# NEUROPSYCHOLOGICAL PREDICTION OF LEARNING AND ADHERENCE IN CARDIAC REHABILITATION

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The relationship between specific aspects of cognition and adherence is examined in a group of individuals participating in the *Dr. Dean Ornish Program for Reversing Heart Disease,* an intensive lifestyle modification program. This research was guided by a hypothesis of supply and demand – the information-processing skills in highest demand for adherence may be in short supply due to how the cardiovascular disease process impacts the brain. This hypothesis was evaluated by using results of neuropsychological testing administered to participants before they began the Ornish program to predict specific learning and adherence outcomes. Hierarchical regression was used to evaluate the contribution made by neuropsychological and non-neuropsychological variables (disease, demography, amount of Ornish lifestyle knowledge at the time of program entry and self-reported emotional status, psychosocial adjustment, and quality of life) to the prediction of adherence and program-specific learning. Nine outcomes were examined including behavioral adherence (diet, exercise, group support, and stress management), in-program learning (knowledge acquisition and procedural learning), staff perceptions of participant learning, and the level of program intensity required at the end of twelve weeks (Phase II Stratification). Neuropsychological variables made the most significant and unique contributions to the majority of predictive models. Measures of working memory and executive control were strongly represented in the adherence models. Explicit verbal memory and working memory were, respectively, significant facilitators of in-program knowledge acquisition and improvements in the accuracy of food diaries. Also, working memory was an important predictor of the level of program intensity participants needed at the end of twelve weeks. In summary, most aspects of the neuropsychological supply – information-processing demand (NIP) model were supported. By carefully selecting neuropsychological measures that capture vulnerable areas of cognitive processing in individuals with cardiovascular disease, the importance of cognitive information-processing capacity to adherence and adherence-based learning is demonstrated. Moreover, the research validates previous studies showing that critical cognitive moderators of adherence and learning cannot be discerned by health care professionals delivering clinical care, even when this contact involves intensive educational interventions. Only through the administration of a broad-based neuropsychological assessment battery are these essential cognitive facilitators of learning and adherence identified.

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# 1. INTRODUCTION

## 1.1. General Background

This research examines the relationship between learning and adherence in the context of cardiovascular disease. The majority of adherence studies have focused on psychological factors, such as the limiting effects of anxiety and depression, and one's readiness and confidence in the ability to change (i.e., stages of change, self-efficacy). While these factors play undisputed roles in moderating adherence, minimal attention has been given to the cognitive learning that supports adherence. This may be a critical oversight, particularly when studying diseases that disrupt brain function.

Cardiovascular disease and its surgical treatments affect blood and oxygen transport systems of the body, thereby rendering the brain vulnerable to compromise. This can result in a host of emotional, motivational, and cognitive processing problems, even in minor forms of disease. This research explores how these problems, collectively known as neuropsychological impairment, affect individuals' ability to learn about their illness and adhere to medical treatments prescribed to them. A predictive model, named the *neuropsychological supply – information processing demand (NIP)* model, is proposed. The NIP model combines information processing variables with psychological variables already known to influence adherence. The NIP has been designed to (a) investigate the importance of specific types of

information processing in relation to adherence-based learning, (b) determine whether specific neuropsychological tests can predict specific adherence and medical outcomes, (c) provide a practical way to identify individuals at risk for poor adherence before they attempt lifestyle changes, and (d) establish theoretical and scientific foundations that will guide improvements in the instructional methods used in clinical education/intervention programs.

To better conceptualize how problems with information processing are expected to interfere with medical adherence, it is useful to reflect upon a routine visit to the doctor. Most people have had the experience of not adequately understanding a health problem and what the doctor says must be done about it. In fact, simply taking a medication as prescribed requires a much higher level of information processing than may be consciously realized. One needs to understand (a) why the prescription is needed, (b) the importance of following the dosage schedule, and (c) what positive and adverse effects can be expected in the short- and long-term. It is necessary to commit at least some of this information to memory and access it in subsequent hours, days, weeks, and/or months. Beyond remembering to take the medication, information about its usage must be processed in ways having broader, future-oriented significance. For example, if one understands the long-term benefits of the medication, this could help sustain adherence if/when faced with adverse effects that are inconvenient in the short-term. Specific information processing skills are expected to support this kind of adherence, including the ability to learn facts, follow procedures and schedules, and strategically plan and anticipate consequences prospectively. In the language of contemporary learning theories, the information processing skills needed include, but are not limited to, explicit (factual) memory, working memory, procedural learning, and executive control (Baddeley, 1992; Denckla, 1993, 1996a, 1996b; Martin, 1993; Park et al., 1999; Park & Jones, 1996; Shallice, 1982; Shallice & Burgess,

1991; Shallice, Fletcher, Frith, Grasby, Frackowiak, & Dolan, 1994; Squire, 1992; Squire & Kosslyn, 1998; Tulving, 1983).

