Outcome Oriented

The Online Newsletter of the
Center for Outcome Measurement in Brain Injury **(COMBI)**

Winter 2003

Measuring Up!

The COMBI continues to add more important scales to its resource center. As of November 2003 there are currently twenty-two measures featured and detailed in the COMBI.

Agitated Behavior Scale (ABS)

Alcohol and Substance use items

Awareness Questionnaire (AQ)

Coma/Near Coma Scale (CNC)

Community Integration Questionnaire (CIQ)

The Craig Handicap Assessment and Reporting Technique (CHART)

The CHART Short Form (CHART-SF)

The Craig Hospital Inventory of Environmental Factors (CHIEF)

Disability Rating Scale (DRS)

The Family Needs Questionnaire (FNQ)

Functional Assessment Measure (FAM)

Functional Independence Measure (FIM)

Glasgow Outcome Scale (GOS)

Extended Glasgow Outcome Scale (GOS-E)

Levels of Cognitive Functioning Scale (LCFS)

Mayo Portland Adaptability Inventory (MPAI)

Neurobehavioral Functioning Inventory (NFI)

The Orientation Log (O-Log)

The Patient Competency Rating Scale (PCRS)

Satisfaction With Life Scale (SWLS)

Service Obstacle Scale (SOS)

Supervision Rating Scale (SRS)

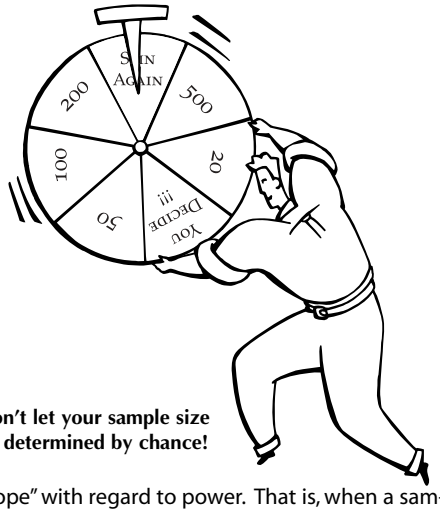
Mysteries Revealed Inside:

Statistical Power Analysis: How Large Should My Sample Be?

Scott R. Millis, PhD, MEd
Traumatic Brain Injury National Data Center
Kessler Medical Rehabilitation Research & Education Corporation

In determining the number of participants to recruit for a study, an investigator considers many factors, such as the amount of time and money available for the study or the prevalence of disease or disorder of interest. Expensive research protocols or rare disorders may lead to small samples. More informally, the final sample size in some studies is determined when a grant ends, when a paper is due, or when the investigator loses interest in the study. In other cases, researchers may employ general "rules of thumb" to determine sample size. For example, Currier (1984) recommends a minimum of 15 participants per group in experimental studies involving group comparisons.

Although the practicalities of time, money, and study feasibility cannot be ignored, formal sample size calculations (also known as a "power analysis") need to be conducted prior to the initiation of every study to preclude waste of resources. Statistical power is the capacity to detect a treatment difference or association when one is actually present. Sample size acts as a statistical "microscope" with regard to power. That is, when a sample size is small, the study may lack sufficient power to detect a treatment difference even when one is present – much like using a toy microscope to try to see tiny micro-organisms. It is better to know upfront if a proposed study will require an unachievably large sample to detect a treatment difference than to go ahead with the study that will yield murky results at best. In their discussion of under-powered studies, Halper, Karlawish, and Berlin (2002) have argued, "Because such studies may not adequately test the underlying hypotheses, they have been considered scientifically useless and therefore unethical in their exposure of participants to the risks and burdens of human research" (p. 358).



Don't let your sample size be determined by chance!

