## REHAB SERIES—INTRODUCTORY PAPER

# Cognitive rehabilitation in the elderly: A randomized trial to evaluate a new protocol

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### **Abstract**

This study provides an introduction to, and overview of, several papers that resulted from a randomized control trial that evaluated a new cognitive rehabilitation protocol. The program was designed to improve general strategic abilities in ways that would be expressed in a broad range of functional domains. The trial, which was conducted on a sample of older adults who had experienced normal age-related cognitive decline, assessed performance in the following domains: memory, goal management, and psychosocial status. The general rationale for the trial, the overall experimental design, and the approach to statistical analyses that are relevant to each paper are described here. The results for each functional domain are reported in separate papers in this series (*JINS*, 2007, *13*, 120–131.)

Keywords: Aging, Memory, Treatment outcome, Cognition, Frontal lobe, Neuropsychology

## INTRODUCTION

With support from the JSF McDonnell Foundation, a team of scientists at the Rotman Research Institute of Baycrest undertook to develop an approach to cognitive rehabilitation that could be effectively applied to individuals who, for various reasons, suffer from memory and memory-related problems. Our objective was to devise a comprehensive program that incorporates scientifically based principles of cognitive function and current thinking about rehabilitation practice. In the series of papers that comprise this spe-

cial section, we report the first phase of the project—an experimental trial that was conducted on a population of older adults who were experiencing normal cognitive decline.

Many studies have assessed the efficacy of different cognitive interventions in the elderly. A focus has been on training memory and related functions, the typical result suggesting beneficial effects in older adults (e.g., Anschutz et al., 1985; Glisky & Glisky, 1999; Greenberg & Powers, 1987; Kliegl et al., 1989; Stigsdotter Neely & Bäckman, 1993a, 1993b; Yesavage, 1985; Yesavage & Rose, 1983; Zarit et al., 1981). Moreover, there is evidence that benefits from training can be maintained for a considerable period of time beyond training (Stigsdotter Neely & Bäckman, 1993a, 1993b). As an example, Ball and colleagues (2002) completed a large scale study in older adults comparing

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three different cognitive training interventions (memory, reasoning, and speed of processing) to a no-contact control group. There was content-specific improvement for each training group. As well, with the aid of booster training 11 months after initial training, improved performance was maintained at 2-year follow-up.

Our study extends these efforts in several ways. Our primary emphasis was on improving the use of general strategic abilities, because (as noted below) strategic functioning is particularly vulnerable to the aging process. As well, in some research, there is the suggestion that such abilities are amenable to rehabilitation training (Levine et al., 2000). Because of the variability of the aging process and because of our concern that a narrowly based rehabilitation program would not be effective for everyone (Glisky & Glisky, 1999; Hertzog et al., 1992; Shammi et al., 1998; West et al., 2002), we decided to take a comprehensive and multidimensional approach (see, e.g., Stigsdotter Neely & Bäckman, 1993a, 1993b, 1995). We developed an integrated modular program that provided training in three distinct domains: memory, goal management, and psychosocial function. Finally, because of the progressive nature of cognitive decline in the elderly, and because of the need for shorter interventions in braindamaged populations, our program was designed to be administered over a relatively short training period.

As part of the overview, we summarize the general rationale for the study, our thinking about cognitive aging, and our approach to promoting recovery of cognitive function. As well, we outline the experimental design used in the trial, general principles and methodology that are common to all papers, and the consistent approach to statistical analysis of data. Details of each module and results of testing in each domain are provided in the respective papers.

## The Approach

In developing our program, we adopted scientifically based principles of strategic processing. This theoretical approach was chosen for several reasons (see below), but mainly because of our commitment to the importance of basic research in contributing to evidence-based rehabilitation practice (Levine et al., 2000). Accordingly, we incorporated current thinking about rehabilitation practice, borrowed from various approaches to rehabilitation and drew heavily on previous research (e.g., Flynn & Storandt, 1990; Kramer & Willis, 2002; Verhaeghen et al., 1992). Having reviewed the various approaches, we decided on a small group format in which individuals as a group met weekly in relatively short (3-hr), highly interactive sessions. In addition to providing formal training and encouraging group discussion, a certain amount of time in each session was devoted to informing participants about specific objectives, the underlying rationale, and even scientific evidence that supported our particular approach. To complement our group-oriented approach and, in recognition of the importance of personalizing the rehabilitation process, several one-on-one meetings were held between the group leader and each participant (see below for details). The purpose of these meetings was to set personal goals, discuss progress, and deal with any individual issues that arose over the course of training.

