Evaluating technology for rehabilitation: A model for promoting programmatic research

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The Development Process in Rehabilitation Research

Evaluating a promising treatment from its inception to use in clinical practice follows a sequence of phases with an ordered progression of research activities conducted at each phase. The research methods used, and outcomes assessed will change systematically with the phase (and goal) of the research. Various models approach the phasing requirements differently (e.g., Food and Drug Administration model (FDA, 2009) proposes 4 stages; the National Cancer Institute (NCI) model (Greenwald and Cullen, 1985), describes a 5 phase model; and for discussion see Robey and Schultz, 1998). However, in all models, a treatment's *efficacy* (benefit under ideal, controlled conditions) is established definitively with evidence collected in a Phase III clinical trial.

Robey and Schultz (1998) have proposed a modification of the NCI 5 phase clinical-outcomes research model that is tailored to the evaluation of behavioral treatments of aphasia. This model essentially removes requirements driven by safety and dosage issues in pharmacology trials and addresses communication rather than medical issues. The objectives of research at each stage are briefly summarized as follows:

- Phase I. Identify the presence and magnitude of a therapeutic effect, including any negative effects that threaten safety
- Phase II. Investigate therapeutic effect in relation to various dimensions (e.g., the population, the minimum dosage for obtaining change); manualize the protocol; and conduct other necessary preparations for a clinical trial
- Phase III. In a large scale clinical trial, provide a definitive demonstration of *efficacy* under ideal, controlled conditions
- Phase IV. Assess the *effectiveness* of a treatment under routine clinical conditions; continue efficacy experiments (e.g., with different populations, variations of the treatment protocol)
- Phase V. Continue to evaluate effectiveness; address research questions that move from clinical outcomes to cost-benefit, consumer satisfaction and quality of life assessments

Evaluating technology for rehabilitation

A growing movement in the delivery of aphasia therapy is the use of computer-based treatments (see, for example, Lingraphica: Aftonomos, Steele, & Wertz, 1997; ORLA: Cherney, Halper, Holland, & Cole, 2008; Sentactics: Choy, Holland, Cole, & Thompson, 2009; MossTalk Words: Fink, Brecher, Schwartz, & Robey, 2002). While there is a small body of experimental literature that attests to the benefits of these various programs, large clinical trials demonstrating their efficacy are sparse. This is not surprising given the amount of preliminary research and preparation that must precede a Phase III trial and the time and cost of running a clinical trial.

Recent publications have called attention to the fact that there are risks both of research "stalling" along this path, and of it being prematurely accelerated to the point of a clinical trial, without completing the necessary groundwork (Whyte J, Gordon W, Gonzalez-Rothi L, 2009; Whyte, 2009).

As more investigators and clinicians implement treatments on the computer it is important to foster research that would move promising treatments in a programmatic way and help shape those factors (e.g., patient selection criteria, manner and intensity of administration, etc.) that are prerequisite to a large-scale clinical trial, a level of evidence considered critical to establishing treatment efficacy. Without such preliminary research, conduct of large clinical trials could prove wasteful (Whyte, 2009). In this paper we report on a successful model that was used to build a collaborative network and facilitate programmatic research on an aphasia treatment software program called MossTalk Words® (MTW). We describe the treatment that was targeted for investigation; the methods for organizing a network of researchers to study the treatment; the support and consultation that was provided; and the outcomes that emerged.

MossTalk Words: a computer implemented treatment

Word retrieval deficits are present in most, if not all, individuals with aphasia. MossTalk Words was designed to treat this ubiquitous symptom. 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 non computerized experimental studies (e.g., word-picture matching; Howard, Patterson, Franklin, Orchard-Lisle, & Morton, 1985a,b; and hierarchical cueing: Linebaugh & Lehner, 1977).

A small 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 on the practicality of integrating MTW into a clinical therapy program. Importantly, the data demonstrated that patients and their family members -- even those with limited prior computer exposure -- could learn to use the program.

Encouraged by these findings we developed a plan to disseminate the software to researchers and clinicians to facilitate its further study. 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 outcomes. This paper focuses on the methods used in facilitating this effort and the research collaborations that emerged.

Methods

Developing a collaborative network.

Securing Funding

In any multi-site project, one individual or facility must take the lead in organizing the collaboration and obtaining the necessary support to facilitate their participation. For this project support was provided by the NEC Foundation of America, in the form of a 1-year grant, and by the Northeast Cognitive Rehabilitation Network (now called the Neuro-Cognitive Rehabilitation Research Network – NCRRN; www.NCRRN.org). While neither source provided pilot funding for any of the research projects that were to emerge, the NEC grant and NCRRN support were critical for enabling the PI to develop the network, coordinate the effort, provide the software and technical support for its use; and host communication about the software among collaborators.

Recruiting Participants

Letters of invitation were sent via direct mail, e-mail and targeted websites, including the NCRRN website, to a select group of rehabilitation researchers and clinicians who treat and/or conduct research with individuals with aphasia. 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). In return for their participation, participants received a copy of the software for themselves and any individuals with aphasia they deemed suitable candidates along with unlimited training and support (methodological and technical) during the first year.

Aphasia researchers and clinicians (henceforth, "collaborators") from 18 sites (10 research, 7 clinical) met the criteria and agreed to participate in this project. 30 potential collaborators from these sites registered for the initial training workshop.

Providing Training and Support

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.

Facilitating research and collecting data

We asked researchers to propose, design and implement a study of their choosing and to submit status reports of their proposed research at the end of 6 months and again at the end of 1 year. We asked clinicians to use the software with each person with aphasia who they deemed a suitable candidate and to submit use and satisfaction data on a monthly basis. We initiated and maintained regular contact via telephone or e-mail to provide support and guidance and to ensure that participants followed the established timeline and completed the requirements. A sample status report form is shown in Appendix A.

As previously mentioned, we did not provide pilot funding for any of the proposed projects.

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). Collaborators from three sites 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, Raymer et. al, under review; 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 B.

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.

Summary and Conclusions

This project aimed to facilitate programmatic research on MTW, a computer-assisted treatment for aphasia. 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.

The developmental path toward large-scale clinical trials of rehabilitation interventions must provide preliminary answers to questions such as: who is a suitable candidate? on what schedule and at what intensity should the treatment be administered? and others of similar complexity (Whyte, et al., in press; Robey and Schultz, 1998). We believe the MTW collaborative research model holds promise for fostering research along the developmental path. The model's essential features are:

- Identification of a treatment that is nearing readiness for definitive efficacy and effectiveness research
- Facilitating the organization of a network of interested collaborators

- Providing them with support and consultation to address clinically-relevant research questions in parallel; and
- Determining, based on the results of the collaborative studies, the optimal parameters of the treatment intervention to go forward into a proposed Phase III clinical trial.

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Appendix A
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 B
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).
