

Group Intervention Studies in the Cognitive Rehabilitation of Individuals with Traumatic Brain Injury: Challenges Faced by Researchers

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Abstract There are many factors to consider in designing and interpreting group studies. These include both analytic considerations, such as the selection of valid and reliable outcome measures, and subjective considerations, such as the selection of outcomes that are perceived to be important to participants and researchers. In this paper, we review key issues to consider in the design of group studies in neurorehabilitation, using problem-solving studies in traumatic brain injury as an example.

Keywords Cognitive rehabilitation · Traumatic brain injury · Randomized control trials

A few months ago, a group of experienced speech-language pathologists and neuropsychologists met to discuss the strength of evidence for treating deficits in executive function. Upon hearing some of the methodological concerns across studies, one participant commented, “I don’t understand. All the things you’re describing as missing from these studies, are the very things we all learned about controlling for in graduate school. Aren’t these common sense if you’re a researcher?” It is true that we all learned about placing certain controls in intervention studies to assure the findings’ validity. In reality, however, researchers do the best they can in designing intervention studies given the constraints within their therapeutic context, and the state of their knowledge at that point in time.

Over the past five years, as part of an effort by the Academy of Neurologic Communication Disorders and Sciences, we have reviewed the research evidence for evaluating and treating cognitive and communication disorders in individuals with traumatic brain injury (TBI).¹ We have systematically reviewed the research literature, created tables of evidence, written technical reports, and created practice guidelines for formal and informal assessment (Coelho, Ylvisaker, & Turkstra, 2005; Turkstra et al., 2005), direct attention training (Sohlberg et al., 2003), the use of external memory aids (Sohlberg et al., *in press*), and intervention for self-regulation of memory and learning (Kennedy & Coelho, 2005). This process has shown us first-hand the challenges faced when making clinical recommendations from intervention studies that vary across numerous parameters; these parameters being the very ones that researchers attempt to meet if the outcomes are to be considered valid. In this paper, we discuss those challenges. We present the recommended parameters established for group intervention studies and provide examples of studies that were exemplary in meeting these parameters. We also discuss the challenges and the realities faced by researchers when designing group intervention studies for individuals with TBI. Throughout the paper, we discuss the caveats of interpreting and generalizing from group studies to individual clients.

Cognitive rehabilitation for individuals with TBI is a relatively new discipline when compared to rehabilitation for individuals with stroke or neurological disease. As a

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¹ The Academy of Neurologic Communication Disorders and Sciences (ANCDS) established writing committees in 1997 to develop evidence based practice guidelines for various clinical populations. The writing committee on Evidence-based Practice of Cognitive-Communication Disorders after Traumatic Brain Injury was established in 2001. For details about these committees and their work (see Frattalli et al., 2003).

discipline, cognitive rehabilitation has both breadth and depth, though some areas are less developed than others. Some areas have evolved rapidly out of urgent need, and other areas have evolved slowly out of advanced understanding of cognitive disorders. For example, the need for intervention studies on effective strategies for managing challenging behavior grew out of an urgent need for individuals trying to return to school, work and home. On the other hand, intervention strategies for attention disorders focused on training discrete types of attention early on, while more recently intervention strategies have focused on more complex attention skills (e.g., multitasking) used in distracting contexts. In the latter example, researchers have had more experience grappling with and controlling the threats to validity, stability, and ecological importance.

Recently, there has been a major conceptual shift in cognitive rehabilitation. In early clinical practice and research, there was an assumption that cognitive processes such as attention, memory, and executive functions were distinct or discrete and could be treated as such, and that cognitive recovery after brain injury followed a hierarchy. There also was an assumption that gains observed in clinic would transfer to daily living, a notion sometimes referred to as “train and hope.” More recently, however, outcome has been conceptualized as a complex interaction of factors affecting performance in different contexts. This notion was formalized in the World Health Organization International Classification of Function, Disability and Health (2001) (www3.who.int/icf/icftemplate.cfm), which provided language for a variety of deficits ranging from the pathophysiology of the brain to participation in society. In this framework, deficits of underlying processes are “impairments” in body structures or functions (e.g., hematomas, anterograde amnesia), impaired skills during activities are “limitations” (e.g., difficulty using the telephone), and the effect of impairments and limitations in one’s home and family, workplace, school, and community are ‘restrictions’ (e.g., inability to return to work) (Bilbao et al., 2003). Two added factors that affect performance are personal factors, such as the individual’s motivation, and environmental factors, such as the availability of cognitive supports. The implication of this framework is that now researchers can investigate the effectiveness of a particular intervention that targets an activity (e.g., asking strategic questions to solve a problem, or managing time in a complex activity with constraints) while investigating whether impairments and participation change as well. Additionally, our knowledge of how neural networks work broadly across various activities, and the absence of generalization effects from isolated process-specific intervention to everyday activities, has provided support for intervention that targets specific behavior and activities rather than “discrete” impairments. The benefits of this expanded framework are that it allows for consideration of outcomes