In the rehabilitation literature, there are several reports of improved memory and other cognitive abilities following training (see Cicerone et al., 1996, for a review; Rasmusson et al., 1999; Stigsdotter Neely & Bäckman, 1993a; Storandt, 1992; Yesavage & Rose, 1983). However, because of methodological and design limitations, it is often difficult to attribute benefits solely to the treatment effect (Cicerone et al., 2000, 2005; Levine & Downey-Lamb, 2002; Turner & Levine, 2004). We extended the studies that did use a control group (e.g., Ball et al., 2002; Jobe et al., 2001; Stigsdotter Neely & Bäckman, 1993a, 1993b) by combining a randomized control experimental design with interventions that draw upon the relevant research and theory in the cognitive neuroscience of strategic processes, and rehabilitation practice.

The program, administered over 12 weeks, consisted of three distinct 4-week modules, two developed specifically for the program, and one (Goal Management Training) adapted for inclusion in the program: (1) Memory Skills Training, where participants were shown how to use external and internal strategies for learning, retaining, and recovering information; (2) modified Goal Management Training (GMT; Levine et al., 2000), where the emphasis was on managing goal-directed behavior in "real-life" situations; (3) Psychosocial Training, which was designed to enhance psychological well-being and build participants' confidence in their cognitive abilities.

These three modules were selected for specific reasons. Memory loss is the most common symptom in individuals experiencing cognitive decline, suggesting the need to emphasize memory rehabilitation. Our approach to memory was based on theoretical work that has delineated different types of memory (Craik & Lockhart, 1972; Moscovitch, 1992; Schacter, 1994; Tulving, 1983), and the knowledge that both strategic and more automatic processes required for successful memory performance can be differentiated (Craik & Grady, 2002; Moscovitch & Winocur, 1992). Lesion and imaging research have documented the role of frontal (strategic) and limbic (more automatic) circuits in memory (Alexander et al., 2003; Stuss et al., 1994; Tulving et al., 1996). As well, research involving elderly individuals also provided evidence for the importance of both strategic and more automatic processes in successful memory functioning (Craik & Grady, 2002; Stuss et al., 1996; Winocur et al., 1996). Contrary to other approaches, we did not believe that there was much to be gained by trying to enlarge memory capacity, which is less under conscious control. Rather, our focus was on improving the strategic component of memory functioning, and, overall, providing a more adaptable set of strategic process-

A basic assumption underlying the development of our protocol was that reduced cognitive function in normal old

adults and people with brain damage is the combined effect of biological and nonbiological factors, and that environmental/psychosocial factors are critical to maximizing cognitive rehabilitation efforts (Antonucci & Akiyama, 1997; Ben-Yishay & Prigatano, 1990; Prigatano, 1999; Regnier, 1997). There is growing evidence that psychological and social factors, as well as lifestyle-related activities, can interact in important ways to reduce adverse effects of brain dysfunction on cognition (e.g., Dawson et al., 1999; Hultsch et al., 1999; Wilson et al., 2002). This can result in a combination of benefits that include, for example, enhanced brain function (e.g., improved cerebral blood flow, neurogenesis), an improved sense of psychological well-being that is manifested in higher motivation and increased confidence, and an improved ability to attend to and engage cognitive challenges. Accordingly, we adopted a multidimensional approach that, in addition to emphasizing cognitive strategic processes, took into account the importance of optimal psychosocial function for the realization of full cognitive potential.

Our approach to rehabilitation has the additional benefit of addressing a serious limitation of many cognitive rehabilitation programs—the well-established fact that benefits observed on specific tasks in the clinic do not necessarily generalize to other tasks or situations (Turner & Levine, 2004). Assessments in cognitively oriented programs often do not include outcome measures that relate meaningfully to "real-world" performance. This important issue was addressed in part by including the modified version of Goal Management Training (Levine et al., 2000; Robertson, 1996), an approach that emphasizes the enhancement of attentional control to reduce everyday slips, to monitor goal attainment, and to simplify cognitively demanding real-life tasks. As well, our outcome assessment battery included tests specifically designed to assess changes in participants' ability to perform such tasks (see also Cahn-Weiner et al., 2000, 2002). Another measure of the generalizability of traininginduced benefits was the inclusion of two tests of verbal fluency in our outcome measures. These tests assessed language function that was not directly targeted for rehabilitation and the results, while not formally reported in the papers in this series, are described in the Overview paper (Winocur et al., 2007a).