The cognitive resources needed to manage a chronic disease are expected to far exceed those required for time-limited medication adherence. A host of lifestyle changes are usually needed in diet, exercise, and health habits. While these *behavioral prescriptions* are more complex than medication prescriptions, the fundamental information processing demands are expected to be similar. Individuals must learn and remember factual information about how lifestyle changes will impact their illness and quality of life (explicit verbal memory, working memory, and learning), follow specific procedures for things such as food preparation, exercise routines, and stress management (procedural learning), and strategically incorporate these changes into their lives in enduring, future-oriented ways (executive control). Noncognitive factors such as motivation and emotion influence how well individuals adhere to various aspects of the behavioral prescription although in this research, these are conceptualized as second-order concerns. The issue of first order is whether or not the individual possesses the fundamental information processing resources needed to process and learn information in ways that promote adherence. The ability to do so is called into question when one considers the type and frequency of neuropsychological impairments linked with cardiovascular disease.

The neuropsychological impairments associated with heart disease and corrective cardiac surgeries have been carefully characterized through two decades of research (Byrne, 1996; McDaid, Lewis, McMurray, & Phillips, 1994; Murkin, Newman, Stump, & Blumenthal, 1995). Neuropsychological impairments vary as a function of disease type, but disturbances of memory and learning are ubiquitous across the spectrum of cardiac diseases. These are present in even the most benign and latent expressions of disease and their epidemiological significance are

potentially, enormous. Cardiovascular disease is the first-ranking cause of death and disability in the United States and without changes in diet, exercise, and lifestyle, the risks for premature death and disability are accelerated (American Heart Association, 2003; Blumenthal, Mahanna, Madden, White, Croughwell, & Newman, 1995; Schuster & Waldron, 1991; Vingerhoets, Jannes, DeSoete, & VanNooten, 1996; Young, 1993). If ineffective learning is a primary deterrent to heart-healthy living, then reducing cardiac mortality means increasing learning. In this way, cardiac-based neuropsychological impairments are phenomenologically similar to other disorders of learning. Early identification will improve both short- and long-term prognoses if followed by instructional programming that matches the needs of the learner. When framed this way, *cardiac-based learning disorders* represent a paramount public health concern. These can begin early in life, perpetuate disease in those at risk, and hasten premature death. This cycle must – and can – be broken. There is mounting evidence of a direct empirical relationship between the physical and neuropsychological impairments associated with cardiovascular disease. As physical (cardiac) status improves, so do certain aspects of neuropsychological functioning (Emery, Hauck, & Blumenthal, 1992; Shay & Roth, 1992; see also Dustman et al., 1984 and Miller, 1984 as cited in Lezak, 1995).

The potential for learning problems to interfere with the management of cardiac disease is recognized in the neuropsychological literature. Vingerhoets and colleagues (Vingerhoets, VanNooten, & Jannes, 1997) pose the following question and admonition:

> Does cognitive impairment in cardiovascular pathology result in difficulties with patients' adherence with the strict medical and pharmaceutical regimen that is often necessary in the treatment of cardiovascular disease? Especially in elderly patients with chronic cardiac disease, a screening of memory functions could be necessary to evaluate whether nonadherence with the prescribed regimen is not in part due to memory deficits. (p. 483)

Moser et al. (1999) acknowledge the same problem.

> Although CR [cardiac rehabilitation] patients may not be grossly neuropsychologically impaired as a group, it is highly likely that many will exhibit some degree of neuropsychological dysfunction. This has important implications for clinical care….it may be useful to evaluate patients' neuropsychological profiles before their entry into CR,….These data may help staff to impart health care information in a manner that is most effective for each patient and may also be useful in the formation of realistic expectations and treatment goals. (p. 96)

The recommendations of both Moser et al. (1999) and Vingerhoets et al. (1997) are well founded. Standardized neuropsychological tests have dual utility – they can be used to *identify* cognitive processing problems and *predict* several self-care behaviors important to the long-term management of cardiovascular disease (Emery et al., 1992; Richardson, Nadler, & Malloy, 1995). However, neuropsychological measures have not yet been used to predict how well individuals *learn* the essential facts and strategies that support adherence to heart-healthy lifestyles. For this type of research, it is necessary to make hypotheses regarding (a) the type of information processing skills supporting adherence-based learning and (b) how these skills are disrupted by heart disease. Thereafter, these hypotheses must be scientifically tested in ways that have pragmatic relevance for clinical educators working with cardiac patients.