that might be more meaningful to the participants than standardized test scores and that it provides researchers with a variety of primary study endpoints from which to choose. The challenge is in selecting appropriate outcome measures from this array of choices.

In the following sections, group intervention studies for problem-solving, planning, and organization deficits after TBI are used to illustrate the challenges that researchers face when designing and interpreting group studies, and the challenges that clinicians face when applying study results to their individual client. The ANCDs writing group searched the Medline, PsychInfo, CINAHL and Eric databases, and identified 15 intervention studies that were published prior to 2005 and met our criteria. Of these, 9 (60%) used group designs and are used in the following sections to illustrate key points about designing group studies in cognitive (Fasotti, Kovacs, Eling, & Brouwer, 2000; Fox, Martella, & Marchand-Martella, 1989; Levine et al., 2000; Manly, Hawkins, Evans, Woldt, & Robertson, 2001; Marshall et al., 2004; Rath, Simon, Langenbahn, Sherr, & Diller, 2003; Stablum, Umilta, Mogentale, Carlan, & Guerrini, 2000; von Cramon, Matthes-von Cramon, & Mai, 1991; Webb & Gluecauf, 1994).

Group intervention studies

The primary goals of a group intervention study are to determine whether or not a particular therapy effectively results in a desirable change in behavior in the sample population, and whether the intervention would have similar results in a different sample of that same population (e.g., patients who have similar characteristics, such as severity of memory impairment or awareness of disability). Therefore, the degree to which the outcomes can be attributed to the intervention depends on the extent to which the researcher provided experimental “control” by carefully selecting the sample population, providing detailed and sufficient intervention, and using reliable outcome measures.

The American Academy of Neurology developed criteria for group intervention studies (AAN, 2004) and have classified studies accordingly. The classification of each study is based on the number of criteria that are met by that study, and whether there is random or non-random assignment to treatment and control groups. The strongest classification (Class I) is a randomized clinical trial (RCT) that satisfactorily meets the following criteria:

- inclusion and exclusion criteria were provided and are representative of the population;
- scorers were blinded to assignment;
- outcomes were clearly defined and reliably measured;
- baseline measures of groups were equivalent; if not, then adjustments were made in the statistical analysis to handle

dissimilarities in baseline characteristics (e.g., age, socioeconomic status, intellectual ability).

Researchers using group design studies may or may not randomly assign participants to treatment conditions. Randomizing is not always possible, particularly for researchers working in rehabilitation programs in which every individual will receive rehabilitation services. These are class II studies, defined by the AAN as prospective matched group cohort studies in which the outcome assessment is masked, and the other criteria for RCTs are satisfied.

In designing treatment studies, it is important to recognize that RCTs have significant limitations and are by no means the only mechanism for generating evidence of treatment efficacy. The RCT framework has been adopted by behavioral therapists, but its structure was designed for clinical drug trials, many features of which are not appropriate, practical, or relevant in behavioral intervention research. Even in the case of drug studies, an over-reliance on RCTs is counter to the goals of the initial EBP guidelines by Guyatt and colleagues (Guyatt et al., 2000). A narrow definition of “evidence” also excludes potentially useful information from qualitative studies, which have made an important contribution in areas such as the study of long-term psychosocial outcomes from TBI (e.g., Bedell, Cohn, & Dumas, 2005).

The sample population

The AAN (2004) recommends that optimally, randomized group studies should apply the same inclusion and exclusion criteria to the study’s sample that would describe the general population. The rationale for this is that the extent to which results can be generalized from the study sample to the target population (in this case, individuals with TBI) depends on the extent to which the target population was represented in the sample. Further, researchers can only replicate a study if the sample is well described. This is a challenge in TBI rehabilitation research because, like many clinical populations, survivors of TBI are a highly heterogeneous group of individuals.

