Backgrounder on ACTIVE Dementia Incidence Study

Introduction. This science "backgrounder" for the press is intended to summarize and synthesize a large and often unread body of scientific literature directly related to the findings in the ACTIVE Study on dementia, so that members of the press can appreciate and explain to the public how this new set of findings "fits" with what is already known.

There is a huge amount of new brain science being published every day – more than 18,000 journal articles on the sub-specialty of brain plasticity have published in the past five years. No one can be an expert and up-to-date on all of it. An "expert" in Alzheimer's or in "aging and cognition" may have little knowledge of recent findings in brain plasticity or in its sub-specialty of plasticity-based brain training – which is the sub-sub-specialty that is producing these new results. After reading this "backgrounder" you will know as much (or often more) about the relevant literature than many of the experts you might interview. If you skip to the end, you can read about common misconceptions that may be prevalent among even experts who have not read or been briefed on the recent literature, and you should be better positioned to make sense of this field for your audience.

This backgrounder (1) begins with a description of the ACTIVE Study; (2) reviews the performance of speed training across previously released measure of aging by the ACTIVE Study; (3) summarizes the dementia results; (4) summarizes results from speed training (used in ACTIVE) in other studies related to aging; (5) summarizes other studies of similar speed of processing training related to dementia; (6) summarizes other studies of similar training related to aging; (7) describes how this type of training is designed and thought to impact the brain; and (8) clarifies some misconceptions and suggests some take-aways regarding how these results fit the literature and may advance the field.

1. Description of the ACTIVE Study. The Advanced Cognitive Training for Independent and Vital Elderly (ACTIVE) study was a multi-site, randomized controlled trial, funded by the National Institute of Health, and focused on the impact of different cognitive training interventions on aging and cognition. The study enrolled 2,832 adults aged 65 and older (average age at study commencement was 74). The study population was 75.8 percent female, was 72.1 percent white; and on average had 13.5 years of education. The study focused on healthy older adults and excluded participants at risk for immediate functional decline (those who had existing cognitive impairment, poor corrected vision, hygiene or dressing dependencies, a stroke during the prior year, limited life expectancy due to cancer, active chemotherapy or radiation treatment, or difficulty communicating). [1]

The participants were randomized into four arms. There were three cognitive intervention arms and a no contact control, in which participants were assessed on the same schedule as participants in the three interventions. Study organizers chose three types of cognitive training believed to be helpful in aging adults: (1) a

strategy-based memory course; (2) a strategy-based reasoning course; and (3) a computerized visual speed of processing training.

Each participant in the study was assessed at the beginning of the study, then after an initial 5 weeks of training and again at years 1, 2, 3, 5, and 10. There were three main types of assessments. *Proximal assessments* meausured the trained cognitive domains: memory, reasoning, and speed. The *primary assessments* were measures of generalization to real-world function, called instrumental activities of daily living. *Secondary assessments* included standard measures of depressive symptoms, locus of control, health-related quality of life, and driving ability.

Each participant in a cognitive training intervention group trained for two hours per week for five weeks at the beginning of the study period. Sixty percent of each study group was asked to complete booster sessions at month 11 and month 35 of the study. Each booster session was another four hours of training.

The six study sites were Johns Hopkins, Penn State, Wayne State, University of Alabama Birmingham, Indiana University, and Hebrew Senior Living of Boston. The Steering Committee for the Study had nine investigators and more than 40 additional co-investigators participated in running the study and evaluating data.