An example involving dietary adherence brings further clarity to the kind of research that is needed. It is already known that those who have greater knowledge of nutritional facts and keep food diaries show higher levels of dietary adherence (Kirscht & Rosenstock, 1977; Lin, Ko, Tsai, & Chen, 1995; Streit, Stevens, Stevens, & Rossner, 1991; Winkleby, Flora, & Kramer, 1994). This supports the notion that specific cognitive processes are needed for dietary adherence and specifically, explicit memory (i.e., knowledge of nutritional facts) and procedural learning (i.e., keeping food diaries). Using the language of information processing theories of

learning to frame the problem holds limited practical relevance for clinical educators, however. It provides no way to identify individuals who are expected to have trouble *before* they experience failure, nor does it help educators modify their teaching methods in specific, theoretically-driven ways to facilitate learning and adherence. By combining neuropsychological methods with cognitive theories of learning, it may be possible to help clinical educators bridge the chasm between knowing what the problem is and fixing it. Through the administration of neuropsychological tests, it is possible to identify what aspects of information processing and learning are most vulnerable. Statistical analyses can determine whether or not test performances predict dietary adherence. If the model is validated, it will then be possible to use information processing theories of learning to modify the teaching methods in specific ways that will enhance adherence-based learning.

Two areas of related research provide relevant foundations for the current research study. Denise Park and colleagues have been investigating how age-related cognitive changes interfere with the ability to assimilate medical information for more than a decade. Many of their studies have examined how age-related decrements in more "effortful" forms of cognitive processing limit both medication adherence and the learning of new information critical to managing medical problems. Their focus on these more effortful aspects of cognition – namely, speed of information processing, working memory, and inhibition – is congruent with the supply/demand hypothesis advanced in the current study. Specifically, the aging process diminishes the supply of more effortful forms of cognitive processing but these processes (and especially working memory) are in high demand when assimilating new information into long-term memory stores. (An overview of seminal studies in this area is found in Brown and Park, 2003.) In terms of overall research design, neuropsychological studies involving alcohol treatment programs also

provide a relevant precedent. These studies include individuals having a high risk for cognitive impairment and have shown clear correlations between neuropsychological test performances and specific treatment outcomes. One limitation of those studies is that a majority have used descriptive rather than predictive research designs. A number of factors support the feasibility of a predictive design for the current research, however. Cardiac-related neuropsychological impairments have been carefully characterized in the extant literature and the predictive validity of tests used to quantify these impairments is equally established. This includes knowing which tests are best for predicting specific activities of daily living (ADLs) such as independence in taking medications, cooking, and self-care. Therefore, the NIP model was designed to include tests that (a) quantify the neuropsychological problems most frequently seen in cardiac-related diseases *and* the kinds of information processing hypothetically linked to adherence and, (b) are already known to predict medical outcomes and self-care ADLs.

A study of this type can only be conducted in the context of a highly structured intervention program that offers uniformity of treatment and monitored outcomes. A specific intervention program known as the *Dr. Dean Ornish Program for Reversing Heart Disease*, hereafter referred to as the Ornish program, provides an ideal setting for this research. Participants in the Ornish program receive specific behavioral prescriptions for lifestyle changes and their progress is carefully monitored, particularly during the first twelve weeks of the year-long intervention. The Ornish program readily lends itself to the type of scientific investigation proposed in this research. In addition to uniformity of treatment and comprehensive monitoring of adherence and medical outcomes, program participants complete daily "homework assignments" in the form of highly structured diaries that detail their adherence to these

behavioral prescriptions. These diaries provide a cumulative repository of participants' learning and adherence for the first twelve weeks of the program.

The Ornish program is the only known behavioral intervention offering empirical evidence that coronary artery disease can be reversed through specific lifestyle changes. With strict adherence to the Ornish program, it is possible to reduce the volume of arterial plaques and realize other heart-healthy benefits such as reduced LDL cholesterol levels, reduced symptoms of angina, weight loss, and improved feelings of well-being. There is a dose-response relationship for these outcomes; in other words, the best adherence to the comprehensive lifestyle changes yields the best medical outcomes, i.e., reductions in the size of coronary artery plaques, LDL levels, and symptoms of angina (Ornish et al., 1998). Therefore, the adherence-based learning that supports the successful transition to the Ornish lifestyle may be the linchpin of reversing heart disease.

## 1.2. Purpose of Current Study

There is growing interest in the relationship between cognition and adherence but unfortunately, existing studies are methodologically flawed because these do not adequately measure "cognitive function or adherence in a rigorous or comprehensive manner" (Ryan, 2000, p. 9). The majority of existing research in this area has focused on unidimensional aspects of adherence (such as medication adherence) rather than more complex behavioral prescriptions such as making the changes in diet, exercise, and general lifestyle needed for the long-term management of cardiovascular disease. Also, many existing studies have used experimental tools rather than the tests most frequently used in the daily practice of clinical neuropsychology.

The current research addresses these constraints in four ways. First, neuropsychological instruments having demonstrated utility for the characterization of cardiac-based cognitive shortcomings are used to complete a broad-based assessment. Second, tests were carefully selected so as to include measures that have predictive validity for many self-care activities that are important to disease management. Third, the adherence outcomes investigated in the current study are rigorously quantified and monitored through stringent data gathering procedures already built into the Ornish program. Fourth, while previous studies have examined unidimensional aspects of medical adherence, the current research explores more complex behavioral prescriptions involving intensive lifestyle changes. This study was designed to be the first in a series of studies aimed at building and empirically testing a "neuropsychological supply-information processing demand (NIP)" model of adherence for complex behavioral prescriptions.