Fortunately, many characteristics of the TBI population are well known, and samples have been fairly well described in studies of intervention for problem-solving and planning. Some of the more common characteristics that are important to address in TBI research include gender, age, level of education, length of time since injury, severity of injury, severity of impairments, history of prior treatment, and total sample size. It should be emphasized that the relative importance of these characteristics varies depending on the cognitive area being targeted, type of intervention, and desired outcomes.

More males than females sustain brain injuries, with estimates between 2:1 and 3:1. Although every age group is affected by TBI, young male adults make up the single largest group and the incidence of TBI in the elderly is rising. The demographic characteristics of participants in published studies reflect these characteristics to some extent. Seven of the nine group studies that addressed problem-solving and planning had more male than female participants. Of the nine group studies, all but one reported the ages of participants, with ages ranging from young to middle adulthood, whereas none included children or adults over the age of 60. The age range of TBI survivors may change in the future. As preventive healthcare targets various diseases associated with aging, more elderly individuals who live longer will be at increased risk for falls (Injury and Violence Prevention Unit: *Emergency Department-Treated Traumatic Brain Injury Minnesota 1998–2003*, 2005). Furthermore, as helmet laws go into effect, fewer cyclists of all ages may have lasting TBI-related disabilities in the future.

The level of education of study participants may also be an important characteristic to report in cognitive intervention studies, particularly in studies aimed at shaping complex behavior or skills. The typical TBI survivor has completed or nearly completed high school with about 12 years of formal education. Of the nine group intervention studies that focused on problem-solving and planning, seven reported educational experience at approximately 12 years. One study did not report education, though it could be argued that education had little or no bearing on the study’s outcome, since the intervention was comprised of using auditory alerts to prompt individuals to continue with a complex sequence of tasks (Manly et al., 2001). With the advent of alternative forms of education, such as home-schooling or passing a GED exam in lieu of graduating from high school, and increasing numbers of adults returning to high school or college later in life, the years of formal education may no longer be the best indicator of educational experience. Rather, estimates such as the verbal intelligence quotient from the National Adult Reading Test (Nelson & Willison, 1991) for individuals at least one year after injury (Riley & Simmonds, 2003) might be more useful for equating groups than the years of formal education.

As with any clinical population that is recovering, chronicity of disability or the length of time since the injury remains an important indicator of stability of deficits. The extent to which the patient is stable determines the extent to which any change in a skill or behavior could be attributable to the intervention rather than spontaneous recovery. All nine group studies aimed at problem-solving and planning reported the amount of time since the injury. Participants in all but two studies were many months or years past their injury, demonstrating the chronicity of the samples.

In many studies, a general guideline of six months post-injury is used to define the period of spontaneous recovery. This is an oversimplification, however, since the rate of recovery may vary from individual to individual. For example, recovery can be prolonged for those who sustain injuries with concomitant medical complications. Furthermore, severity of injury does not always predict speed of recovery. For example, an individual's physical abilities may recover faster than cognitive abilities, or vice versa. If the individual sustained a very severe injury, then he or she will likely still be improving 12–18 months after the injury, belying the previously unproven assertion that 3–6 months post-injury is the "end" of spontaneous recovery.

Given recent advances in knowledge about brain plasticity in healthy and neurologically-impaired adults, and growing evidence that intervention in the later stages post-injury may be more effective than intervention delivered during the first few days and weeks post-injury (Raymer et al., 2006), future researchers will need to revisit the notion of "spontaneous recovery" and its relevance in rehabilitation research. In the literature reviewed by the ANCDs TBI Writing Committee, there was no evidence of treatment efficacy for interventions delivered during the acute stage post-injury, including intervention for problems in attention, memory, executive function, and social behaviors, but the definition of "acute" varied across studies. This should be carefully considered in future studies, given the implications not only for outcomes research but also for service delivery models and reimbursement.

