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Supplement Article

Developing Brain Injury Interventions on Both Ends of the Treatment Continuum Depends Upon Early Research Partnerships and Feasibility Studies

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Purpose: The purpose of this research article is to describe two very different lines of brain injury treatment research, both of which illuminate the benefits of implementation science.
Method: The article first describes the development and pilot of a computerized cognitive intervention and highlights how adherence to implementation science principles improved the design of the intervention. Second, the article describes the application of implementation science to the development of assistive technology for cognition.
Results: The Consolidated Framework for Implementation Research (CFIR; Damschroder et al., 2009) and the menu of implementation research strategies by Powell et al. (2012) provide a roadmap for cognitive rehabilitation researchers to attend to factors in the implementation climate that can improve the development, usability, and adoptability of new treatment methods.
Conclusion: Attention to implementation science research principles has increased the feasibility and efficacy of both impairment-based cognitive rehabilitation programs and assistive technology for cognition.

It is a new dawn for clinical research in the field of brain injury rehabilitation. The challenges responsible for the divide between research and practice are well described in the foundational articles in this issue (Olswang & Prelock, 2015). The silver lining to this gap is that it has seeded a paradigm shift in our clinical research. Implementation science is taking root. The fact that it takes more than a decade for treatment evidence to be incorporated routinely into clinical practice has spawned new ways of conducting research that rely on early partnering between researchers, clinicians, and the clients for whom the interventions are designed to benefit (Burke & Gitlin, 2012; Green & Glasgow, 2006; Sussman, Valente, Rohrbach, Skara, & Pentz, 2006). Because the types of controlled interventions studied in experiments, and the contexts for delivering them, are often incompatible with current constraints in healthcare delivery, researchers have begun to recognize the need to merge studies of efficacy with studies of effectiveness early on in the research process (Curran, Bauer, Mittman, Pyne, & Stetler, 2012).

Of particular import to the field of brain injury rehabilitation are the implementation research practices that encourage efficient development and early validation of innovative treatments. There is an urgent need to fill the evidence gap in the management of cognitive–communicative disorders given the demand for research to direct clinical decision making and the increasing attention to inconsistent and compromised quality of healthcare (Redle & Atkins, 2013). The Consolidated Framework for Implementation Research (CFIR; Damschroder et al., 2009) offers an approach to meet this need. CFIR is composed of five different research domains necessary for structuring a research line that optimizes the conditions for producing evidence-based interventions that will be adopted by practitioners and will provide meaningful patient outcomes. Of particular relevance to the design of cognitive–communicative interventions for people with brain injury are the CFIR research domains labeled *intervention characteristics* and *inner setting*. Within these domains, Damschroder et al. (2009) describe the importance of attending to factors such as adaptability of interventions, trialability, and the implementation climate. We have witnessed a lack of uptake or

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adoption of our own tools, even when shown to be effective, because we did not attend to the implementation climate in the very early stages of designing a tool or intervention. Powell et al. (2012, 2015) describe another implementation research framework that provides direction for researchers attempting to design and evaluate cognitive interventions. They describe research strategies within the *planning* and *quality management* phases that ensure partnerships are forged with all stakeholders. Again, our own work has been enhanced when we have worked collaboratively with all interested parties from the inception of a project.

The purpose of this article is to describe two very different lines of brain injury treatment research, both of which illuminate the benefits of research strategies that attend to the intervention characteristics described by Damschroder et al. (2009). We first discuss the preliminary development and evaluation of an impairment-targeted, computer-delivered treatment for the rehabilitation of attention and executive function impairments in pediatric brain injury. This is followed by a description of the research processes involved in the development of assistive technology for cognition for use by people with acquired cognitive impairments.

Implementation Science Applied to the Pilot of a Computerized Cognitive Intervention

In a recent pilot study, we investigated the use of a computerized cognitive rehabilitation program, Attention Improvement Management (AIM), for the treatment of attention and executive function impairments in children with traumatic brain injury (Sohlberg, Harn, MacPherson, & Wade, 2014). AIM is a 10-week, individualized treatment program that incorporates goal setting, the use of metacognitive strategies, and computer-based exercises to improve various aspects of attention and working memory. The AIM program is highly manualized. The program selects specific attention exercises using an algorithm derived from ratings of attention domains on an intake survey that occurs after cognitive tests and parent interviews have been administered. The selection of attention tasks is modified throughout the training program using objective decision rules and criteria for advancement or for scaling back on the basis of the participant's accuracy scores and self-effort ratings.