Four questions are addressed through this research: (1) Do neuropsychological variables significantly improve the prediction of cardiac rehabilitation outcomes beyond what is accounted for by program knowledge, demographic, disease, and psychological variables? (2) How much variance in each outcome is accounted for by a combination of top-ranking neuropsychological and non-neuropsychological predictors? (3) Which of the non-neuropsychological variables are important to include in the predictive models? (4) Which of the neuropsychological tests commonly used to identify cognitive impairments in cardiovascular disease are the best predictors of specific learning and adherence outcomes?

## 1.3. Limitations of the Research

Two primary limitations of this research need to be recognized. These relate to sample characteristics and the scope of learning and adherence outcomes being analyzed. It is important to recognize how naturally occurring sample characteristics may impede the validation of the NIP model. It is likely that individuals having the most severe cardiac-based neuropsychological impairments will *not* be represented in the sample population due to self-selection and selective attrition. Enrollment in the Ornish program is completely voluntary and most often, self-initiated. In some cases, a physician has recommended participation but usually, the individual has become familiar with the program through friends and/or advertisements. Due to this self-selection, individuals who choose to participate in the Ornish program are apt to be highly motivated. However, even highly motivated individuals may not be cognitively or emotionally equipped to undertake the challenge of the program and therefore, some drop out. This problem, known as selective attrition, may cause an *underestimation* of the magnitude of learning problems because subjects having the greatest neuropsychological impairments are removed from the majority of statistical analyses dealing with outcomes. Future studies will evaluate this problem of selective attrition through data analyses of completers versus noncompleters to determine if those who drop out of the program have greater neuropsychological impairments.

The second limitation relates to the restricted scope of learning and adherence outcomes under investigation in the current study. All outcomes were selected because they hold practical significance for success in the Ornish program as well as prognostic relevance for long-term medical adherence outcomes. The treatment time analyzed in this research study is relatively

brief (i.e., first twelve weeks of the program; approximately twenty-four sessions) although this study was designed to support a program of research beyond the dissertation project.

## 1.4. Significance of the Research

A great deal of research has already been dedicated to the psychological factors influencing medical adherence. While a number of moderating factors have been identified, these have neither the strength nor specificity to be practically useful. By combining psychological variables known to influence adherence, together with new experimental variables, an attempt is made to develop a predictive model that has pragmatic relevance. The three most significant contributions made by this research are expected to be the validation of (a) the key role that specific kinds of information-processing play in relation to adherence, (b) a practical way to identify individuals at risk for poor adherence, and (b) a scientific foundation that paves the way for future research.

If neuropsychological factors – and cognitive learning in particular – prove to be missing pieces of the adherence puzzle, this has far reaching significance. The direct contribution to structured interventions like the Ornish program is clear. The NIP could be administered before individuals begin the program to determine who may need more than routine levels of support and instruction. Because the development of the NIP was guided by information processing theories of learning, this makes it possible to develop specific instructional methods grounded in these theories. Therefore, scientific validation of the NIP not only provides a pragmatic way to identify at-risk individuals but also, a theoretical foundation that will make specific pedagogic improvements possible in the future. Also, this research is relevant to the clinical management of medical problems other than cardiovascular diseases. Many chronic diseases – diabetes,

hepatic dysfunction, obstructive pulmonary diseases, human immunodeficiency virus (HIV), and various types of substance addiction – are accompanied by neuropsychological problems that may interfere with adherence and worsen if the disease is poorly managed (Berry et al., 1993; Byrne, 1996; Lezak, 1995, pp. 268- 270; Manschreck, Scheyer, Weisstein, & Laughery, 1990; Prigatano & Levin, 1988; Roseli & Ardila, 1996; Ryan, 1988; Strickland & Stein, 1995; Tarter, Van Thiel, & Edwards, 1988).

The long-term goals of future research studies in this area are relevant for public health research aimed at both disease prevention and early intervention. Like other systemic illnesses, the evolution of cardiovascular disease is insidious and neuropsychological impairments are often present long before physical symptoms of disease emerge. Because impairments may impede heart-healthy learning from early in life, these could directly advance the disease process, cause further cognitive compromise, and make heart-healthy learning increasingly more difficult. Adherence to lifestyle interventions has the potential to not only reverse the cycle of disease but also, some of the neuropsychological impairments associated with the disease. This has potentially far reaching significance in terms of disease epidemiology and public health costs, although the individual quality of life improvements are most important. Finding ways to improve adherence not only enhances physical health but also, cognitive and psychological well-being.

