times throughout the study, when a participant uses the TheraTrainer as part of this investigation, study staff will take field notes to capture the clients' level of social engagement, and other behavioural or anecdotal findings that may emerge immediately prior to, during, or shortly after the exercise session.

To assess clients' experiences, they will be approached by study staff once a week (on different days throughout the week, depending on the client's schedule). The study staff will ask the clients if they would like to answer a few short questions related to their experience with the TheraTrainer (either with or without Motiview). Following their assent, the clients will be asked a maximum of four short questions related to their exercise experiences, reminiscence, and general health and well-being during each micro-interview. Each client will have the opportunity to take part in up to six micro-interviews in total throughout the study. The clients' responses will be audio recorded with their assent; for those who do not wish to have their responses recorded, study staff will take field notes related to the clients' responses instead (if assent is provided).

Follow-up: When each client has completed their GDH program, they will be asked to return to the Bruyere Continuing Care (room 441D) to complete the baseline outcome measures as a pre-post design.

Semi-structured interview questions will be posed to all clients who elect to take part in interview session as part of the study. The interviews will be held at the end of the study period. The questions were developed with the aim of employing a phenomenological approach, enabling the clients to elicit their own responses and experiences. Using the interview guide to lead the discussion, client responses may be probed to gain further clarity or insight. The interviews will be audio recorded by study staff. Study staff will also write field notes to document client responses and other observations to supplement and provide context for the transcripts.

Recruitment will continue until 15 clients (control group) have been enrolled and all have completed their geriatric rehabilitation program. After 15 clients have finished the study, Motiview will be placed into the GDH and recruitment of 15 (experimental group) additional clients will commence.

Carer

Same as Baycrest protocol.

Staff

Participation: Prior to the first client enrollment, staff will participate in a brief session (approximately 10 minutes) on proper use of the TheraTrainer, Motiview. The staff will be encouraged to use the TheraTrainer and Motiview as part of their rehabilitation protocol (TheraTrainer activity bikes will be used in place of the NuStep cycle currently in the GDH).

Follow-up: Semi-structured interview questions will be posed to all staff members who elect to take part in an interview session as part of the study. The interviews will be held after 15 clients use the TheraTrainer alone as well as after the 15 clients that use TheraTrainer and Motiview. The questions were developed with the aim of employing a phenomenological approach, which provides staff with the opportunity to elicit their own responses and experiences. Using the interview guide to lead the discussion, staff members' responses may be probed further to gain additional clarity or insight. The interviews will be audio recorded by study staff. Study staff will also write down field notes to capture any notable observations and to add further context to clients' responses, which will ultimately supplement the transcripts.

STATISTICAL ANALYSIS PLAN (SAP)

Qualitative Analysis

All of the audio recordings (with clients/residents, staff, and informal caregivers or family members) will be transcribed verbatim, and any of the audio recordings obtained with French-speaking clients will be translated and transcribed into English. All of the transcripts will first be reviewed by each study site to ensure that no personally identifiable information is present (any that is will be de-identified by each study site); the de-identified transcripts will then be sent to the Baycrest study staff for coding and analysis. Moreover, the field notes will be typed and de-identified by study staff at each site, and the Baycrest staff will receive the de-identified notes for analysis. Similarly, open-ended survey questions will also be typed and de-identified by research study staff at each site, who will then send these responses to Baycrest study staff.

Following these initial steps, the transcripts and field notes will be uploaded into qualitative analysis software (NViVo). Baycrest research staff members will begin coding the data based on the various themes and sub-themes that emerge in the clients' comments and responses. Interim analyses will be performed on an ongoing basis to determine if additional questions need to be asked during the micro-interviews, or to assess whether the interview guide questions or open-ended survey questions need to be revised (particularly if new themes emerge during the analysis process). Once coded, thematic analysis will be performed to highlight the major themes and sub-themes that arose from the clients' responses, which will be supplemented by de-identified quotes to illustrate these themes. Further, a comprehensive report featuring all themes, subthemes, and the associated de-identified quotes will be compiled and disseminated to the research leads/teams at all three research sites.

Quantitative Analysis

All quantitative data will be analyzed using SPSS 20 software with an α of 0.05.

Descriptive statistics (mean ± standard deviation, frequencies, and proportions, where appropriate) will be used for clinical, professional and demographic group characteristics. Between group (control vs experimental and between sites) differences will be assessed using t- tests and chi-square tests.

RISK AND BENEFITS

Potential Risks

- Potential risks
    - There are no risks during the use of the TheraTrainer beyond the risks that may normally be associated with any type of physical activity (e.g., fatigue resulting from exertion). The audio/visual component of the Motiview technology should not pose additional risks.
- Procedures to reduce risks
    - Activity sessions will be closely monitored by trained research associates and/or staff.
- Procedures to maintain confidentiality
    - Every individual enrolled will be assigned a participant code:
        - Client: CL01, CL02 etc.
        - Carer: CA01, CA02 etc.
        - Staff: ST01, ST02 etc.
    - Original documents will be encrypted and/or password protected. All data will be stored on Baycrest's encrypted V: drive, located on Baycrest's servers; no data will be kept on individual employees' computer desktops or on public computers/servers. Moreover, any paper copies of documents or USB drives will be stored in locked file cabinets with limited access by study staff only.

    - All individuals that are involved with the project that may be on site during data collection/recruitment will have completed Tri-Council Policy Statement Ethics 2 (TCPS2) training.

Potential Benefits

- Potential benefits
    - As this is the first study assessing the potential benefits of Motiview, the benefits are uncertain. We hypothesize that the addition of Motiview to the TheraTrainer will result in a more enjoyable and effective activity modality.
- Risk/benefit assessment
    - Although there may be some risks (detailed above) to the participants as a result of participating in this study, there will also be procedures in place to reduce these risks. Thus, it is anticipated that the level of actual risk to participants will be low. Given the nature of this study, there is a high chance that participants in this study will provide valuable feedback on the Motiview system to inform its use in healthcare settings through this evaluation.

FUTURE DIRECTIONS

Following this project, de-identified and aggregated summary results will be provided to Motitech (industry partners) for dissemination. Any limitations to implementation and use will be described to the industry partner for improvements to the technology.

The results for this project will ultimately be submitted to peer-reviewed journals for academic dissemination.