2. Prior Results from the ACTIVE Study. A series of peer-reviewed reports from the ACTIVE Study began being published in 2001. Those findings include:

- **Participants got better in the cognitive area trained.** Participants in the memory group improved in measures of verbal memory. Participants in the reasoning group got better at measures of reasoning. Participants in the speed group got better at measures of visual processing speed. As hypothesized at the beginning of the study, training in one modality did not transfer to another. For example, training in visual speed did not result in improvements in verbal memory. While training effect waned over time, significant between group difference persisted at 10 years – with the training groups favored in the areas in which they had trained.[2]

- **Each type of training showed some generalization to daily life.** Each cognitive training group performed significantly better than the control group at instrumental activities of daily living (IADLs) when measured five[3] and 10 years[4] after training. IADLs are a standard measure of performance at daily life activities (such as managing finances, managing meds, and getting around town) that are associated with functional independence - a person's ability to live independently in their own home. These results demonstrate *far transfer* - the ability of cognitive training to improve cognitive skills that are not directly trained. In addition, both at years 1 and 5, participants in the speed training group who were asked to do booster sessions also showed significantly better outcomes than the control on timed IADLs, a directly observed measure of everyday tasks (eg, making change with coins, looking up a phone number,

determining salt levels in packaged food). This is a further demonstration in the speed booster group of far transfer to real-world, untrained tasks.

- **Only speed training showed broad generalization to most secondary measures**. The ACTIVE Study included a number of secondary measures in its assessment battery, including feelings of control, depressive symptoms, health related quality of life, and driving. Only speed training showed significantly better results than the control across these ACTIVE study secondary measures:

    - **Depressive Symptoms**. The study used a standard measure of depressive symptoms, the CESD-12. At the 1-year follow-up assessment, researchers found that the speed training group had 38% protection against the risk of the onset of suspected clinical depression than the control.[5] At years 1 and 5, researchers found a 30% protection against the risk of a clinically significant worsening in depressive symptoms among those who did the speed training as compared to the control.[6] There were no significant differences between the other interventions and the control group.

    - **Locus of Control**. The study used a six-item standard measure of feelings of control over your life, the abbreviated Lachman locus of control index. At year 5, researchers found that the participants in the speed training group were 68 percent more likely to show a significant improvement at this measure than the control.[7] The reasoning group had a similar outcome and there was no statistically significant difference between the memory group and the control on this measure.

    - **Self-rated Health**. The study used the SF-36 standard measure of self-rated health from QualityMetrics, commonly used by Medicare and the Veterans Administration in studies. At years 2 and 5, respectively, researchers found a 38 percent[8] and 26 percent[9] protection against the risk of a serious decline in health-related quality of life in the speed training group. In addition, researchers looked at results for the SF-1 measure ("How would your rate your health?") at years 2, 3, and 5 and found that speed training provided a significant protection against decline on this measure compared to the control group.[10] There were no significant difference between the other interventions and the control group.

    - **Predicted Healthcare Costs**. The US Department of Health & Human Services through its Agency for Healthcare Research & Quality used the SF-36 and its substantial Medicare records to build a model that predicts healthcare expenses based on SF-36 results. The ACTIVE researchers found that only the speed training group had significantly lower predicted medical expenses (3.3 percent reduction) as compared to the control at year 1. At year 5, once again, only the speed training group had significantly lower predicted medical expenses (though the size of the difference had waned by about 40%).[11]

- **At-Fault Car Crashes**. ACTIVE researchers drew on the databases of departments of motor vehicles to compare at-fault crash rates of study participants at year 6. They found a 48% decrease in the risk of at-fault crashes among the speed training group as compared to the control.[12] The memory group was not statistically different than the control; the reasoning group had comparable results after adjustment for differences in depressive symptoms.

3. Dementia Results. As is being reported at AAIC on July 25, the ACTIVE Study researchers looked at the incidence of dementia of participants in the study, comparing each of the three interventions against the control group. Only the speed training group had a significant reduction in the incidence of dementia. The reduction in risk of dementia for the speed training group, as a whole, was 33%. When researchers conducted a dose-response analysis, looking at those who were offered booster sessions (such that their training exceeded 10 hours) only the speed training group had a statistically significant reduction in risk of dementia -- a 48% reduction in that booster group.

