Title: Evaluating technology for rehabilitation: A model for promoting programmatic research

Background

A growing movement in the delivery of aphasia therapy is the use of computer-based treatments, and there is a small body of experimental literature that attests to the benefits of this approach (see, for example, Aftonomos, Steele, & Wertz, 1997; Cherney, Halper, Holland, & Cole, 2008; Choy, Holland, Cole, & Thompson, 2009; Fink, Brecher, Schwartz, & Robey, 2002; Pedersen, Vintner, & Olson, 2001). As more investigators implement treatments on the computer it is important to foster research that would move promising treatments in a programmatic way and help shape factors (e.g., patient selection criteria, manner and intensity of administration, etc.) that are critical to a large-scale clinical trial. Here we report on a project that aimed to facilitate programmatic research on an aphasia treatment software program called MossTalk Words® (MTW).

MossTalk Words was designed for individuals with aphasia who have word-retrieval deficits. Developed by a team of researchers and clinicians, the software was intended for use in the clinical setting as well as by patients working independently. It provides extensive practice in word comprehension and production using multimodality cues and feedback. MossTalk's two main treatment modules, *Cued Naming (CN)* and *Multimodality Matching (MMM)* were modeled after treatments that are typically used by clinicians and have been shown to be effective in experimental studies (e.g., word-picture matching; Howard, Patterson, Franklin, Orchard-Lisle, & Morton, 1985a,b; and hierarchical cueing: Linebaugh & Lehner, 1977).

A preliminary study of MossTalk's Cued Naming module (Fink et al., 2002) showed that the program could be used with minimal guidance and that it was effective in improving naming skills in individuals with aphasia who have moderate to severe naming disorders. Clinical experience and use and satisfaction data collected from clinicians and patients (Sobel, Fink, & Schwartz, 2000) lent support to the experimental findings and provided evidence that MTW could be integrated into a clinical therapy program and that patients and their family members could learn to use the program, even those with limited prior computer exposure.

Encouraged by these findings we developed a plan to disseminate the software and facilitate its study by other researchers and clinicians. Our aim was to generate additional data that, among other things, could shape the writing of a clinical trials grant application. More specifically, the project had two goals: (1) to get additional feedback about use and satisfaction, and (2) to foster research on clinical effectiveness and outcomes. This abstract concerns the second goal. We report on the methods used in facilitating this effort and the research collaborations that emerged.

Methods

Participants

Rehabilitation researchers and clinicians who treat and/or conduct research with individuals with aphasia were invited to participate via direct mail, e-mail and targeted websites, including the Northeast Cognitive Rehabilitation Network (now called the Neuro-Cognitive Rehabilitation Research Network - NCRRN) website (www.NCRRN.org). As a condition for participation,

invitees agreed to 1) participate in a brief training program; 2) complete a set of evaluation forms; and 3) use the software to evaluate its effectiveness in a controlled experimental study of their design (or, in the case of clinicians, to collect use and satisfaction data in the clinical setting). Aphasia researchers and clinicians (henceforth, "collaborators") from 18 sites met the criteria and agreed to participate in this project (Appendix A).

Training and Support

30 potential collaborators registered for a 2-hour workshop presented via videoconference. A videotape of the conference was sent to those unable to participate online. During the workshop the principal investigator provided an overview of the software and all of its features; trained participants to use each treatment module; explained the reporting requirements of the project; and facilitated interaction among the collaborators. Following this workshop, collaborators received ongoing training, technical assistance and support via telephone, e-mail and an electronic bulletin board. The bulletin board was hosted by the NCRRN website to stimulate discussion and interaction among researchers and clinicians.

Data collection

Researchers were asked to propose a study and submit status reports of their proposed research at the end of 6 months and again at the end of 1 year. A sample status report form is shown in Appendix B.

Results/outcomes

At the end of the first year of the project, collaborators from seven of the ten research sites had developed research proposals and six of the seven research projects were in various stages of implementation (e.g., collecting data, awaiting IRB approval, proposal submitted for external funding).