On the other hand, a large sample is like an electron microscope in the sense that almost any treatment difference, no matter how small, can appear to be large and important. Therein lies the challenge in power analysis: we want our sample to be large enough to determine if a new treatment is working but not so large as to inflate the importance of a trivial intervention. In addition, all research carries some risk to participants. Some

Continued on Page 2

A COMBI Primer

The Center for Outcome Measurement in Brain Injury (COMBI) is an online resource center cataloguing information on brain injury outcome and assessment scales. The COMBI is funded by the National Institute on Disability and Rehabilitation Research (NIDRR) and is a collaborative project of eleven TBI Model System Projects. Information on the COMBI is available free of charge.

Currently, the COMBI contains information on 22 outcome or assessment scales. Materials available include scale syllabi, administration and scoring guidelines, training and testing materials, information on scale properties, references, scale forums, and frequently asked questions (FAQs). Rating forms for most of the measures are also available for downloading. COMBI users have the advantage of instant access to the materials they want.

Absolute Power... (cont from Page 1)

investigational treatments have potential for severe adverse events. Even surveys require that participants give time that might be better spent in other activities. Hence, investigators should not employ more research participants than is necessary. Power analysis can assist the researcher in striking a proper balance.

What Do I Do?

In most cases, the power analysis needs to be done in consultation with a statistician. However, it is important for researchers to have a basic knowledge of the type of information that the statistician will need to determine the proper sample size. Let's take a hypothetical example in which an investigator proposes that a new medication will reduce fatigue that is commonly reported by persons with traumatic brain injury (TBI). The proposed research design is a parallel groups design in which participants will be randomly assigned to the medication group or to the placebo group. The primary outcome measure is a fatigue scale completed by participants.

In order to do the power analysis, the investigator will need to provide: (a) an estimate of the average score on the fatigue scale for untreated persons with TBI; (b) an estimate of the average score on the fatigue measure for persons with TBI given the new medication (i.e., how much improvement will the medication cause?); and (c) an estimate of amount of variation on the fatigue measure, i.e., the standard deviation on this measure in persons with TBI. In our hypothetical study, we estimate that the average score on the fatigue score is 20 for persons without treatment ($\mu_{control}$) with a standard deviation of 4.5. We believe that the medication will reduce fatigue to an average of 15 on the fatigue measure ($\mu_{treatment}$). We enter these parameter estimates into the following formula from van Belle (2002) and we determine that we will need about 14 patients per group for a total of 28 patients. In using this formula, we have 80% chance of detecting a medication treatment effect if present (i.e., power = 80%) and a 5% chance of calling the treatment effective when it is not (i.e., alpha = .05).

$$n = \frac{16}{d^2}, \text{where } d = \frac{\mu_{control} - \mu_{treatment}}{sd}$$

Where I Do Get the Parameter Estimates?

There are several sources of information on which to base your estimates of treatment effects and score variation (Halper et al., 2002; Hulley et al., 2001): (a) consult the research literature involving similar measures, patients, or interventions; (b) use established definitions, such as the percentage reduction of reported pain to define efficacy of analgesics; (c) conduct a pilot study to obtain estimates of the mean and variance for the primary outcome measures; (d) assume that most interventions will have small to moderate treatment effects and the commonly accepted definitions of small and moderate effect sizes (d in the formula) are 0.20 and 0.50, respectively.

What if the Power Analysis Tells Me That I Need More Participants Than I Can Recruit?

One should not panic if the initial sample size estimate seems unrealistically large. There are several methods to minimize sample size and maximize power (Hulley et al., 2001). First, select a primary outcome measure that has a continuous scale (i.e., interval scale) rather than binary. Second, consider selecting a primary outcome measure that is more sensitive to the treatment intervention. Third, where appropriate, use a cross-over design in place of a parallel groups design. Fourth, obtain a baseline measure on the primary outcome measure to use as a covariate in an analysis of covariance. Fifth, in some settings it may be easier to recruit healthy control participants than persons with the target disorder, or vice versa. Power can be increased by increasing the size of one group to twice the size of the other.