# Rationale

Theoretical perspectives about cognitive changes with aging provided a framework to test our hypotheses about the importance of strategic processes. One prevalent view is that agerelated cognitive changes in different functional areas occur at similar rates, as a result of decreased speed of information processing (Salthouse, 1993) or reduced attentional capacity (Craik & Byrd, 1982) following nonlocalized brain deterioration. The effect is to produce progressive linear deterioration in most human abilities after approximately age 25 (Doppelt & Wallace, 1955; Park & Hedden, 2002; Salthouse, 1988, 1991, 1992; Verhaeghen & Salthouse,

1997). There is considerable evidence for this linear effect of aging—in various cognitive and neuropsychological tests (Park & Hedden, 2002; Salthouse, 1988, 1991); in neurophysiological measures (Picton et al., 1984); in the pattern of recovery after traumatic brain injury (Stuss et al., 2000a); and biologically in reductions in brain weight, brain volume, and blood flow (Colcombe et al., 2003; Jernigan et al., 2001; Raz, 2000). If the changes are related to nonspecific, progressive atrophy, one might indeed hypothesize that cognitive deterioration in old age follows a linear pattern that affects most cognitive processes at the same rate. This might lead to the assumption that interventions could be successful only if they directly targeted the full range of affected cognitive processes, an approach that would have serious practical limitations.

An alternate view is that different abilities decline at different rates (Bäckman et al., 1997; Balota et al., 2000; Moscovitch & Winocur, 1992; Rabbitt et al., 2001; Rypma et al., 2001; Stuss et al., 1996) and that the cognitive abilities most vulnerable in aging, and earliest affected, are those with a substantial strategic (frontal lobe) component (Haug & Eggers, 1991; Moscovitch & Winocur, 1992; Raz, 2000; Stuss et al., 1996; West, 1996). Thus our training emphasized "frontal lobe" strategic processes rather than a general cognitive approach to training. Importantly, from the perspective of cognitive rehabilitation, there is growing evidence that strategic processes in the areas of attention, information processing, and planning, are amenable to retraining (Levine et al., 2000). Moreover, training-induced benefits in these areas are reflected indirectly in improved performance in other areas where a high level of function depends on strategic support. It is also possible, however, that in early stages general atrophy would selectively affect strategic processes. Because we were not certain which strategic processes were important, we did not emphasize any particular strategic mechanism.

Our program is based on the fundamental premise that individuals experiencing cognitive loss need assistance in learning appropriate strategies (regardless of the reasons for deterioration), and also in making the necessary effort to select and implement strategies for the task at hand. We decided to teach multiple strategies to maximize the likelihood of success, despite evidence for fractionation of these abilities (Shallice, 2002; Stuss & Levine, 2002). Our approach focuses on the development of basic and practically oriented strategies for learning, remembering, and problem solving, combined with an explicit emphasis on enhancing psychosocial well-being. With respect to the elderly, a basic assumption is that the capacity for strategic organization and planning, while compromised, is underutilized. On this view, with proper direction and support, older adults are potentially capable of making the necessary efforts directed at selecting and implementing strategies that are appropriate for a great variety of tasks.

Our expectation was that, with insights gained from our multidimensional protocol and the necessary commitment on their part, elderly participants' use of strategies would increase and their general cognitive performance would improve. Importantly, as they become increasingly familiar with the use of various strategies on a day-to-day basis, we anticipated that this essential cognitive operation would be accomplished with reduced effort and incorporated into their daily lives.

The following is a summary of the protocol, along with its essential design and operational features.

### **METHODS**

# **Participants**

A total of 49 older adults (27 women and 22 men; age = 71 to 87 years; M = 78.7; SD = 3.9) participated in the research. Participants' responses on a self-report questionnaire (form available from the corresponding author) determined their eligibility for inclusion in the study.