Traditionally, severity of injury was an important factor to consider when designing an intervention study. More recently, evidence about the kinds of deficits that are long lasting and the effects of rehabilitation on TBI survivors suggests that describing current cognitive status, functional deficits, and inclusion and exclusion criteria are indeed more important than classifying participants by the initial severity of injury. An individual who sustained a moderate injury may be left with complicated memory, self-awareness, and executive function deficits at the time of the study, whereas an individual who sustained a severe initial injury may have severe memory impairment but good executive functions. There are several examples in the rehabilitation literature of studies that provided severity of injury and severity of deficits information. For example, Fasotti et al. (2000) used well-defined selection criteria and test scores to describe a group of severely and very severely injured, chronically-disabled adults, some of whom were in a subacute rehabilitation program, while excluding adults with aphasia and severe intellectual impairment. In a study that investigated the effects of goal management training, Levine et al. (2000) provided a thorough description of participants who were independent, had no language or memory problems, but had strategy-application disorders that were identified in a prior

study. These participants had made a good to moderate recovery at the time of the study, even though injury severity was documented with coma scores, post-traumatic amnesia, and neuroimaging reports. Participants were excluded based on a long list of co-morbid behaviors.

Intuitively, it seems important to document the amount and type of prior cognitive rehabilitation. However, if participants are years post-injury and the pool from which they were recruited was sufficiently described the treatment that occurred years ago may have little bearing on the existing study. Practically speaking, once years pass, it becomes very difficult for researchers to obtain past treatment records, let alone find detailed reports and documentation of progress. On the other hand, when participants have sustained their injuries more recently, such as less than one year prior to the study, treatment history could confound the results of the study. When this is the situation, regardless of the outcome of study, the researchers should review each participant's treatment history, including the type and amount of treatment, and interpret the results in light of that information. Given the challenge of obtaining prior treatment records, it is not surprising that only four of the nine group intervention studies that focused on problem-solving and planning provided even general descriptions of participants' prior treatment (Fox et al., 1989; Marshall et al., 2004; von Cramon et al., 1991; Webb & Gluecauf, 1994). Of those that did not describe treatment history, only the study by Fasotti et al. (2000) included individuals with more recent injuries.

When considering participant selection criteria and methods for equating groups, there are several issues to consider. The first issue is the practicality of constructing clinical trials that address all relevant characteristics of participants and rehabilitation techniques (Montgomery & Turkstra, 2003). For example, suppose a rehabilitation facility wishes to compare inpatient vs. outpatient treatment for memory disorders. Participant characteristics such as age, length of time post-injury, severity of various cognitive impairments, and prior treatment history may play an important role in the study's outcome, along with treatment variables such as the type, frequency, and intensity of treatment. There are many published approaches to memory intervention that have demonstrated some evidence of efficacy for individuals with TBI, including environmental modifications, techniques for training external memory aid use, errorless learning, and spaced-retrieval training. If participants were divided into groups representing all possible combinations of treatments and conditions, this study would need more than 300 arms, a task too daunting for any researcher. Clearly, no researcher would attempt this. Instead, he or she would choose a design that is logical and practical, given the facility's resources and goals, the previous literature, and the available participant population. That is, the researcher would make a decision based on information extrinsic to the analysis itself.

A separate but important issue is the size of the sample. The general thinking about sample size among researchers (and clinicians) is that the larger the sample size the greater the power; that studies with small numbers of participants do not provide strong evidence, regardless of the outcome. The problem with applying this as a broad principle to a heterogeneous population such as TBI, is that the larger the sample, the more heterogeneous it becomes and the lower the likelihood that all participants will benefit from the intervention. The important question is one of sufficiency: What sample size is sufficient to obtain positive outcomes?

The requisite number of participants for a study can be estimated using a power analysis, but only if there are prior studies to use as a reference. An earlier study must be relevant to the current study being planned, such that a similar sample population, intervention, and outcome measures were used. Unfortunately, prior studies with these precise specifications usually do not exist. When this occurs, the researcher can use a general guideline that involves the ratio of number of participants to the number of dependent variables, i.e., outcomes. More conservative ratios are 20 to 1, although 10 to 1 can produce positive outcomes when the sample is more homogeneous (e.g., Schiavetti & Metz, 2005). Is it not impressive when a researcher has identified a precise subgroup from the general population that has benefited from a specific intervention leading to positive outcomes that are maintained over time? Indeed it is, regardless of the sample size.