Other Considerations

We typically think of performing a power analysis for studies that assess the effectiveness of new treatments. However, power analysis can be, and should be, done with other types of research designs such as observational studies. For example, a researcher may be interested in predicting when persons with TBI return to work, based on a set of observed variables. Multiple regression is often used to determine which variables are most predictive. Power analysis in this case involves striking the proper balance between the number of subjects and total sample size. Generally, it is desirable to have 10 to 20 subjects per predictor variable. Harrell (2001) provides additional guidelines for sample sizes for logistic regression and survival analysis.

References

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Hully SB, Cummings SR, Browner WS, Grady D, Hearst N, Newman TB. *Designing clinical research. 2nd ed.* Philadelphia: Lippincott, Willians, & Wilkins; 2001.

van Belle, GB *Statistical rules of thumb.* New York: Wiley; 2002. ☑

COMBI's historical perspective on power...

We thought, because we had power we had wisdom.
Stephen Vincent Benet (1898-1943)

Let not thy will roar, when they power can but whisper.
Thomas Fuller (1654-1734)

I have found power in the mysteries of thought.
Euripides (484-406 BC)

NEW on the COMBI

Technical Report on Substance Use

Problematic Substance Use Identified in the TBI Model Systems Dataset

John D. Corrigan, PhD; Jennifer Bogner, PhD; Gary Lamb-Hart, MDiv; and Niccole Sivak Spears, MS
Ohio Valley Center for Brain Injury Prevention and Rehabilitation,
Department of Physical Medicine and Rehabilitation, Ohio State University

This technical report is intended as a resource to researchers in traumatic brain injury (TBI) who are studying substance use disorders or would like to include a measure of this construct in the data they are collecting. While the measurement portions of this review are based on the TBI Model Systems methodology, that method is in turn based on the most widely used surveys of substance use in the general population—the National Household Survey on Drug Abuse (Substance Abuse and Mental Health Services Administration, 1998) and the Behavioral Risk Factors Surveillance System (Centers for Disease Control and Prevention, 1998). Thus, this information should be useful to researchers regardless of whether they are involved in the TBI Model Systems.

This report is organized into three sections:

• Research on Traumatic Brain Injury and Substance Abuse;

• Defining Problematic Use of Alcohol and Other Drugs; and

• Measurement of Substance Use in the TBI Model System.

The first two sections provide background information that is useful for considering measurement issues presented in the third. ☑

MPAI Version 4 Now Available

The Mayo-Portland Adaptability Inventory (MPAI) was primarily designed to assist in the clinical evaluation of people during the postacute (post-hospital) period following acquired brain injury (ABI) and to assist in the evaluation of rehabilitation programs designed to serve these people.

MPAI-4 items represent the range of physical, cognitive, emotional, behavioral, and social problems that people may encounter after ABI. MPAI-4 items also provide an assessment of major obstacles to community integration which may result directly from ABI as well as features of the social and physical environment.

Now in its fourth revision, the MPAI-4 and its three subscales (Ability Index, Adjustment Index, Participation Index) offer measures with highly developed and well documented properties. These measures may be effectively employed in research applications as well as in clinical settings. The brief 8-item Participation Index may serve as a particularly useful measure of the final common aim, societal participation, of rehabilitation or other intervention efforts.

Throughout its development, the MPAI has been designed for possible completion by professional staff, people with ABI and their significant others. Recent research establishes the reliability of completion by these various rater groups and also documents characteristic biases of each. The MPAI-4 offers the possibility for combining results of the inventory completed by two or three rater groups to provide a potentially more reliable and representative measurement. ☑

Assessing The COMBI

Log Files 101

Did you know that every time you access a web page, a record of what you did is created? These records, called log files, give webmasters a lot of information about you and what you looked at on the site. We use the log files to assess how the COMBI is being used.

The Stats

In the last twelve months (December 02 –November 03) the COMBI has logged in 131,500 visitors. That's over 360 users a day! During this period 528,036 pages of information were reviewed (that's 5,477 megabytes of data).

The COMBI logs show that 88% of our users are within the United States and 12% are from 62 other countries. The COMBI is especially popular in Canada, the United Kingdom, Australia, Italy, and Japan. Our biggest referrals come from Google, Yahoo, MSN, AOL, and stroke-site.org .

