Evaluation of the Online Memory & Aging Program and Online Goal Management Training

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Study 17-24

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Study Protocol

The study is designed to test the effectiveness of online versions of the Memory & Aging Program (MAP) and Goal Management Training (GMT), on the measures used for in-person MAP and GMT in healthy older adults experiencing subjective cognitive impairment.

Background

Normal aging is associated with decline in some aspects of memory, such as memory for recent information (e.g., where did I put my glasses?), associations (e.g., what was your name again?), and intentions (e.g., why did I come in this room?), as well as changes to executive functions, such as sustaining attention, problem-solving, and planning. These age-related cognitive changes can be a source of frustration and anxiety and may be a risk factor for reductions in everyday functioning, which threatens the independence of otherwise healthy older adults. Secondary prevention programs that target positive adaptation to age-related cognitive changes, including lifestyle behaviour change to maximize cognitive health and compensatory strategies for mitigating the functional impact of normal memory & executive functioning change, are a promising avenue to enhance the health and wellness of our aging population.

The Baycrest Memory and Aging Program (MAP) is an education and intervention program for older adults experiencing normal age-related memory changes. The program is offered quarterly at Baycrest. Over 1,000 clients have participated since its inception in 1997. The goals of the program are to (a) increase participant knowledge about memory and aging, (b) expand participants' repertoire of evidence-based strategies for learning and remembering, (c) increase participant confidence in memory ability, (d) foster adoption of healthier lifestyle practices, and (e) reduce intention to use unneeded health care resources. Two prior formal program evaluation studies have demonstrated efficacy of the MAP in achieving these stated goals (Troyer, 2001; Wiegand, Troyer, Gojmerac, & Murphy, 2013). Goal Management Training™ (GMT) is another evidence-based cognitive intervention program developed at Baycrest that targets executive functioning. The program includes an engaging narrative that increases awareness about these cognitive abilities, teaches strategies to help control automatic processing that hinders flexibility of cognitive performance, provides practice exercises and assignments that help internalize and harness these strategies, and teaches meditation techniques that promote mindfulness (Levine, et. al., 2000; Levine, et. al., 2007; Levine, et. al., 2011).

As in any in-person intervention, participation may be restricted for some individuals because of obstacles that prevent them from attending sessions at Baycrest, such as physical disabilities, transportation impediments, scheduling difficulties, or living outside of the Toronto area. Recently, online versions of the MAP and GMT were designed to overcome some of these limitations and increase the outreach of the program to a broader audience. These versions consist of weekly modules that relay the material in a variety of forms including videos, animations, interactive games, discussion boards, live chats, and homework assignments. The current project seeks to evaluate participant outcomes following the online version of the MAP and GMT using a randomized controlled pretest-posttest design.

Objectives
The online program was designed to be similar to the in-person version in terms of content and activities to provide similar levels of engagement. We therefore expect similar outcomes, namely:
For MAP: that compared to the control groups, participants in the intervention group will demonstrate greater knowledge about memory and memory strategies, increased confidence and satisfaction with their memory, healthier lifestyle behaviors, and decreased intentions to seek unnecessary medical attention;
And for GMT: that compared to control groups, participants will demonstrate increased executive functioning and decreased cognitive failures.

Method

Study population
200 healthy community-dwelling older adults will be recruited by newspaper and online advertisements (see Appendix).

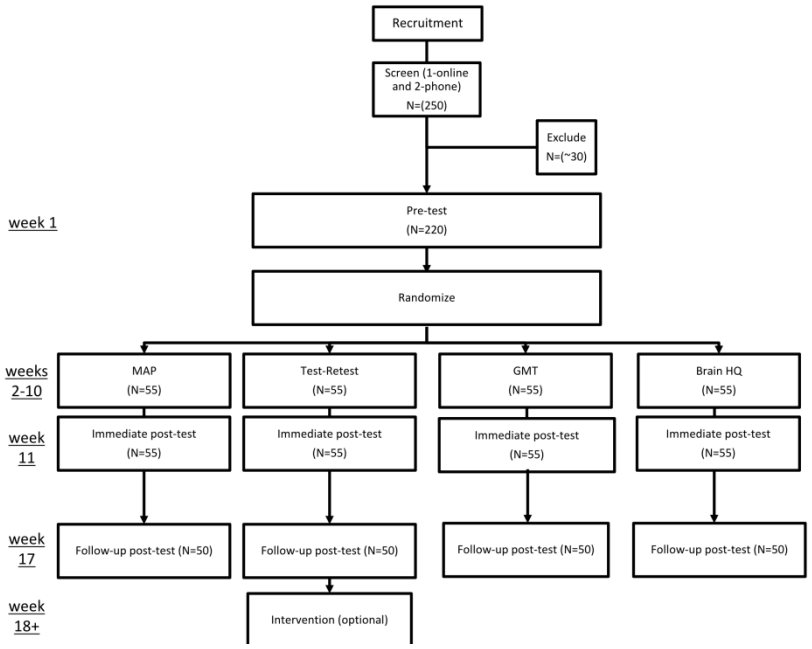
Inclusion criteria:

(a) Age 60+
(b) Available to participate in all testing and intervention sessions and access to a computer
(c) Computer familiarity
(d) Cognitive complaint/concern/frustration

Exclusion criteria:

(a) Health conditions with major effects on cognition, including a current or previous history of stroke, brain surgery, or diagnosed neurological disorder;
(b) Dependence in instrumental activities of daily living
(c) Cognitive impairment, defined as performance below cutoff for cognitive impairment on a standardized cognitive screening measure, the modified Telephone Interview for Cognitive Status (Welsh et al., 1993)
(d) Affective impairment, defined as performance below cutoff for depression on standardized depression screen, the Geriatric Depression Scale (Yesavage et al., 1983)

Study Procedures
Study procedures are illustrated in figure, below. The estimate of the number of participants reflects the expectation of attrition due to the length of the study. Potential participants will be screened online and over the telephone for inclusions and exclusions as outlined above. Informed consent, pretest, posttest, and follow-up testing sessions will be completed online. The online cognitive training protocols are largely completed online from the participants' home or other location of their choosing. All protocols include interactive components; in some cases this involves telephone calls and/or online discussion with research personnel. Total participation duration is 17 weeks. Data collection is planned to be completed within one year of REB approval.



Interested participants who replied by email to the study advertisement (see Appendix) will be emailed the information sheet portion (excluding the signature section) of the informed consent, and will be asked to complete the online screening form and phone screening interview (see script in Appendix). Eligible participants will then be emailed a link to an online pre-test assessment. As the bulk of the study will be taking place online, participants will accept provisions of the study through an online consent form.

Following completion of the pre-test assessment session, participants will be randomly assigned to one of four groups according to a blocked randomization scheme (stratified on age, gender, and education) created by a study team member unknown to participants or otherwise involved in data collection procedures. Participants will be informed of their group allocation by email and then begin the assigned program at their convenience, immediately following the completion of the pretest.

The intervention groups are as follows:

1. Online Memory and Aging Program: consists of weekly modules, and will take approximately 10 hours to complete over eight consecutive weeks. The content of the program includes: (a) the provision of factual information (i.e., about memory, age-related memory changes, lifestyle factors affecting memory, and memory strategies); and (b) memory intervention (i.e., practice and application of several evidence-based memory strategies). The information is delivered in a variety of formats, including videos, animations, interactive games, discussion boards, and live chats. As in the in-person MAP, participants will complete homework assignments in a Participant Workbook that will be mailed to them at the onset of the intervention. The program includes pre/post

assessment of knowledge, memory and lifestyle behaviours, and personal goals for reducing impact of memory change.

2. Test-retest group: This group will complete two assessments of knowledge, memory and lifestyle behaviours, and personal goals for reducing impact of memory change. These assessments will include a mix of online questionnaires and a telephone interview. Our prior research has shown equal attainment of personal goals for memory and lifestyle change in the face-to-face Memory and Aging program and a test-retest condition. Participants in this group will be offered the opportunity to complete the online Memory and Aging Program after study completion.
3. Online Goal Management Training: consists of 9 weekly modules composed of videos, interactive applets, and assignments, which take about approximately 20 hours total to complete. The program presents factual information about automatic processing, teaches strategies to stop and control automatic processes while maintaining focus on the current task goals and sub-goals, provides assignments that raise awareness into participants' own automatic processing and cognitive control, and provides games that allow participants to practice and build on the strategies acquired throughout the program. The program includes pre/post online assessment of cognition.
4. BrainHQ: is a commercial brain training platform that has a variety of short tasks. We will be using a customized training regimen that focuses on games designed to hone attention, memory, and brain speed. The program involves about an hour of training on this platform per week, which consists of a series of short games (5 min each) for half an hour at a time. The program includes pre/post online assessment of cognition.

<u>Pre-/Post-test measures</u>

Measures were selected based on previous findings from the in-person MAP and GMT evaluations. Most are standardized questionnaires and/or tasks, and most have been used previously, as noted below, and during preliminary pilot testing of the program. All measures will be administered during each testing session, and all will be administered online.

Primary Outcome Measures:

- Memory knowledge quiz, modified from Troyer (2001), will be used to quantify memory, lifestyle, and strategy knowledge
- Health Promoting Lifestyle Profile II (Walker, Sechrist, & Pender, 1987) will be used to quantify healthy lifestyle behaviours
- Memory strategy toolbox (Troyer, 2001) will be used to quantify application of strategies in memory-demanding everyday situations
- Multifactorial Metamemory Questionnaire (Troyer & Rich, 2002), will be used to quantify subjective memory abilities, satisfaction, and strategy use
- Dysexecutive functioning questionnaire (DEX; Burgess, Alderman, Wilson, Evans, & Emslie, H. (1996)
- Cognitive Failures questionnaire (CFQ; Broadbent, Cooper, FitzGerald, & Parkes, K. R. (1982)

Secondary Outcome Measures (embedded within intervention conditions):

- Conditions 1 and 2:

    - Psychological Normalization Inventory will be used to quantify feelings of normalization of memory concerns
    - Memory Impact Questionnaire and Patient-Specific Functional Scale (Horn et al., 2012) will be used to quantify the impact of memory changes on daily activities and self-image
    - Intentions to seek medical attention modified from Wagner, Phillips, Radford, and Hornsby (1995) will be used to quantify change in intentions to seek medical attention pertaining to memory concerns
- Conditions 3 and 4:
    - Cambridge Brain Sciences online cognitive assessment (Hampshire et al., 2012)
    - Face-name memory task (Troyer et al., 2012)

Statistical Analysis Plan

Data management

An anonymized database will be created to link identifying participant information to the outcome measure data. Participants will be given unique ID numbers, and information that links identifying information to participant ID numbers will be stored on a password-protected secure server.