Study design and outcomes

Designing randomized clinical trials in cognitive rehabilitation

At first glance, randomly assigning participants to treatment conditions appears to be optimal and is a worthy goal. However, most rehabilitation researchers find that they have access to individuals who are heterogeneous in the type and severity of impairments which increases even more when comorbid diagnoses are added to the mix. Typically researchers have to choose the important characteristics that they will try to equate across groups (e.g., age, time since injury, severity at the time of study), rather than to attempt equate groups on all characteristics. Even so, random assignment does not necessarily mean that groups will be equal on important variables. Fortunately, researchers can (and should attempt to) manage differences between (or within) groups statistically.

There are several features of RCTs that limit their application specifically to rehabilitation studies. A key feature when designing an RCT is to “blind” or “mask” participants to their group assignment. The intent of blinding is to minimize the potential for effects associated with knowing one is in the treatment arm of a study, and to identify placebo ef-

fects such as the effect of the perception that one is receiving a “newer” or “special” treatment rather than conventional care. In reality, however, it is often impractical to expect participants to be truly ignorant of their group membership. For example, participants attending the same rehabilitation facility are likely to know that they are not all receiving the same type of therapy, and in studies using crossover and A-B-A (Baseline-Treatment-Posttreatment) designs, participants are aware that they are receiving different treatments over time.

Another feature of RCTs that limits their application to rehabilitation is the assurance that those delivering therapy are blinded to the intervention condition. Clearly this is challenging for studies that involve changing or shaping behavior, although the alternative of not even attempting to control for this seems unacceptable as well. For example, procedures could be established for other rehabilitation professionals involved in the individual’s care, to be “masked” from knowing the treatment condition to which the participant is assigned, even though this would not prevent the client from informing others about the therapy. It is often the case that the treatment involves numerous rehabilitation team members who need know its nature. Clearly, blinding those who deliver the intervention or even those who have contact with the participant is nearly impossible. Consistent with this, no studies of intervention for problem-solving and planning reported masking those who delivered the intervention.

Choosing and scoring outcomes

Another important decision that the researcher must make is to choose outcome measures that best represent the treatment results. The ICF provides researchers and clinicians with categories of outcomes that can be measured, but perhaps with varying degrees of reliability. Early in the field of cognitive rehabilitation, outcomes reflected the perspective that cognitive processes were distinct; outcomes from these studies would now be classified as “impairments” revealed by formal assessment batteries designed to evaluate attention, memory, executive functions, and other aspects of cognition. When researchers attempted to document “real life” changes in daily activities or societal participation, they often used anecdotal reports from clients and families. Fortunately, there are now several questionnaires, rating scales, and structured interviews that have reliably achieved this goal and have largely replaced anecdotal descriptions of functional outcome. This is positive news for researchers and clinicians who need not only reliable, but also valid measures of real-life performance. This is particularly important in light of the emerging evidence of the variability in performance across different high-level cognitive tasks as the demands, context, and stimuli change. For example, Keleman, Frost, and Weaver (2000) reported that the ability of healthy adults, to accurately

self-assess the learning of word-pairs (an impairment-level task) is not related to the ability to self-assess narrative learning (an activity-level task). Kennedy (2004) found similar results for adults with TBI.

Using multiple outcomes to measure treatment efficacy and effectiveness presents its own challenges for researchers. Traditionally, RCTs are designed to measure change using a single, primary outcome. When secondary and tertiary outcome measures are included, the possibility increases that Type I errors will occur. To guard against this, researchers can select specific outcomes a priori that are appropriate to the sample and based on the severity and type of deficits, the needs of the participants, the potential for follow-up after treatment, etc. For example, faster response times (RTs) in individuals with little mobility elicited during computer games may have clinical validity if RTs transfer to environmental control systems that allow individuals to be more independent. Even though response time is considered an “impairment” measure, its effect could have real-world consequences.

Two areas of cognitive rehabilitation have been exemplary in their use of activity and participation outcomes with the TBI population: intervention studies investigating the effectiveness of external memory aids and intervention studies aimed at improving problem-solving and planning. From a systematic review of the evidence, Sohlberg et al. (in press) found that all intervention studies in which external memory aids were used to compensate for memory impairment reported improvements in everyday activities or a reduction in the number of missed opportunities relative to forgetting. Likewise, intervention studies aimed at improving problem-solving resulted in positive changes in number of errors, on-task behavior, accurate problem-solving, number of steps when managing complex tasks, etc. However, only three of the nine group studies reported both impairment and activity-type outcomes (Fasotti et al., 2000; Rath et al., 2003; von Cramon et al., 1991).