The COMBI newsletter, *Outcome Oriented*, is primarily disseminated in Portable Document Format (PDF) from the website. Over the last twelve months, 9,570 newsletters were downloaded by COMBI users.

The COMBI continues to be very successful as a dissemination effort. In the past twelve months over 33,000 rating forms were downloaded. Itemized scale activity is summarized in the table below.
But please, no wagering. ☑

Scale Activity (Number of Visitors & Downloads)
December 2002 to November 2003

Scale	Visitors	Downloads
ABS	2470	940
AQ	2320	4811
CHART	1745	1966
CHART-SF	850	1080
CHIEF	950	1382
CIQ	3100	2057
CNC	1955	2128
DRS	5745	1150
FAM	4960	4396
FIM	10330	na
FNQ	1505	na
GOS	7770	na
GOS-E	2245	na
LCFS	2535	1053
MPAI	2995	5274
NFI	1435	na
O-LOG	1045	1123
PCRS	1975	4477
SOS	775	567
SRS	1155	891
SUBS	875	858
SWLS	4605	na

Future Directions

This is the second *Outcome Oriented* newsletter for this funding cycle (2002-2007). We are updating materials for all of our current measures. We are also working with the University of Washington TBIMS to bring you the EuroQol.

We are looking to add more training and testing materials for COMBI measures, and to make the existing materials more interactive (automatic email of results from testing exercises).

Please email us at <combi@tbi-sci.org> with your thoughts and suggestions. Let us know how we measure up! Thank you for allowing us to be your brain injury outcome measure resource! ☑

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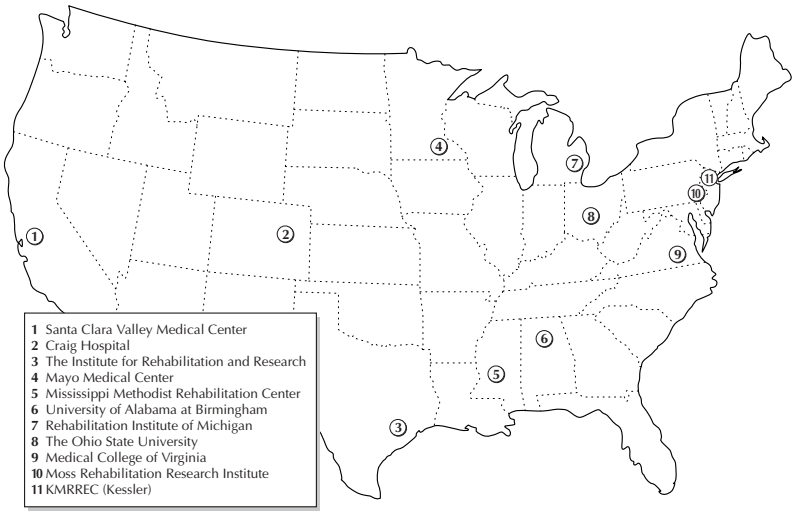
Address inquiries to
***Jerry Wright**, Editor. Phone (408) 793-6430;*
Email jerry.wright@hhs.co.scl.ca.us

This document is available online at:
<www.tbims.org/combi/combinews.html>

Credit to Our Collaborators



The COMBI is a collaborative project of eleven brain injury centers located across the US. Without the expertise of these centers this project would not be possible. We would like to offer special recognition to the individuals at these facilities who have taken the time to prepare materials for the COMBI and act as contacts:

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Tessa Hart, PhD at Moss Rehabilitation Research Institute

Scott Millis, PhD at Kessler Medical Rehabilitation Research and Education Corporation ☑

SANTA CLARA VALLEY MEDICAL CENTER

Rehabilitation Research Center for TBI & SCI
Santa Clara Valley Medical Center
751 South Bascom Avenue
San Jose, CA 95128

UPDATE
Center for Outcome Measurement in Brain Injury (COMBI)
<www.tbims.org/combi>

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