In 2012, the ACTIVE Study published its five-year findings on dementia, and at that time, none of the intervention arms had results that were significantly different than the control – although the speed training had the strongest trend toward reduced risk.[13] The average age of participants at year 5 was 79. At year 10, the average age of participants was 84 and the incidence numbers for dementia were larger., allowing a more powerful statistical analysis that showed the significant effects of speed training on the incidence of dementia.

4. Speed of Processing Results in other Studies Related to Aging. The speed training used in the ACTIVE Study has been used in a number of other studies related to aging and cognition. Researchers have consistently found that the speed training participants significantly outperform study participants engaged in active or passive control activities on measures of cognitive function. Such results include:

- **Cognitive**. In the 681-person IHAMS Study, researcher found that the speed training group significantly improved at speed of processing and that the training generalized to significant improvements in standard measures of executive function (the ability to categorize, plan, reason and decide) as compared to the control group, which engaged in computerized crossword puzzles.[14] In the ACCELERATE Study among 159 older adults randomized into speed training or internet-social training, researchers found that the speed training group performed significantly better than the control at a standard speed of processing measure and a standard attention measure.[15]

- **Functional Independence**. In the SKILL Study with 660 participants, researchers compared a speed training group with an active control that engaged in computer and social activities for an equal amount of time. They

found that, in participants at risk for function decline, the speed training group performed significantly better than the control at measures of both speed of processing and at timed IADLs (a measure of functional independence).[16] A separate study at UAB looking at timed IADLs showed similar results in all participants.[17]

- **Driving**. A study of older adults who tested as high risk for crashes randomized participants into speed training or training in a driving simulator, and compared them to a reference group of low risk drivers. Researchers found that those who did speed training had significantly better performance at a speed of processing test and lower risk of dangerous driving maneuvers in an on-road test than either the active control or the low risk reference group.[18] The speed group also outperformed the stimulator control group in a reaction time test, gaining 22 feet of stopping distance at 55 mph. In the SKILL study, researchers found those who did the speed training were significantly less likely to stop driving over the subsequent three years than those in the internet-social training group or in the no contact control.[19] Driving cessation correlates to a 4-6 times greater risk of dying within three years.[20] The speed training group drove further, more frequently and under more varied weather and lighting conditions.[21]

5. Results in Other Studies Related to Dementia. The speed training is currently marketed by Posit Science Corporation (and their Canadian Partner DynamicBrain Inc.) as the Double Decision exercise (Double décision in French) in BrainHQ plasticity-based, brain training program. Posit Science has built many other exercises based on the same principles. There is a suite of visual speed of processing exercises (including the original exercise) that has been used in a number of studies of people with pre-dementia conditions. Such studies have found:

- **Cognitive Function and Brain Connectivity Networks**. People diagnosed with the pre-dementia condition amnestic Mild Cognitive Impairment (MCI) who trained for 20 hours with a five exercise visual speed suite (including the exercise used in the ACTIVE Study and four others designed by Posit Science to complement and extend that exercise) were compared to an active control using crosswords, Sudoku and other computerized brain games for an equal amount of time. People with amnestic MCI generally are experiencing rapid cognitive decline and that is what researchers saw in the active control group; however, the visual speed intervention group experienced significant improvement in cognitive measures (speed, attention, memory). In addition, brain imaging was used to look at the effect on two neural networks that typically decline with amnestic MCI: the Central Executive Network (CEN) and the Default Mode Network (DMN). DMN stabilized and CEN improved in the visual speed training group, while both declined in the control.[22]

- **Memory and Brain Imaging**. A study of people who used auditory speed of processing exercises from Posit Science against a control group who played video games found a significantly better performance in verbal memory, which

as accompanied by significantly improved brain activation of the hippocampus as seen with brain imaging, as compared to the control.[23]

- **Global Cognition and Memory.** In a 74-person 3-arm trial of people with subclinical dementia, researchers found that both plasticity- based training and the same training combined with motivational training drove significant gains in a measure of global cognition (3MSE) as well as verbal learning and memory compared to the video games control, which declined.[24]