Proponents of RCTs stress the importance of “masking” the individuals who are scoring the outcome measures from the treatment condition. This is possible only when the scorers are independent from the study, i.e., when they have no prior knowledge of the purpose of the study or the treatment conditions. Presumably, if scorers have this knowledge they could be biased toward or against one of the treatment conditions and inadvertently bias their scores. Practically speaking, most researchers have naïve scorers who can be trained to score the results of tests or activity-based measures. However, this is impractical when documenting changes in participants roles at home, work, or school, i.e., participation outcomes. By definition, participation outcomes are reports of personal and societal attitudes and roles, and are typically obtained from the participants themselves, or their family, friends, employers, teachers, therapists, and others.

Of course, these individuals would be aware of the TBI individual’s participation in a study. Therefore, this notion that individuals who are responsible for scoring (or reporting) be “masked” to the intervention is not only impractical, it does not make sense if trying to document change at the participation level.

Analyzing and reporting outcomes

Traditionally, analyzing outcomes from RCTs is done in accordance with the “intent-to-treat” (ITT) principle, or analyzing the results of treatment provided differentially to randomized groups. The underlying assumption of ITT is that participants have been randomly assigned to treatment groups, and therefore, analyzing all the outcomes regardless of compliance guards against the potential for bias. ITT analysis is commonly used in drug studies. As such, ITT provides “typical” rather than “ideal” compliance (e.g., Ellenberg, 1996).² Compliance refers to the amount, duration, frequency, or type of treatment within each treatment arm and can be coded accordingly. The degree to which compliance accounts for the outcomes can then be accounted for statistically by using compliance (codes) as covariates in an analysis of covariance (ANCOVA).

In any new field such as cognitive rehabilitation, it is imperative to first establish results under ideal conditions. Applied to cognitive rehabilitation studies, ITT analysis would provide a treatment’s “effectiveness” rather than its “efficacy,” i.e., with typical rather than ideal results. However, all of the studies that focused on problem-solving and planning reported outcomes used “as-treated” analysis rather than ITT analysis. As-treated analysis may be biased if either group changed after random assignment to their treatment condition. A solution is to manage these changes statistically, as discussed above.

For many cognitive rehabilitation studies, dropout rates are a more serious concern than managing differences between groups. The AAN recommends a goal of less than 25% of participants dropping out of the study. If the rate is higher than 25%, a randomized study receives a lower classification of Type II or III evidence depending on whether there are other methodological concerns. The reality of conducting intervention that extends over many weeks or even months is that the researcher rarely has much “control” over maintaining a low dropout rate, particularly if the participants are outpatients who are trying to return to the community, work, or school. These individuals are more independent and mobile, and have more complex daily schedules than individuals whose cognitive or physical disabilities require full-time

² ITT analysis is useful for RCTs in which the treatment arms include an experimental condition and a placebo condition. ITT analysis is inappropriate when a randomized, crossover design is used.

assistance. Rather than applying an arbitrary percentage as a requirement for “strong” studies, it may be more important to evaluate the demographics of those who discontinued intervention post-hoc and provide an explicit explanation of whether this could have affected the results. For example, if the individuals who discontinued the study had less self-awareness than those who finished the study, then the positive outcomes could be inflated, since having self-awareness has been related to success in many rehabilitation programs and therapies. However, if there is good reason to believe that self-awareness has little to do with the treatment effects, then the missing data did not bias the results. Thus, knowing how individuals who dropped out affected the results is a more important issue than knowing their number. The former can be explained by the study’s authors (and sometimes called “explanatory hypotheses”), whereas the latter cannot necessarily be controlled.

Alternatively, researchers can anticipate participants dropping out of studies by collecting outcome data at various points of time during treatment. If participants discontinue, their “last-observation-carried-forward” can be statistically estimated over time. Even though this kind of estimation would be preferable over “missing data,” none of the cognitive rehabilitation studies reviewed to date by the ANCDs writing committee included this type of analysis.