When conducting the pilot study, participants came in for weekly face-to-face sessions and completed five or six attention exercises while practicing their metacognitive strategies with research assistants trained in cognitive rehabilitation techniques. Attention task performance was measured by accuracy data as well as participant ratings of perceived effort to complete assigned tasks. During the intervention, participants were also expected to complete between two and four home practice sessions per week, and the accuracy and effort data from the home practices were available to the researchers for analysis.

The traditional research pipeline requires moving from highly controlled efficacy trials to effectiveness trials (Olswang & Prelock, 2015). In the case of piloting AIM, a traditional research progression would begin by measuring the impact of a tightly controlled intervention on selected outcomes. Adherence to the decision rules for attention task selection would be an important treatment fidelity measure. Treatment variations, such as identifying possible differences in outcomes on the basis of the attention task selection, would be systematically evaluated in later studies. However, this more conventional process does not engage key stakeholders; in this case, clinicians. The lack of stakeholder engagement may hinder the ultimate uptake of AIM in "uncontrolled" contexts and conditions despite the possibility that the AIM program may prove to be efficacious in improving attention and executive function impairments.

Hence, in our pilot study we wanted to evaluate clinical decision making with respect to clinician task selection. We adhered to the principles of implementation science that encourage early evaluation of treatment adherence and adaptability. From the outset, we also studied the factors that drove the interventionists to override the objective established criteria for moving to an easier or harder task by auditing clinician feedback during the quality management phase of research using the AIM program (Damschroder et al., 2009; Powell et al., 2012, 2015). The manual specified task advancement criteria (e.g., performance greater than or equal to 80% accuracy for three out of four trials with effort rating of 4 or less). We were interested in learning about the factors that might influence a clinician's selection of task or deviation from a prescribed protocol while we were conducting the efficacy pilot. Ongoing feedback from interventionists suggested that their behavioral observation of clients (including client comments) during attention training led them to diverge from task selection decision rules because they believed different tasks would enhance client adherence and optimize program effects. Therefore, during the pilot study, the interventionists were allowed to modify the choice of attention tasks, even if the decision rules did not warrant a new task, if they perceived that the participants were not benefitting from that task level. Whenever a new attention task was introduced, the interventionist recorded the clinical rationale from a closed set of choices derived from clinician feedback obtained prior to the study: (a) objective criteria for task modification were met, (b) participant seemed bored or disinterested in the current task, (c) participant appeared discouraged and lacked self-efficacy when completing the task, (d) participant disliked particular task and was resistant to doing it, or (e) other. For example, if a participant indicated he or she felt bored and interventionist observation supported this perception, the interventionist could increase the task difficulty even if the criteria for mastery had not been reached. Qualitative session notes explaining additional rationale were also an option.

An analysis of these clinical rationale data revealed that the primary reason for selecting new tasks was because participants had met task performance criteria. However, in more than half the participants, there were two or more occasions when task selection criteria were not followed because the interventionists judged that the participants' affective states while completing the target tasks were preventing them from benefitting from the AIM program. In particular, there were occasions when the interventionists perceived the participants to be either bored or discouraged to such a degree that it interfered with the level of task engagement, and they selected new tasks accordingly. In qualitative notes, interventionists described hypotheses for why participants occasionally lacked engagement and what they felt helped. These findings led us to develop a guide to enhance participant engagement as shown in Table 1 in order to increase the potential impact of this drill-based therapy. Our attention to the implementation climate and associated clinical decision-making factors helped us improve the intervention while we were evaluating efficacy, and resulted in a modified program that will not only have larger chance of uptake, but has the potential to be efficacious (Damschroder et al., 2009; Powell et al., 2012).

Another implementation characteristic that was measured during the AIM pilot was factors related to home practice. The theoretical rationale for the AIM program relies on principles of neuroplasticity that contend that the repeated stimulation of discrete brain networks will facilitate reorganization (Sohlberg et al., 2003). As such, sufficient treatment intensity is required in order to achieve the necessary repetition. In order to provide treatment intensity, the AIM program has a homework USB drive that allowed the interventionist to load that week's target exercises, which enabled participants to practice at home. Part of the AIM treatment session protocol was to review home performance and update the exercises on the drive. Because the home-practice component was judged to be critical to the treatment efficacy, the pilot study collected data on factors that influenced adherence to home-practice guidelines. Examples of reasons that participants and/or parents cited for failure to complete home practice included the following, listed in order of frequency: (a) technical issues with using computer or drive, (b) forgot, (c) not enough time, (d) somatic issues (e.g., headache) preventing screen use, and (e) not motivated.