# 2. REVIEW OF THE LITERATURE

## 2.1. Basic Assumptions and Scope of Literature Review

### 2.1.1. Basic Assumptions

Neuropsychological impairments have been identified in all forms of coronary disease, regardless of type or severity. To better understand these problems, it is important to recognize the cumulative risks that cardiac individuals face, many of which have their origin in heritable factors and minor disease forms. Particularly for those who have advanced disease because they poorly managed problems such as hypertension and hyperlipidemia earlier in life, the risks for neuropsychological impairment are multiple and compounded. Each cardiac-based symptom that emerges, together with the chronicity of the disease, can negatively affect thinking and emotions in ways that can be measured by standardized neuropsychological tests.

Three fundamental precepts help us understand how the brain is cumulatively compromised by coronary disease. First, many factors contribute to neuropsychological impairments in cardiac disease but in general, these are directly and proportionately related to disease severity. Second, elderly individuals are more likely to be neuropsychologically impaired by virtue of their cardiac disease(s) as well as other disorders of aging. Third, many factors contribute to the brain dysfunction associated with cardiovascular diseases although the

primary causes include (a) circulatory problems (i.e., cerebral hypoxia and hypoperfusion) and (b) vascular lesions (i.e., major and minor stroke, small vessel disease, and emboli).

Individual differences influence the expression of these neuropsychological impairments because specific subject attributes can lessen/intensify the functional impact of cardiac-based brain changes. In addition to age and disease type, education and gender influence the expression of cognitive and emotional changes. A related influence is "cognitive reserve," which refers to the resiliency of brain function in the midst of damage and trauma (Mortimer & Graves, 1993). It is a protective buffer, chiefly influenced by how much the individual has exercised the brain through learning. Educational level is the primary way cognitive reserve is quantified although other factors, such as ongoing participation in learning activities, basic intelligence, and employment status, are contributory also. The cognitive reserve construct is not uniformly accepted by neuropsychologists, although the link between education and a vast array of outcomes is undisputed. Education is predictive of various physical and mental capacities in the elderly (Snowdon, Ostwald, Kane, & Keenan, 1989) as well as specific neuropsychological disorders such as dementia (Mortimer & Graves, 1993). In general, even in the face of significant cerebrovascular pathology, a more favorable prognosis is expected for individuals who have higher levels of education (Heaton, 1992; Heaton, Grant, & Matthews, 1991). These findings demonstrate that a host of subject attributes influence the manifestation and level of debilitation associated with cardiac-based neuropsychological impairments.

### 2.1.2. Scope of Literature Review

The literature dealing with how the brain is compromised by cardiac disease is voluminous, making it necessary to limit the literature review in specific ways. Only the most common causes and manifestations of cardiac-based neuropsychological deficits are reviewed, along with their hypothetical relevance to adherence-based learning.

Regarding the pathophysiology of cardiovascular diseases, the literature review is confined to how vascular and oxygen disturbances affect the brain in diffuse ways; in other words, the effects of focal lesions (i.e., stroke) are not addressed in any specific way. Limiting the literature review in this way is warranted by the phenomenological assumptions guiding this research. Hypothetically, less than obvious neuropsychological impairments are disrupting activities of daily living and these unrecognized problems are contributing to poor adherence. The goal is *not* to determine the exact biological causes of neuropsychological impairments but rather, to document their presence and functional significance in relation to adherence. It is necessary to provide sufficient biological evidence of why such problems are anticipated, but unnecessary to explore each contributing factor in minute detail. For these same reasons, the neuropsychological impairments associated with medications commonly prescribed to cardiac individuals are not specifically reviewed. Antihypertensive and lipid-lowering medications have been associated with neuropsychological impairments although as summarized by Moser et al., (1999), "…the preponderance of medical evidence has concluded that such effects are minimal or nonexistent" (p. 95). An overview of this sizeable body of literature can be found in Stein and Strickland (1998).

Limits imposed on the types of cardiac diseases presented in the literature review were determined by anticipated sample characteristics. Only those diseases most frequently represented in the target population are reviewed, beginning with the problem of elevated blood pressure (i.e., hypertension). While it is unlikely that an individual would participate in the Ornish program due to hypertension alone, many individuals with more advanced forms of cardiovascular disease also have hypertension. Moreover, hypertension can cause specific neuropsychological problems that can disrupt learning and adherence. Following a review of the neuropsychological impairments associated with hypertension, more serious cardiac diseases are explored, including myocardial infarction, cardiac arrest, and various corrective heart surgeries. Also included is a brief review of the combined effects of diabetes mellitus and cardiovascular disease in relation to the expression of neuropsychological impairments.