With the burgeoning need to provide practice recommendations to clinicians and the advent of meta-analyses, it has become important that we, as researchers, are mindful of the needs of future researchers and clinicians who will want to draw conclusions and make recommendations across intervention studies. Thompson (2002) has called for researchers to use “meta-analytical thinking” when planning for a study’s results or outcomes. Thompson defines *thinking meta-analytically* as both (a) the prospective formulation of study expectations and design by explicitly invoking prior effect sizes, and (b) the retrospective interpretation of new results, once they are in hand, via explicit, direct comparison with the prior effect sizes in the related literature” (p. 28). Thompson recommends that researchers plan their study based on the effect sizes (ES) of the outcomes of prior studies, and their outcomes be compared and contrasted with outcomes from other studies. An ES is an indication of the magnitude of a finding (statistically significantly different or not); although collected as continuous variables, they are typically interpreted as small (.20) medium (.50) and large (.80) (Cohen, 1988). Although conceptually this kind of planning and interpretation is not new, reporting ESs and not just the level of statistical significance has only recently become common practice in reports of empirical investigations.

A temporary problem for those developing practice recommendations from trends across current studies is that only the most recently published studies report ESs. The *Publication Manual of the American Psychological Association*,

5th Edition (2001) instructs researchers on how to report ESs and most peer-reviewed journals from medical, educational, rehabilitation and psychological fields now require them. Of the group studies that focused on improving problem solving and planning, only one study reported ESs (Fasotti et al., 2000).

When ESs are not reported, they can be estimated as long as all the necessary data are explicitly provided (Cooper & Hedges, 1994). Unfortunately, this is not always the case; some authors only report group means and standard deviations when the differences between groups (or conditions) are statistically significant.

Finally, Thompson (2002) also stresses the importance of reporting confidence intervals in a graphic display with ESs, so that future researchers can make explicit comparisons between former outcomes and outcomes from their study. The inclusion of confidence intervals also helps clinicians determine the likelihood of getting results that would be similar for individual participants or clients.

An additional consideration for researchers is whether to report group or individual data. Most group studies report only aggregate data, but these data are somewhat limited, as illustrated in a study by Hashimoto, Okamoto, Watanabe, and Ohashi (2006). These authors compared psychosocial, educational, and vocational outcomes between 25 adults with TBI who received rehabilitation and a comparison group of 12 who did not. Hashimoto and colleagues reported statistically significant differences between groups on the outcome measures in favor of the rehabilitation program, and noted that 23/25 participants in the treatment group improved on the Community Integration Questionnaire (Willer, Ottenbacher, & Coad, 1994) vs. 5/12 in the comparison group. These results alone are of limited utility, since it is unclear how much each group member improved. What if the five comparison group participants improved sufficiently to return to work, while the 23 in the treatment group improved but not enough to change their life outcome? The statistical comparison does not answer this question. Fortunately, Hashimoto and colleagues also provided individual data, reporting, for example, that nine of the treatment group participants returned to work or school, compared to two in the control group. These results are more compelling.

Conclusion

Many factors must be considered in designing and interpreting group studies. These include both analytic considerations, such as the selection of valid and reliable outcome measures, and subjective considerations, such as the selection of outcomes that are perceived to be important to participants and researchers. As researchers we can more broadly *think meta-analytically* as we use continually updated

evidence about clinical populations to equate groups on *selected* characteristics. We can also *think meta-analytically* by controlling for *features of randomized studies that make sense* given the constraints of conducting research with teams of professionals. Reporting outcomes that include ESs and their confidence intervals will not only assist future researchers who are investigating similar interventions or similar sample populations, but will also become a part of the research evidence that will eventually be used to create practice recommendations for clinical groups.

As researchers and clinicians, we recognize that even the most carefully designed, well-controlled study will never be sufficient to determine the best clinical practice for an individual client. This requires clinical judgment, which in some circles has taken on a pejorative connotation. Clinical judgment does not mean “anything goes if it seems reasonable.” Rather, it is the skilled use of logical reasoning, knowledge, and experience to make decisions. The challenge for researchers and clinicians is to generate good judgments, avoid judgments that will not benefit the client, and learn to recognize the difference.

The efforts of the ANCDs writing committees (e.g., Frattalli et al., 2003), previous guidelines authors (e.g., Cicerone et al., 2005), and international colleagues (e.g., PsychBITE authors Tate, Perdices, McDonald, Togher, & Moseley, 2004), have clearly demonstrated the strengths and limitations of the existing literature on group intervention for individuals with neurological disorders. This should inspire us to conduct more carefully controlled research, but also motivate us to study the role of good judgment in clinical practice with the same rigor we devote to clinical trials.

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