6. Results from other Plasticity-based Training in Aging Populations. In studies of older healthy adults in similar plasticity-based training from Posit Science, researchers have found:

- **Speed**. In the IMPACT Study of 487 healthy adults aged 65 and older (led by researchers at the Mayo Clinic and USC), participants who did auditory training exercises on their own at home for 40 hours, were shown, on average, to have more than doubled the speed at which they could process auditory information, as compared to little change in the active control arm (which did computer-based learning). The improvements were wide-spread, with some 93% showing speed of processing gains.[25]

- **Attention and Memory**. In the IMPACT Study, researchers saw improvements generalize, as hypothesized, from speed and accuracy to auditory memory. These improvements, on average, were about 0.25 standard deviations, which was both clinically and statistically significant. In lay terms, 0.25 standard deviations is about the amount of decline that healthy adults over age 50 experience each decade on these standardized tests. Two earlier smaller studies with 72 and 161 participants produced similar results.[26,27] An imaging study of 30 healthy older adults training on the Posit Science suite of visual speed training showed increased brain activity that correlated with gains in working memory.[28] Another EEG study showed gains in attention.[29] Another 58-person study, on selective visual attention, found users of a Posit Science exercise significantly outperformed two active controls using the video games Tetris® and Medal of Honor®.[30]

- **Executive Function**. In another study, researchers at George Mason found evidence of far transfer to everyday problem solving and reasoning. They also found that the brain changed physically – improving the integrity of occipito-temporal white matter, associated with improvement in untrained everyday problem solving.[31]

- **Real World Activities**. Numerous studies have shown improvement in real world activities, including the following: Participants in the IMPACT Study were assessed using a normed instrument for everyday cognitive activities, and researchers found significant gains for auditory speed training compared with the control arm;[25] two studies reported significant improvements in key

measures of hearing (speech in noise, auditory memory), as well as other cognitive abilities, among those who used auditory speed exercises as compared to the control, which engaged in computerized learning;[32,33,34] and two studies in the Chicago area showed improvements in balance and gait, with reductions in fall risk.[35,36]

7. Plasticity-based Training Design and Mechanisms. The visual speed training used in the ACTIVE study produced striking results in cognitive and real world outcomes. Knowing what it does is not the same as knowing how it does it.

We turn briefly to rat neurology to understand a bit more about how speed training affect the physiology of the brain. Researchers measured dozens of aspects of the brains of younger and older rats, noting the many physical measures by which the older brains were slower, less precise, had diminished coordination, and deteriorated neural wiring. The older rats then engaged in an hour of plasticity-based speed training each day for 20 days. When researchers looked at the brains of the older trained rats they found virtually every physiological measurement had improved. The trained older rat brain had the restored physiology and functionality similar to a younger brain. Brain-mapping revealed improved speed and precision. Tissue samples revealed increased numbers of specific neuronal cell types that coordinate brain activity, and also heightened levels of key markers of neural wiring.

When the brain gets noisy from aging, an injury or a disorder, virtually everything degrades, and when its elemental functioning improves, virtually everything improves. Similarly, in humans we see plasticity-based training drives improvements in speed and precision, in neural coordination and in neural wiring.

Much of traditional cognitive training has focused on trying to fix a problem either by adopting compensatory strategies or by practicing a cognitive behavior (if you just try to memorize things, you'll somehow remember how to have a good memory).

Instead, plasticity-based brain training starts with elemental cognitive function by first improving the speed and accuracy of sensory perceptions. This becomes the foundation for improved attention. Improved attention is the building block of working memory, and working memory is the building block of pretty much everything else – immediate memory, delayed memory, executive function, reasoning, etc. All of the studies using this approach point in the same direction.