Several investigators who developed projects have subsequently completed multiple studies, leading to publications on clinically relevant aspects of the software, including its effectiveness for various etiologies and language symptoms (Jokel, Cupit, Rochon, & Leonard, 2006; Jokel, Cupit, Rochon, & Graham, 2007; Jokel, Cupit, Rochon, & Leonard, 2009; Jokel, Rochon, & Anderson, 2010; Raymer, Kohen, & Saffel, 2006; Raymer, Carwile, Matthews, Johnson, & Todd, Under Review); its effectiveness when self-administered (Ramsberger & Marie, 2005; Ramsberger & Marie, 2007; see also Fink, Brecher, Sobel, & Schwartz, 2005); and the impact of therapy intensity on outcomes (Ramsberger & Marie, 2005; Raymer et al., 2006). Data from these studies have also been presented at national and international conferences (e.g., ASHA, CAC and Academy of Aphasia). These studies are briefly described in Appendix C.

At the conclusion of the first year of the project, with support from the NCRRN, we hosted a meeting with representatives from the active research groups to discuss future directions and the possibility of a large-scale clinical trial. At that time there was agreement that the data were encouraging and there was interest in continuing the collaboration, collecting additional data and exploring potential funding sources for a large-scale multi-site study. During that meeting we also began preliminary discussions on the design of such a multi-site study. One investigator took the lead and subsequently submitted a clinical trial grant. The grant was not funded on the initial submission. Provided that the NCRRN is renewed, we hope to be able to provide

additional support for a revised submission.

Summary and Conclusions

This project aimed to facilitate programmatic research on MTW, a computer-assisted treatment. We hosted communication about the software among aphasia researchers and provided key personnel to coordinate that communication. The response to this project from the research community was enthusiastic and a number of positive outcomes resulted, of precisely the sort we aimed to promote. This initiative identified a core group of researchers who successfully implemented multiple small studies leading to publications and presentations on clinically-relevant aspects of the MossTalk program and setting the stage for a large-scale clinical trials grant application.

Many preliminary issues, such as patient selection, schedule and intensity of treatment, etc., must be addressed along a developmental path toward large-scale clinical trials of rehabilitation interventions (Whyte, Gordon, Gonzalez-Rothi, in press). We believe this is a promising model for fostering such development: identification of a treatment that is nearing readiness for definitive effectiveness research, facilitating the organization of a network of interested collaborators, and providing them with methodologic support and consultation to address many of these issues in parallel to arrive at decisions about the optimal form of the intervention to be ultimately assessed.

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Appendix A
Participating sites

Research sites
Boston University
Dalhousie University
Montclair State University
Old Dominion University
University of California - Davis
University of Colorado
University of Connecticut
University of Indiana
University of Toronto
University of Washington

Clinical sites
JFK Johnson Rehabilitation Center
Metro Health Center
New England Rehabilitation Center
Pennsylvania Veterans Administration Medical Center-Philadelphia
Rehabilitation Hospital of Indiana
Rush University
Toronto Rehab
Triangle Aphasia Project

Appendix B
MossTalk Interim Status Report

Research Status Report

1. Project Title:

2. Summary of Proposed project (abstract)

3. IRB status: submitted _____approved_____ other_____

4. Number of subjects screened_____ enrolled_____ completed_____

5. Brief summary of project status and expected completion date

6. Preliminary outcomes or impressions (if available)

7. We would greatly appreciate a brief comment regarding the software

8. (optional) Completed patient satisfaction surveys or anecdotal comments from subjects

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Clinical Status Report

1. Completed Usage logs and Satisfaction Surveys

2. We would greatly appreciate a brief comment regarding the software including anecdotal stories of successes/problems/solutions

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Appendix C
Focus of completed research proposals

Raymer and colleagues studied the effectiveness of the Multimodality Matching Modules on word comprehension and production in individuals with chronic aphasia under different levels of intensity (Raymer et al., 2006). Subsequent research investigated the usefulness of MTW when self-administered and also evaluated generalization effects to items in the same semantic category (Raymer et al., under review).

Rochon, Jokel and colleagues studied the effectiveness of the Cued Naming module to improve word retrieval in individuals with nonfluent primary progressive aphasia and semantic dementia, (Jokel et al., 2006; Jokel et al., 2007; Jokel et al., 2009; Jokel et al., 2010).

Ramsberger and colleagues studied the effectiveness of the cued naming module in individuals with chronic aphasia when self administered at home and under different levels of intensity (Ramsberger & Marie, 2005; Ramsberger & Marie, 2007).