Statistical analyses

Mixed-model ANOVAs will be used to examine pre-test and post-test scores on the outcome measures in the control and intervention groups. We will compare pre-test to immediate post-test and pre-test to follow-up post-test. The multiple test periods will be within-group repeated measures, and group assignment will be a between-groups variable. We expect significant interactions between group and pretest-posttest scores, with greater improvements over repeated test periods in the intervention group than the control.

This analysis will be done for each of the primary outcomes for both interventions. The same tests will be run on secondary outcomes to contrast the relevant intervention-control pair (e.g., GMT secondary outcomes measured/tested for GMT and BrainHQ, MAP secondary outcomes measures/tested in MAP and test-retest (waitlist) group.

No adjustments will be used for these primary and secondary *a priori* analyses.

We will also explore whether key variables including age, degree of engagement with the program, presence of subjective cognitive impairment, and computer familiarity covary with the effects of the intervention, and if so control for them by adding them as covariates in our statistical models.

Informed Consent Form

Below is the informed consent form, which was administered as part of an online survey:

Title of project: Evaluation of online cognitive fitness programs

Investigators: Dr. Susan Vandermorris, Dr. Angela Troyer, Ms. Iris Yusupov, Dr. Brian Levine, Dr. Jordan Lass

Study description:

At Baycrest, we have developed online programs that target common age-related cognitive changes. These online programs are based on well-validated, in-person offerings that have been delivered at Baycrest and other sites for many years. The aim of this study is to evaluate whether the online programs help people achieve the same outcomes as the in-person programming.

Procedures:

Participation in the study will involve completing online programming in your own home using your own computer or tablet. You will be randomly assigned to one of four programming groups. The programs consist of modules composed of videos, slides, activities, memory and thinking exercises, discussion boards, and small homework assignments. Some groups include some brief telephone interviews with a member of the study team. You may complete most of the programming at your convenience, on your own schedule. The programs are designed to take approximately 10-20 hours of your time over 5-9 weeks. These programs will be provided to you free of charge.

You will also be asked to complete three online assessment sessions consisting of questionnaires and tasks pertaining to your memory and aspects of your daily life. These assessment sessions will take place three times over the course of the study, approximately 5-9 weeks apart. The

sessions are about 1-2 hours in duration and may be completed in multiple shorter sittings. You will be compensated $30 per testing session after completion of the study, and prorated based on participation if you withdraw from the study.

Benefits and risks:
Persons who complete our in-person programs have shown increased confidence in everyday memory and thinking ability. You may also experience these benefits. In addition, participants who have tried earlier versions of the online programs have expressed that the programs are enjoyable to them. There are no known risks associated with participation in this study. If new information related to the risks of the study is obtained, you will be informed.

Confidentiality:
If you agree to join this study, we will collect the data from questionnaires and tasks you complete. **Your data will be identified with a study number only and will never be identified by name.**

The information that is collected will be kept in a password protected electronic file. Only the researchers listed at the top of this form will be allowed to look at the data. Data collected in this study may be used for future, related studies by the research team. Baycrest's Research Ethics Committee may also examine collected data to ensure adherence to ethical standards.

All information collected during this study will be kept confidential and will not be shared with anyone outside the study unless required by law. If you decide to withdraw from the study, the information about you that was collected to that point will not be used.

Voluntary participation:
Your participation in this study is completely voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. You may leave the study at any time without affecting the nature of your relationship with Baycrest Health Sciences either now or in the future. You may refuse to answer questions you do not want to answer. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities. It is suggested that you print a copy of this consent form for your own records.

Questions about the study:

If you have any questions, concerns or would like to speak to the study team for any reason, please contact study coordinators at onlinetraining.info@research.baycrest.org or 416-785- 2500 x3104.

If you wish to contact someone not connected with the project about your rights as a research participant, please call Dr. Ron Heslegrave, Chair of the Research Ethics Board at (416) 785-2500 ext. 2440.

Agreement section:

I have read the preceding information, and I understand the purpose of my participation, the procedures involved and the potential risks to myself, as stated in this document. All my questions have been answered to my satisfaction. I understand that I can ask further questions during any stage of the study.

I understand that my participation in the study is voluntary. I may withdraw from the study at any point in time. I am aware that the study will not benefit me specifically, but knowledge will be gained that will benefit others. It has been explained to me that the results of the study are confidential. Neither my identity nor any personal information will be available to anyone other than the investigators. No personal information will be disclosed in any resulting publication or presentation.

- I Agree
- I Disagree