All selected participants were retired middle class healthy community-dwellers who lived independently and functioned successfully. All had been successful in their professions, or positions in the household. At the time of the study, participants expressed subjective complaints of memory or cognitive dysfunction. However, neither they nor their treating family physicians had considered referral for assessment of dementia. Their subjective problems did not affect their daily functioning.

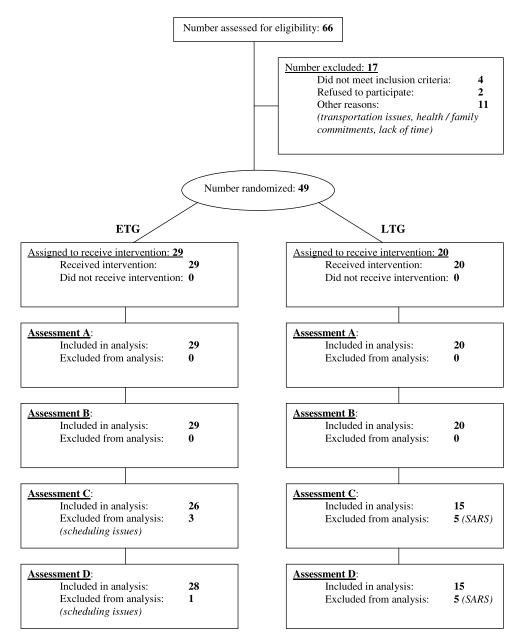
Their level of normal functioning was confirmed at preassessment by their Mini-Mental State Examination (MMSE) score. Despite their subjective complaints, the participants did not fit the criteria for mild cognitive impairment (Petersen et al., 1999). When an estimate of general intelligence (NART-R) was assessed in relation to memory (Logical Memory), only 2 participants had memory scores that were greater that 1.5 SD different from their IQ scores, and the memory scores of these 2 persons were less than 1.5 SD different from normative data. An additional criterion was fluency in written and spoken English. Our formal assessments confirmed the participants' self-reports of general good health commensurate for their age. There was no history of significant medical, psychiatric, or neurological problems; excessive alcohol use or use of nonprescription drugs; and current use of central nervous system-altering medications.

All participants were competent, were presented with an approved information form, and gave their signature consent for participation. Participants were volunteers from the community at large who were recruited through advertising and word of mouth. Recruitment took place over time due to the practical necessity of administering the protocol to several groups. The volunteers who met inclusion criteria were divided into an Early Training Group (ETG; N = 29) and a Late Training Group (LTG; N = 20). Random assignment to the two groups was qualified by the need to equalize the groups with respect to MMSE (all 25 or higher, groups matched  $\pm 2$  points), education (approximately equal numbers within the following grade ranges: grade 8 or lower;

9–10; 11–12; college or higher), sex, and age (all were within the age range of 72–87 years, groups matched  $\pm$  3 years). Thus a blocked randomized procedure was used to maintain an equal balance in both groups on these factors. The ETG entered the rehabilitation program shortly after screening; the LTG first acted as a control group for 3 months, and then underwent the protocol (hence "Late" Training Group). In the control procedure, contact was maintained with participants through an individual meeting with the group leader and by telephone. In addition, participants underwent regular testing according to the prescribed schedule. Missed attendance was negligible. On the few occasions that it did occur, participants were able to make up the session by attending another group or through individual contact with the group leader, with the result that they received the full training protocol, including the one-on-one sessions, with exceptions outlined in Figure 1.

Before admission to the program, volunteers were administered the following neuropsychological tests (average time of administration = 1.5 to 2.0 hr) to characterize various aspects of the groups' cognitive function (baseline testing) and provide a screen for cognitive impairment and general psychological status:

- Mini-Mental State Examination (MMSE; Folstein et al., 1975): a brief assessment of general functioning that screens for dementia. A score greater than or equal to 24 was required for inclusion;
- National Adult Reading Test–Revised (NART-R; Nelson & Willison, 1991): a reading test that provides an estimate of intellectual status. A minimal score of 90 was required for inclusion;
- 3. Digit Span (forward and backward; Wechsler, 1987), forward span measures simple attention, with backward span providing a general index of working memory;
- 4. Logical Memory (Wechsler, 1987), immediate recall of two short stories;
- 5. Judgment of Line Orientation (JLO; Benton et al., 1978), a measure of visual spatial judgment considered primarily sensitive to right parietal lobe functioning;
- 6. Wisconsin Card Sorting Test (WCST; Heaton, 1981; administration following the procedure of Stuss et al., 2000b), a measure of concept learning and switching of concepts following feedback. This test is widely held to be sensitive to frontal lobe functioning if comprehension and visual attention are normal (Stuss et al., 2000b). Our version, derived from the original instructions as described by Grant and Berg (1948; see also Milner, 1963) is similar to the standard version as implemented by Heaton (1981), with the exception that all 128 cards are administered, providing a more sensitive measure of loss of set;
- 7. Boston Naming Test (BNT; Kaplan et al., 1983), a visual confrontation task of naming of objects;



**Fig. 1.** CONSORT-type figure illustrating the maximum number of participants at each assessment. The loss of subjects in the Late Training Group (LTG) for Assessments C and D was secondary to a province-wide pandemic (SARS) which closed hospitals and associated buildings for all nonessential personnel (such as research participants), as indicated in the text. ETG = Early Training Group.

- 8. Beck Anxiety Index (BAI; Beck & Steer, 1990), a self-report index of anxiety symptomatology;
- 9. Geriatric Depression Scale (GDS; Brink et al., 1982), a test of depression commonly used in the elderly population.

Means and standard deviations for ETG and LTG for age, years of education, NART-R, and MMSE are listed in Table 1. The general neuropsychological measures served several purposes as an additional screening beyond the self-report of the participants: comparison of equality of groups;

comparison of participants to normative data; and additional verification of normal level of functioning (data were examined by a board certified neuropsychologist if there was question of impaired functioning; no subject was rejected on the basis of the general neuropsychological measures). The two groups were comparable in virtually every aspect. There were no differences in age, education, sex, intelligence, or scores on the MMSE. The groups were also comparable in general functioning (no significant group differences between the ETG and LTG on the general neuropsychological battery), with the exception of a solitary significant difference in immediate (but not delayed) recall on

**Table 1.** Demographic, neuropsychological screening and normative data summary

Test	ETG $(n = 29)$				LTG $(n = 20)$				Norms	
	Mean	SD	Min.	Max.	Mean	SD	Min.	Max.	Mean	SD
Age	78.38	3.42	72	84	79.25	4.55	71	87	_	_
Years of education	14.36	3.34	7	22	14.55	4.71	9	27	_	_
MMSE										
Total Score	28.24	1.30	25	30	27.70	1.72	25	30	28.00	1.60
NART-R										
Predicted WAIS-R IQ	113.11	7.19	96.60	124.68	115.52	8.14	92.70	125.46	na	na
NART Score	42.21	9.20	21	57	45.25	10.43	16	58		
Digit Span										
Forward Score	$7.11^{b}$	1.76	4	11	7.95a	2.48	3	12	na	na
Backward Score	$6.85^{b}$	1.83	3	12	7.42a	1.84	4	11	na	na
Total Score (forward + backward)	13.96 <sup>b</sup>	2.98	9	23	15.37a	3.85	9	22	15.00	4.00
Logical Memory I & II <sup>8</sup>										
Immediate Recall $^{\gamma\tau}$	13.62°	3.84	4	20	10.35°	4.90	2	19	19.11	6.74
Delayed Recall	10.73°	4.81	4	19	$9.00^{c}$	4.74	1	16	15.33	7.57
Judgment of Line Orientation										
Total Score	24.03	4.41	15	30	23.45	4.45	16	29	25.75	na
Wisconsin Card Sorting Test										
Categories Achieved	5.62°	3.36	1	11	4.70	2.68	0	9	7.18	3.17
Number of Correct Sorts <sup>7</sup>	84.15°	22.86	41	116	79.65	17.65	50	106	95.12	13.89
Non-Perseverations	16.85°	13.82	2	62	19.70	18.39	6	78	11.88	11.25
Unusual Errors	.73°	2.13	0	10	.70	1.42	0	5	na	na
Perseverations to Preceding Criteria	25.58°	15.47	5	60	27.40	17.21	0	69	20.65	9.50
Total Set Loss	1.96 <sup>c</sup>	1.82	0	6	2.25	2.29	0	8	2.53	2.03
Boston Naming Test										
Total Correct (no cue)	27.65°	2.23	22	30	26.05	4.49	12	30	na	na
Total BNT Score	26.11a	7.59	0	30	26.50	4.53	12	30	25.90	3.80
Geriatric Depression Scale										
Total Score	4.90	3.88	0	15	5.85	3.92	0	14	3.20	3.67
									Normal range is 0-9	
Beck Anxiety Inventory	3.68a	3.04	0	13	3.00	2.73	0	10	Normal range is 0–9	