## 2.2. Cardiac Disease Types and Associated Neuropsychological Impairments

### 2.2.1. Hypertension

Simply having a genetic predisposition for high blood pressure can be neuropsychologically significant. For example, entirely asymptomatic young adults who have family histories of hypertension perform worse than normal controls in a number of cognitive areas including visual-spatial functions and speed of short-term memory search (McCann et al., 1990 as cited in Waldstein, 1995; Pierce & Elias, 1993 as cited in Waldstein, 1995; Waldstein, Ryan, Polefrone, & Manuck, 1994). Actually having hypertension places the individual at risk for more encompassing information processing problems as well as transient difficulties related

to fluctuating blood pressure levels (Miller, 1984 as cited in Lezak, 1995). A study of participants in a hospital-based cardiac-rehabilitation program revealed that at least half had moderate to severe hypertension and these individuals had significantly weaker neuropsychological performances than those without hypertension (Moser et al., 1999). The neuropsychological impairments associated with hypertension can vary across the lifespan (Waldstein, 1995) although regardless of disease severity, certain problems are seen regularly. For example, the same visual-spatial and speed of information processing problems seen in the at-risk (asymptomatic) individuals described above are also seen in those who are symptomatic. Poor performances on tests of learning and memory, attention and concentration, executive control, and motor speed and dexterity are commonplace also (Waldstein, Manuck, Ryan, & Muldoon, 1991; Waldstein, Ryan, Mannuck, Parkinson, & Bromet, 1991; Waldstein, 1995, p. 333). These impairments are largely independent of education (Blumenthal, Madden, Pierce, Seigel, & Appelbaum, 1993) but *not* age or disease severity – older hypertensives and those with higher levels of blood pressure have the highest risks for neuropsychological impairments (Waldstein, 1995, p. 333-335). Especially vulnerable are the attention and visual-practic skills of elderly hypertensives (Schmidt et al., 1995).

Waldstein (1995) provides a useful synoptic summary of the pathophysiological brain changes responsible for neuropsychological deficits in hypertension.

These [biological] mechanisms include:

- morphological changes in the brain, such as white matter disease and microaneurysms
- atherosclerosis in the large cerebral or cervicocerebral vessels
- reduced cerebral blood flow
- disturbance of autoregulatory processes
- reduced cerebral metabolism

- alterations in brain neurochemistry
- alterations in cellular function in the brain
- increased cardiovascular or neuroendocrine reactivity. (pp. 338-339)

Given the age demographics of the majority of participants in cardiac rehabilitation programs, the nature of brain changes observed in elderly hypertensives deserves specific attention. Cerebral atrophy is commonly observed on MRI scans, as are punctate areas of white matter hyperintensity. These hyperintense signals are evident throughout the cerebrum and subcortex and thought to be related to widespread, small vessel, white matter ischemic disease (Schmidt et al., 1995). Historically, these characteristics have been referred to as Binswanger's Disease, particularly when observed in elderly hypertensives (Funkenstein, 1988). The more technical term, leukoaraiosis, is preferred in contemporary literature because leukoaraiosis is now known to be a nonspecific finding associated with diseases other than hypertension. The presence of leukoaraiosis in both hypertension and other forms of cardiovascular disease is significant. Individuals with MRI evidence of leukoaraiosis have an increased risk for depression (Coffey, Figiel, Djang, & Weiner, 1990) and this depression predicts future cognitive decline. Through longitudinal studies, Nussbaum and colleagues found that individuals who were neuropsychologically normal at the outset of their study (with the exception of depressive symptoms) were more likely to exhibit gradual cognitive decline if leukoaraiosis was present. By contrast, elderly depressed individuals who did *not* have leukoaraiosis remained neuropsychologically stable over time (Nussbaum, 1994; Nussbaum, Kaszniak, Allender, & Rapcsak, 1995). In the context of cardiac disease, the significance of these findings is twofold. Depressive symptoms may be (a) potentiated by biological factors and possibly, (b) a signpost for progressive neuropsychological decline that lies ahead.

### 2.2.2. Myocardial Infarction/Cardiac Arrest

Individuals with more serious problems, such as myocardial infarction (MI) or cardiac arrest (CA), stand to be neuropsychologically impaired for several reasons. Their risk for neuropsychological impairment not only relates to the acute cardiac event but the underlying cardiovascular disease causing the event. Post-MI and -CA impairments are often mild and can be easily mistaken for general physical debilitation and/or an adverse emotional response to severe illness. However, like individuals with hypertension, individuals who have experienced either MI or CA individuals are at risk for organically-based cognitive and depressive symptoms (Harrington, 1989 as cited in Byrne, 1996).

While many factors influence the risk for neuropsychological impairments in MI and CA, the level of oxygen deprivation (i.e., anoxia/hypoxia) associated with the cardiac event is key. As a general rule, the severity of cognitive and emotional deficits is usually proportionate to the length of time the individual was oxygen-deprived. Regarding pathophysiology, it is known that when there is severe and sustained oxygen deprivation, the brain suffers widespread damage, especially in the brainstem, cerebral white matter, and basal ganglia. Certain areas of the brain are especially vulnerable to the effects of oxygen deprivation and namely, structures in the subcortex and medial temporal lobe (i.e., hippocampi, amygdala, fornix, diencephalon, and temporal neocortex). This is relevant to the current research. These cerebral structures regulate one type of information processing (i.e., explicit memory) that makes factual learning possible (Aberg, 1995; Harrison, 1995).