Although the home-based practice made it possible for participants living distant from the hospital to receive intensive intervention practice, it still required significant parental involvement and child motivation to complete multiple weekly practices and return to the hospital for weekly visits with the clinician. The data indicated there were a variety of barriers to completing the home practice that would make it difficult to identify a single solution. This finding informed the researchers that the next steps in piloting should examine a model for delivery that taps into the practice and therapy within a school context in which teachers could encourage and facilitate engagement in practice sessions (Sohlberg et al., 2014). It is unlikely that this population will be able to complete computerized home exercises independently; hence, the pilot prevented us from moving forward with a program that would not have been adopted. The study of this intervention characteristic, termed trialability, allows a researcher to test an intervention and reverse course if warranted (Damschroder et al., 2009). Future AIM research efforts will focus on the school as the delivery context.

Other cognitive rehabilitation effectiveness studies have similarly benefitted from considering clinician behavior and the implementation climate during the initial research phases. For example, a large, multisite research project compared two different cognitive treatment interventions and used cross-disciplinary clinician teams as interventionists rather than individual speech-language pathologists or researchers (Vanderploeg et al., 2006). In addition, they assessed for treatment readiness and identified barriers to the implementation early on by examining practical factors that affected patient access and recruitment from various sites, including length of stay and availability of patients with a moderate to severe impairment. The

Table 1. Clinician guide for increasing motivation and engagement developed from analysis of clinical rationale for task selection.

Affective state	Possible sources of problem	Clinician responses
Participant seems bored.	Tasks are too easy.	Increase difficulty of tasks.
	Computer program is uninteresting to client.	Affirm that the tasks can be boring and link back to goal that is meaningful. Allow participant to select from menu of tasks.
	Does not like having structured "school-like" activity.	Increase level of connection with student. Use humor, ask about interests, work to make interaction before and after session fun. Explore reinforcers.
Participant seems discouraged.	Tasks are too hard.	Decrease task difficulty level.
	Does not believe program will work.	Provide testimony and examples from others who have participated in the program.
	Does not feel like exercises are "worth it."	Revisit Goal Attainment Scaling if current goals are no longer meaningful. Use motivational interviewing.
	Participant has outside stressors affecting performance.	Decrease task difficulty level to optimize performance. Try pairing with metacognitive strategies that encourage relaxation, such as breathing.
Participant seems confused.	Does not understand how program works.	Use sports metaphor to explain drills.

authors acknowledged that implementation was enhanced by gaining "buy-in and enthusiasm for participation" (Vanderploeg et al., 2006, p. 191). Similar to the development of AIM, assessment of stakeholder characteristics in the planning phase was critical (Damschroder et al., 2009; Powell et al., 2012).

In summary, the AIM pilot study combined efficacy and feasibility research questions by systematically measuring clinician decision making and client adherence (Sohlberg et al., 2014). Had we pursued a traditional line of inquiry with systematic evaluation of treatment variables only after establishing efficacy in a highly controlled context, we would run the risk of developing a program that would not have been feasible or as effective in today's healthcare setting or may not have been adopted by practicing clinicians (Powell et al., 2015).

Implementation Science Applied to the Development of Assistive Technology for Cognition

At the other end of the cognitive rehabilitation continuum from impairment-based, computer-delivered interventions, is the training of compensatory external tools. Although divergent in theoretical rationale and treatment delivery, like impairment-based interventions, the design of assistive technology for cognition (ATC) that is usable and beneficial depends upon implementation science research strategies. We have used implementation science methodology in the development and evaluation of adapted classroom blogs for middle school students with cognitive impairments (Sohlberg, Todis, Fickas, Ehlhardt, & Prideaux, 2011), adapted e-mail interfaces for people with severe memory impairments (Sohlberg, Fickas, Ehlhardt, & Todis, 2005), public transportation aids for people with acquired cognitive impairments (Sohlberg, Fickas, Hung, & Fortier, 2007), prompting systems for people with acquired memory and executive function (Lemoncello, Sohlberg, Fickas, & Prideaux, 2011), and the electronic delivery of comprehensive reading strategies (Griffiths, Sohlberg, Biancarosa, Fickas, & Kirk, 2015).

Implementation science seeks to understand the treatment context and the barriers to and solutions for identifying sustainable effective interventions (Olswang & Prelock, 2015). In the case of ATC, it is vital to appreciate the community contexts in which the proposed technology will be utilized and to involve the target users in the development process from the inception (Sohlberg & Turkstra, 2011). Implementation science begins with a research topic of importance to the community and utilizes a collaborative research orientation that equitably involves all concerned partners in the research process, recognizing the strengths that each brings (Turner, Misso, Harris, & Green, 2008). In this section, we describe the initial research activities that were undertaken to develop two different ATC applications. In both cases, early partnering occurred with all the stakeholders in order to understand the needs, barriers, and abilities of the population and relevant contextual factors. The study of the community was followed by pilot research simultaneously investigating usability and efficacy.