*Note.* Norm information: for MMSE, NART, and GDS, refer to Spreen & Strauss (1998); for Digit Span and Logical Memory, refer to Wechsler (1987); for Judgment of Line Orientation, refer to Benton et al. (1978); for WCST, refer to Stuss et al. (2000 b); for Boston Naming Test, refer to Mack et al. (1992); for Beck Anxiety Inventory, refer to Beck & Steer (1990). For JLO, we averaged the norms for men and women, given the equal distribution in both groups (men = 25.7; women = 25.8. Average norm = 25.75). na = not available.

means were less or equal to .84 SD away from available norms.

Logical Memory Stories in favor of the ETG. This general group equivalence is an important prerequisite for interpreting any group differences secondary to the interventions. In addition, on none of the measures did either group differ more than 1.5 *SD* from the mean score of the published normative data (see Table 1). The lowest scores were in logical memory, but this finding was considered to reflect their memory complaints. In other words, this was a very representative sample of normal older adults living independently and functioning well in the community, who had noticed changes in their cognitive abilities and who wanted to do something to recover apparently diminished function.

The project was approved by the University of Toronto/ Baycrest Research Ethics Committee, and followed the Canadian Tri-Council Ethics Guidelines as well as the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects.

# **Experimental Design**

A within-subject, crossover design was used (see Figure 2). To measure the efficacy of our rehabilitation program, after pre-admission testing, there were four major assessment sessions (each lasting approximately 2.5 to 3.0 hr) identified as Assessments A to D. The group leaders were not involved in the assessment sessions. The complete battery, consisting of experimental neuropsychological, practical task planning, and psychosocial tests, was administered before

<sup>&</sup>lt;sup>a</sup>One missing observation.

<sup>&</sup>lt;sup>b</sup>Two missing observations.

<sup>&</sup>lt;sup>c</sup>Three missing observations.

<sup>&</sup>lt;sup>δ</sup>See text for explanation of missing values for Logical Memory.

 $<sup>^{\</sup>gamma}$ Immediate Recall different between the two groups [F(1,41)=5.97, p=.02]. None of the other variables were significant at an alpha-level of 10%  $^{\tau}$ The LTG means were -1.11 SD away from the norm for WCST (Number of Correct Sorts) and -1.30 for Logical Memory (Immediate Recall). All other

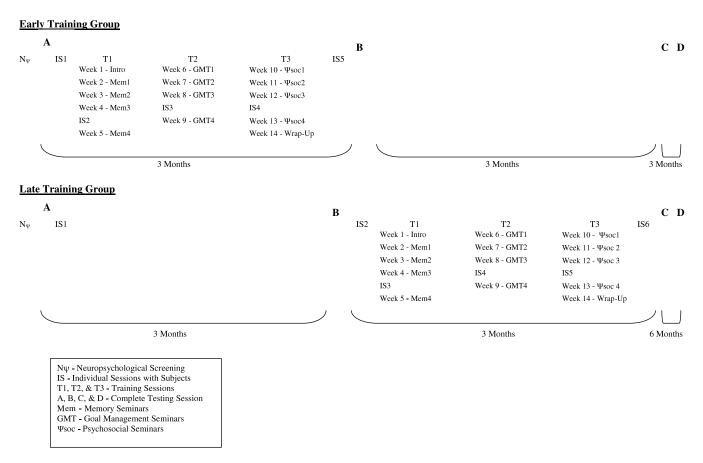


Fig. 2. Within-subject crossover experimental design with the timeline for the early and late training groups.

(Assessment A) and after (Assessment B) the ETG underwent the training protocol. Assessment A indicated whether the two groups were equivalent before training; Assessment B provided a test of the effects of rehabilitation training of the ETG, relative to the LTG whose members performed the control procedure.