While serious anoxic episodes can occur with either MI or CA, it is more common for the individual to suffer a period of circulatory arrest rather than sustained oxygen deprivation. Typically, circulatory arrest produces less severe and qualitatively different neuropsychological impairments than complete oxygen deprivation. This is because arterial oxygen tension usually remains normal when blood flow stops abruptly. Circulatory arrest does *not* have the same effect upon the brain as severe and sustained oxygen deprivation. The hippocampi are typically spared in circulatory arrest and therefore, dense amnesic syndromes are not commonly observed. Rather, the boundary zones (i.e., watershed areas) between the major cerebral and cerebellar arteries are more vulnerable to damage in circulatory arrest, especially arteries supplying the anterior frontal pole of the brain. While spared a dense amnesic syndrome affecting *explicit memory*, problems with a specific executive control function known as *working memory* (i.e., one's "mental scratchpad" for information currently in use) are common. Diffuse damage to structures in and connected to the frontal system of the brain may be responsible for these working memory problems (Baddeley, 1992; Denckla, 1996a).

Findings from early animal studies bring further clarity to how memory problems differ in circulatory arrest versus complete oxygen deprivation. Several minutes of complete or near-complete oxygen deprivation is sufficient to produce amnesia in dogs. By contrast, as long as normal arterial tension was maintained, dogs retained normal memory capacity after as long as six minutes of circulatory arrest. After eight minutes, significant deficits emerged although qualitatively, these were *not* indicative of amnesia. These dogs were able to execute previously learned procedures but were impaired in their ability to solve novel problems (i.e., executive control/working memory) (Grossman, 1967 as cited in Byrne, 1996).

These early studies help explain why neuropsychological deficits can vary significantly in both MI and CA. Those who suffered prolonged and complete anoxia will have obvious deficits – paralysis, dementia, and/or global amnesia – and these are more likely to be recognized by program staff working with them. However, the vast majority of individuals with cardiovascular disease and especially, those participating in the Ornish program, have *not* experienced this type of severe anoxic episode. Their neuropsychological difficulties will be less conspicuous and characterized by a general reduction of cognitive processing speed, short-term memory impairments, and symptoms of depression (Beuret et al., 1993; Druhe & Hartje, 1989 as cited in Byrne, 1996; Kotila & Kajaste, 1984 as cited in Byrne, 1996; Legault, Joffe, & Armstrong, 1992). Another important characteristic of these problems is they are usually not temporary.

A study by Roine and colleagues (1993) found that at the end of one year, neither the nature nor severity of deficits in nearly *half* of the surviving CA patients had changed (Roine, Kajaste, & Kaste, 1993). There are multiple potential causes of these deficits, including a combination of chronic cardiovascular risk factors, the acute event itself, and inefficient function of the damaged heart (Koide et al., 1994). The problem of cardiac inefficiency is further illuminated through a remote study conducted by Goldberg, Raflery, and Cashman (1975 as cited in Byrne, 1996). Using a group of patients referred for consultation due to symptoms of confusion, Goldberg and colleagues assessed cardiac functioning in these individuals by way of 24-hour EKG holter monitors. Prior to EKG monitoring, cardiac anomalies were *not* judged to be the cause of individuals' confusion. Persuasively, the EKG results proved otherwise. Seventy-four percent of these individuals had dysrhythmias and other cardiac abnormalities that went undetected through standard cardiac examinations. The conclusion was that underlying

cardiac disease and inefficient heart function may contribute to cognitive confusion more often than is realized.

Inefficient cardiac function is common in individuals participating in cardiac rehabilitation and this is a significant risk factor for neuropsychological impairment. In a study conducted with a conventional cardiac rehabilitation treatment program, Moser et al. (1999) found that participants who had *both* hypertension and low ejection fraction (i.e., an index of heart pumping efficiency) exhibited the worst neuropsychological functioning. No other risk factors – not even major open-heart surgery – posed a greater risk for neuropsychological impairment. In summary, there are three major causes of the neuropsychological impairments observed in individuals who have suffered acute MI or CA: (a) the cumulative effects of chronic coronary problems such as hypertension, (b) the level of anoxia/hypoxia accompanying the acute event, and (c) the reduced efficiency of the damaged heart muscle.