ATC Example 1: Development of Public Transportation Supports

Our ATC laboratory was interested in developing tools that would increase community access for people with chronic cognitive impairments due to acquired brain injury. Given the increasing availabilities of navigational tools that delivered directional information, we were interested in ways technology might be harnessed for the population of people with moderate to severe cognitive impairments. The nascent state of community navigation research for this population encouraged research using implementation strategies in the planning and exploration phase (Powell et al., 2012). We began by conducting a field study that allowed us to catalogue weekly destinations, mode of travel, travel companions, assistance, challenges, and support strategies used by a sample of participants with brain injury over a 4-month period (Sohlberg, Todis, Fickas, Hung & Lemoncello, 2006). Participants lived in an assisted facility and were able to take care of their own meals and all had moderate to severe cognitive impairments due to brain injury. Participants and care providers convened six times over the course of the study to participate in structured interviews to solicit information on destinations they wished they could travel to but currently did not frequent, the perceived barriers to these desires, and ideas for tools or strategies to increase the ease of desired community navigation. The results of this study indicated that the majority of trips undertaken by participants were routine and assisted, and tended to be for medical appointments or errands rather than recreational or social purposes. The participants' navigational wish lists, the barriers encountered, and their suggested strategies for mitigating problems informed the design of ATC tools.

In order to design assistive navigational tools, we needed to better understand the behaviors of people with cognitive impairments that resulted in getting lost. The navigational profile study just described revealed that becoming lost was a frequent and anxiety-provoking problem. Participants were unwilling to venture to new places because of a fear of getting lost. In a matched control comparison design, we compared the getting lost behavior of individuals with brain injury to matched controls as they followed a route with built-in navigational challenges (Lemoncello, Sohlberg, Fickas, & Prideaux, 2010). We learned that individuals with brain injury required more attempts at reorientation and needed concrete, salient information along with emotional reassurance in order to successfully re-enter the route.

The information gathered from the navigational profile and studies examining the antecedents that led to participants losing their way provided the groundwork to develop navigational prompting tools that were based on input from the individuals that they were designed to assist, with the types of navigation supports that were most important to them (Sohlberg et al., 2007). Had we not conducted these earlier studies of needs, wants, barriers, and suggested solutions by the targeted users of the devices, we would have developed very different prompting tools. In this third study, we evaluated potential differences in route navigation using a within-subject comparison when travelers with brain injury received prompting from four different types of prompt modes (text based, no image; audio, no image; point of view image; and aerial image). Results showed higher navigational scores when participants received prompts via speech-based audio directions. Usability studies of early ATC devices are congruent with the CFIR framework that encourages trialability (Damschroder et al., 2009).

In short, the design of ATC for a particular functional domain, transportation, was enhanced by partnering with people with brain injury in order to understand their priorities and solicit their expertise. In addition, usability studies with participant feedback provided input into the design of initial prompting prototypes from the inception.

ATC Example 2: Development of an Adapted E-Mail Interface

The potential for electronic communication to decrease social isolation in persons with cognitive impairments led us to explore a research agenda dedicated to developing an adapted e-mail interface that could be used by people with severe memory impairments. Our exploration began with an attempt to understand current computer use and usability patterns in people with brain injury through survey and focus group activities (Todis, Sohlberg, Fickas, & Hood, 2005). This work confirmed the desire of the people with acquired cognitive impairments, particularly memory impairments, to utilize e-mail and documented specific accessibility difficulties. We also learned that in addition to difficulty using the actual e-mail programs, there are a number of financial and cognitive barriers to setting up and maintaining a home Internet connection for this population. Individuals with cognitive disabilities have less available money to purchase and maintain a computer and Internet services. Cognitive impairments also lessen their ability to troubleshoot and manage ongoing required computer updates such as keeping up with security alerts or resetting a computer after a power outage. Implementation science encourages research that establishes the needs and the contexts for intervention supports by conducting well-planned local needs assessments, assessing for readiness, and identifying barriers and tailoring the intervention to overcome barriers and honor stakeholder preferences (Powell et al., 2012).