After Assessment B, there was a crossover in which the LTG switched from the control condition to rehabilitation training, and the ETG from training to the control condition. Following the completion of training for the LTG, the test battery was administered to both groups again (Assessment C).

Both groups received follow-up testing 6 months after completion of training (Assessment D) to assess long-term benefits of rehabilitation (see Baltes & Willis, 1982). The difference in delay (see Figure 1) between Assessments C and D for the ETG and LTG was necessary to ensure the same delay between the end of training and the long-term follow-up test.

The tests used in Assessments A through D were as follows: Cognitive/Memory: Alpha Span, Brown-Peterson, Hopkins Verbal Learning Test, Logical Stories Memory, Verbal and Semantic Fluency; Goal Management: simulated real-life tasks (organizing car pools, swimming lesson); Psychosocial: Dysexecutive Function Test, Everyday

Activities, Locus of Control, Life Orientation Test, and the Memorial University of Newfoundland Scale of Happiness. The descriptions and references for these tests are provided in the corresponding papers. As explained in the specific papers, alternate forms were used, where feasible and appropriate, We decided in favor of understanding the effects of test order rather than counterbalancing because of the relatively limited sample size, common in studies of this type.

In addition, we administered a self-assessment questionnaire (SAQ) at the end of the training program querying how well participants had responded to rehabilitation training. The SAQ consisted of statements, of which 15 were related to the Psychosocial component (e.g., "I am leading a more active lifestyle"): 8 statements to the goal management component (e.g., "I am better at setting goals for myself"), and 7 to the Memory component (e.g., "My memory seems better because I am concentrating more"). Participants were asked to respond to each statement based on how they felt "today as compared to last month," according to a 4-point scale. The maximum total score was 120, distributed across the three components as follows: Psychosocial, maximum = 60; modified GMT, maximum = 32; Memory, maximum = 28. The SAQ results are summarized in the Overview paper (Winocur et al., 2007a)

# The Training Protocol

The program was administered to groups of 5-6 participants, with each group run by an experienced leader who had been trained specifically to lead the sessions. Before the start of the program, individual goals were identified for each participant to establish personal motivation and to ascertain reasons for his/her involvement (Prigatano, 1999). In addition, to ensure engagement and active participation, the group leader met for approximately 1 hr each time with each participant individually over the course of the program (ETG, five times: one before start of program to identify goals, one after the third session of each module, and one at the end of the program to evaluate progress related to goals; LTG, 6 times: because of the delay in starting training, an additional session was held before the start of their training program to see if they made progress on their goals on their own during the control wait period, and to reestablish goals for the actual program).

The entire rehabilitation program spanned 14 weeks and included an introductory seminar, 12 weekly training sessions, and a wrap-up seminar. Test sessions and individual meetings with participants were conducted during this period, as scheduled (see Figure 1). The training program consisted of three distinct modules, each consisting of 4 consecutive weeks. The groups met once per week in 3-hr sessions. The modules were presented in fixed order: Memory Training, modified GMT, and Psychosocial Training. The contents of each module are presented in the papers related to the respective modules. Each training session adhered to a prescribed format and was highly interactive, with the group leader assuming the roles of instructor and facilitator. Most sessions included practical projects related to the theme of the module.

To maximize learning and to generalize the training to home environments, participants were given home assignments of approximately 1 hr in duration, to complete during the week. These assignments were designed to encourage participants to apply strategies and techniques learned in that week's training session to their day-to-day lives. To ensure completion, the home assignments were monitored for each participant in the weekly sessions.

## **Statistical Analyses**

We compared baseline performance between the two groups using analysis of variance to test for possible differences on each of the measures at Assessment A. Because volunteers were assigned to the two groups using a block randomization procedure, we predicted that there would be no differences between the groups on any of the measures at baseline.

At each of the two subsequent assessments (B and C), we investigated differential change between the two groups on each measure relative to performance at the preceding assessment using analysis of covariance. Effect sizes ( $\eta^2$ ) are reported alongside these significance tests of differential change between groups. To indicate the size of the effect,

following the definitions of Cohen (1988): small,  $\eta^2 = .01$ ; medium,  $\eta^2 = .06$ ; large,  $\eta^2 = .14$ . Hypothesis tests were set at an  $\alpha$ -level of 5%. To avoid unacceptable loss of power in this exploratory study, adjustments for multiple comparisons were not made. Accordingly, however, appropriate caution was taken in interpreting the results. Where informative, we also present results of repeated measures analysis of variance within groups to provide a further index of the effect of rehabilitation on performance over consecutive paired assessments.