Brain training needs to be focused on improving speed to meet varying real world conditions; it needs to intensively and progressively improve accuracy; it needs to be adapting continuously and minutely (e.g., by thousandths of a second) to each person's performance and ability (based on algorithms that review all prior exercises results); it needs to be designed so the task gradually generalizes to real world experience; it needs to be engaging in a manner that naturally stimulates

neurotransmitters (chemicals in the brain that enhance attention, learning and mood) and that brings you back to do the exercises again and again. The scientists at Posit Science call these five principles SAAGE – for Speed, Accuracy, Adaptivity, Generalization and Engagement.

8. Some Misconceptions and Take-aways.

Misconceptions. Most scientists will not have been briefed on these reults before they are released at AAIC. [If you email press@positscience.com, we will provide a list of scientists who were briefed before the conference.] Because they are breakthrough results, you may hear some comments from "experts" that do not make a lot of sense to someone familiar with the relevant literature (as you now are). Such comments may include:

*"**Cognitive training is filled with conflicting results. This is just one study.** "* The field of cognitive training is, in fact, littered with a lot of failure. But cognitive training is a very broad field. This comment is analogous to saying "some pills seem to work and others don't." When we look at the efficacy of drugs we look at individual drugs and at classes of drugs. We need to do the same with cognitive training. When looking at these results the reference point is not all cognitive training, it is this exercise and similar plasticity-based brain training, which targets implicit (rather than declarative) learning – that is, learning to refine sensory perception and not fact-based or strategy-based learning.

*"**The problem with cognitive training is it never generalizes to everyday life.**"* In most of traditional cognitive training, users (at best) get better at the task trained and those effects do not "transfer" or "generalize" to standard cognitive measures, nor to real world activities. As you've read above, this particular brain exercise, and its class of plasticity-based training, has been shown over and over again to have both near transfer to proximal cognitive measures and far transfer to measures of behavioral, functional and real world outcomes.

"***These results will need to be confirmed in another study***." That is usually a reasonable thing to say with breakthrough results - breakthrough claims require substantial support. In this case, substantial support comes from the design and execution of the ACTIVE study and from previous studies showing improved cognitive function, improved real-world function, and protection against declines in key measures of cognitive health. In fact, given this strong body of published data, it would have been surprising had the new analysis *not* shown protection against the onset of dementia. Furthermore, the ACTIVE Study is the largest study of its kind -- involving thousands of participants, with six different sites for comparison, with a team of more than 50 researchers reviewing one another's work. It took more than 15 years to plan and execute, and was independently funded by the NIH at a cost of more than $30 million. Of course, there is always a need for a next study - science never stops - but that study should ask specific questions around how to maximize the benefits established in ACTIVE, and while that study is being planned and

managed, given the high benefit and the zero risk of speed training, people should have the opportunity to use speed training given all its demonstrated benefits to cognitive health.

"***Other things like physical exercise and diet have been shown to have similar effects***." This is not correct. There is no other prospective, large-scale, randomized controlled trial that has ever shown any drug, lifestyle change or other intervention has reduced the incidence of dementia in healthy adults. Physical exercise, heart healthy diets, and other behavioral changes have been shown in some studies to improve cognition in older adults – though the study results on diet and exercise are actually mixed – but this is not the same as showing a reduction in the incidence of dementia. Similarly, there are correlation studies indicating that certain behaviors (eg lifelong education) are correlated to lower incidence of dementia, but these correlational studies cannot resolve whether the behavior is a cause or an effect of lower predilection toward dementia.

Take-Aways. What does this study (and the related literature) tell us about the aging brain? Here are some take-aways.

1. This is the first prospective, randomized controlled trial to show that there is an intervention that can reduce the incidence of dementia.
2. Not all cognitive training is the same – of the three examined in this study, only one had a protective effect, so advice to "stay mentally active" must now be narrowed to types of engagement proven to be as good or better than speed training.
3. The amount of speed training performed in this study was rather modest and the study showed that more training had greater protective effect, suggesting we need to learn more about optimal dosing.
4. Greater scientific resources need to be directed toward the benefits of this particular type of training; how it might be optimized; and how it might be combined with other interventions.

Footnotes

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