Results of the previous study suggested that an e-mail program might not be usable by the target population unless they had public computing options. This led to a systematic evaluation of public computing contexts that would be available for people with cognitive impairments (Fox, Sohlberg, Fickas, Prideaux, & Lemoncello, 2009). A telephone survey was administered as a semistructured interview to 145 informants representing seven types of public facilities across three geographically distinct regions using a snowball sampling technique. We learned about the factors that rendered different places more or less accessible for public computing. For example, libraries had the highest percentage of access barriers, including complex queue procedures, login and password requirements, and limited technical support. The study also allowed us to predict trends in public computing including the emergence of widespread Wi-Fi and limited access to terminals that permit auto-launch applications, which gave direction for how to design an adapted e-mail program. Through this study, the authors were able to identify and analyze the costs associated with the intervention. The CFIR (Damschroder et al., 2009) encourages examination of resource constraints as part of the intervention characteristics that affect adoption of intervention.

Using a collaborative, iterative design process involving software engineers, rehabilitation researchers, and people with brain injury, we developed an adapted e-mail program that could be used on public computers. We then conducted an efficacy pilot study to assess whether a group of people with severe memory impairments who had failed in previous attempts to use computers would be able to use the e-mail program independently. The study included a longitudinal evaluation of e-mail use to identify long-term supports that were needed for maintaining e-mail use, and to measure potential changes in social isolation and self-esteem, the two areas people hoped would change by being able to use e-mail (Sohlberg et al., 2005). The positive results of this study led to the commercialization of the adapted e-mail tool.

Similar to the development and initial evaluation of the transportation prompting systems, a collaborative, iterative design process that included evaluation of contextual variables allowed us to design a tool efficiently that could meet the needs of and be usable by the target population. In implementation science, the strategies of considering inner setting and engaging the necessary stakeholders in the implementation process allows researchers to design an ATC tool with optimal chance for high usability (Damschroder et al., 2009). Accounting for stakeholder characteristics, specifically patients' needs and resources, also informed the researchers of how the innovation needed to be adapted. Managing quality of the intervention by collaborating with consumers from the target population and intervening with consumers to enhance uptake and adherence were effective in transforming a protocol into a highly usable tool (Powell et al., 2012). Table 2 shows how the design of tools in two different ATC domains incorporates implementation science research strategies. Other ATC studies have likewise utilized implementation science strategies to enhance the usability and impact of their tool. For example, the design of CogSMART, a symptom management tool for veterans with ongoing cognitive impairments following concussion, was informed through careful stakeholder assessment (Twamley, Jak, Delis, Bondi, & Lohr, 2014).

Table 2. Correspondence of ATC development research activities to implementation science frameworks.

ATC research		Implementation science	
Need	**Activity**	**Phase: *Discrete strategy*[a]**	**Factor[b]**
Understand navigational patterns.	Conducting a field study.	Planning phase: *Local needs assessment.*	Process: *Planning, engaging.*
Identify barriers to transport access for the target population.	Exploratory study conducted to analyze "getting lost" behavior.	Planning phase: *Assess for readiness and identify barriers, tailor strategies to overcome barriers and honor preferences.*	Intervention characteristics: *Cost associated with intervention.*
Determine patient preference.	Study to evaluate preferred prompting method.	Quality management phase: *Obtain and use patient/consumer feedback.*	Stakeholder/individuals' characteristics: *Knowledge and beliefs about the intervention.*
Understand current computer use and usability patterns in target population.	Survey and focus group activities.	Planning phase: *Conduct local needs assessment, assess for readiness, and identify barriers*. Build buy-in: *Conduct local consensus discussions.*	Intervention characteristics: *Trialability* Stakeholder/individuals' characteristics: *Knowledge and beliefs about the intervention.*
Identify resource barriers (contextual and technological constraints).	Systematic evaluation of public computing contexts via phone interviews with persons distributed in geographically distant regions.	Planning phase: *Conduct local needs assessment, assess for readiness, and identify barriers.*	Intervention characteristics: *Trialability, cost.*
Determine if target audience would be able to independently utilize the program.	Efficacy pilot study.	Planning phase: *Stage implementation scale-up.*	Process: *Planning, engaging, executing.*

[a]Powell et al. (2012, 2015). [b]Damschroder et al. (2009).

Conclusion

Implementation science is helping to close the gap between research and practice by designing efficacious treatment interventions that address the priorities of clinicians and participants (Redle & Atkins, 2013). The CFIR (Damschroder et al., 2009) and the menu of implementation strategies described by Powell and colleagues (2012, 2015) provide a roadmap of research factors to consider when designing an intervention. In our experience, attention to these principles and strategies has increased the feasibility and efficacy of both impairment-based cognitive rehabilitation programs and ATC.

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