At Assessment B, we predicted a rehabilitation training effect in the ETG relative to the LTG, which acted as the control group at that point. Analysis of covariance performed on the dependent measures at Assessment B included Assessment A performance as a covariate to increase precision by accommodating natural heterogeneity between subjects within a group. It was predicted that within-group analyses would show improvement in the ETG but not the LTG.

At Assessment C, we expected a rehabilitation training effect in the LTG relative to the ETG. No change was expected in the ETG because they were anticipated to be in "maintenance" mode. Because Assessment C scores were adjusted to compensate for differences in Assessment B scores in this analysis of covariance, we predicted a significant difference between groups in favor of the LTG that had just received rehabilitation training.

Assessment D provided an examination of the long-term benefits of rehabilitation training for each group. To evaluate improvement between Assessments A and D, we performed either repeated measures analysis of variance on the two scores or linear regression of adjusted Assessment D score on adjusted Assessment A score. For the latter, with both measures adjusted by subtracting mean Assessment A score, the intercept for this regression model was interpreted as a relative change between assessments.

Some inability to obtain data at Assessments C and D was encountered for the last subset of LTG participants. This loss of data was the result of logistical problems and was not due to motivation of the volunteers. After the last LTG subgroup had received Assessment B, and after their training sessions but before Assessment C, severe acute respiratory syndrome (SARS) broke out in Toronto and, as a result, essentially all hospitals in Toronto were closed for several months. Research subjects were not permitted to enter the hospital or research buildings. Because this development precluded data collection for Assessments C and D for one of the LTG subgroups, we did not consider it to be related to the efficacy of the rehabilitation program. Nevertheless, the reduction in the number of participants does raise the issue of power, and the long-term follow-up data should be interpreted with caution. For these reasons, our analytic approach should be considered an observed cases approach, and not intent-to-treat. A degree of data reduction was achieved using composite scores where multiple measures were correlated and were hypothesized to be nonhierarchical (e.g., G7 composite score in the Psychosocial paper; Winocur et al., 2007b).

### **Predictions**

The following general predictions guided the trial:

- 1. At Assessment A, there would be no differences between the groups on the defined measures.
- 2. At Assessment B, group differences favoring the ETG were expected. This finding would indicate that there was a specific effect of rehabilitation for the ETG because, at this point, the LTG would be acting as a control group.
- 3. At Assessment C, after the LTG had received training, there would be no difference in the two groups' overall performance. Statistically controlling for performance at the prior assessment, however, would allow analyses to show training-related group differences. It was expected that a within-group analysis from Assessment B to C would reveal improvement in the LTG, confirming the effect of training.
- 4. At Assessment D, there would be no group differences. While some decrease in scores was expected at Assessment D, relative to those recorded immediately after rehabilitation training, it was predicted that both groups would perform better at Assessment D, as compared to Assessment A, thereby reflecting long-term benefits of training.
- Training would have direct benefits on frontal lobemediated strategic processes with derivative benefits to cognitive functions associated with other brain regions (e.g., episodic memory).

# **CONCLUDING REMARKS**

In this study, we outline the rationale and advantages of our approach to cognitive rehabilitation, as well as the design and methods followed in our experimental trial. The design allowed us to conclude that changes in strategic processing can be trained in the elderly, and that in this case any changes observed were the direct result of rehabilitation. Studies that involve repeated testing are always prone to potential practice effects. Our design took this factor into consideration in that both groups received equal practice on the tests for which there were multiple versions. As well, some of our most significant results were obtained on measures of strategic processing that are relatively insensitive to practice effects. Our data point to long-term benefits of rehabilitation. However, this must be qualified by the unavoidable subject attrition in the LTG, which may have affected the power of statistical analysis.

It is uncertain if any single module, or combination of modules, provided the most benefit, and how efficient our approach is compared with other therapies (see Winocur et al., 2007a). Our multidimensional approach, which focused on improving strategic processing, was designed to allow the flexibility that we believed was needed to accommodate the considerable variability that characterizes a relatively healthy, functional elderly population with real and perceived concerns about cognitive decline.

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