### 2.2.3. Corrective Cardiac Surgeries

In cases of advanced cardiac disease, it is often necessary to perform corrective surgeries. While gaining the benefit of improved physical functioning and in some cases, extended longevity, the neuropsychological costs can be high. Walzer and Herrmann (1998) report that neuropsychological impairments occur in as many as 80% of all individuals undergoing heart surgery. Whether new neuropsychological impairments will be acquired as a result of surgery depends largely upon the complexity of the procedure and individual subject attributes. In general, more lengthy procedures carry greater risks for inadequate blood circulation (i.e., hypoperfusion). In the elderly, these risks are intensified by the fragility of the vascular system

and the cumulative effects of chronic cardiovascular and other co-morbid diseases (Mills, 1995). On the other end of the age and disease spectrum, there is a favorable prognosis for young individuals whose surgeries are less radical, have less general anesthesia, and require no external heart/lung life-supports.

To better understand anticipated post-surgery outcomes, it is useful to contrast procedures at each end of surgical complexity. Several studies address this by comparing pericutaneous transluminal coronary angioplasty (PTCA) with more complicated cardiac surgeries such as coronary artery bypass graft (CABG) and cardiac valve replacements. Unlike CABG and cardiac valve surgeries, PTCA is not an *open*-heart surgery; a thin catheter with a ballooning tip is inserted into the coronary artery to widen segments that have been narrowed by cholesterol plaques. Modest neuropsychological improvements (i.e., reaction time) are usually seen after PTCA while neuropsychological decrements are the norm after CABG and valve replacement surgeries (Blumenthal, et al., 1991). Another cardiac surgery that can improve neuropsychological functioning is heart transplantation. This does *not* mean these individuals are free from neuropsychological impairments, however. A host of residual deficits typically remain, and their magnitude depends upon the pre-transplant severity of their cardiovascular disease. Pre-transplant hemodynamic pressure (i.e., increased pulmonary artery and right atrial pressure) is a specific risk factor correlated with performances on tests of memory, attention, and executive control (Putzke, Williams, Rayburn, Kirklin, & Boll, 1998). Two additional risk factors for post-transplant neuropsychological decline are age and the functional efficiency of the new heart (Bornstein, Starling, Myerowitz, & Haas, 1995). Functional inefficiency of the transplanted heart can produce mental status impairments of fluctuating duration and severity in individuals of all ages. Not unexpectedly, older heart transplant patients tend to have more

severe deficits – both transient and enduring neuropsychological deficits – than younger individuals. Across studies, the most frequently occurring cognitive difficulties associated with heart transplantation involve attention, executive control, verbal memory and learning, and psychomotor speed (Farmer, 1994; Nussbaum & Goldstein, 1992; Strauss et al., 1992).

Coronary artery bypass graft (CABG) is the surgical procedure receiving the most attention in neuropsychological literature. The reported incidence of post-CABG neuropsychological impairment ranges from 33% to 83% across studies (Newman, Croughwell et al., 1995, p. 1326). Along with general mortality concerns, these neuropsychological risks call into question the cost/benefit ratio of CABG, especially when performed on elderly persons who have uncertain prognoses for recovery (Aberg, 1995; Mills, 1995; Peterson et al., 1995). The risk for both pre- and post-surgery impairments in CABG patients seems to relate to a number of factors, including the effects of chronic vascular disease, age, and the efficiency/integrity of cardiac function (Tuman, McCarthy, Najafi, & Ivankovich, 1992). Cognitive reserve factors, such as low intelligence and education, play a role also (Byrne, 1996; McDaid, Lewis, McMurray, & Phillips, 1994). Unfortunately, if neuropsychological impairments are present *before* CABG, these are likely to be worse after. A study by Iguchi and colleagues (Iguchi et al., 1993) provides some insight into why this is so. Results of pre-surgery CT scans of the brain were used to classify 104 subjects into one of three comparison groups. The largest group ($n$ = 73) had normal CT scans. Of the 31 individuals with abnormal scans, moderate to severe atrophic changes were observed in half ($n$ =16). Of the 15 remaining individuals, CT scans revealed evidence of diffuse leukoaraiosis that was most prominent in frontal regions of the brain. Behavioral comparisons of these three groups after surgery were noteworthy. Only the group having CT evidence of leukoaraiosis prior to surgery displayed obvious mental status

deficits. These included symptoms of bizarre behavior, dementia, disorientation, and signs of motor dysfunction such as pseudobulbar signs and disturbances of gait. Because subcortical and frontal regions are most susceptible to the kind of damage that commonly occurs in CABG surgery (i.e., hypoperfusion, hypoxia, and micro- vascular and -embolic lesions), it is logical that individuals who already have compromised function in those vulnerable areas will show further decline (Benedict, 1994; McDaid et al., 1994; Willner and Rabiner, 1979 as cited in Byrne, 1996). Like the depression studies conducted by Nussbaum and colleagues (Nussbaum, 1994; Nussbaum et al., 1995), the research by Iguchi et al. (1993) points to the significance of leukoaraiosis as a biological marker for incipient neuropsychological decline. The combined effects of hypoxia and embolic lesions lodging in small blood vessels are thought to be responsible for post-CABG neuropsychological deficits. Specific perioperative factors are contributory, including the length of cardiac bypass time and the number of emboli in the circulating blood during surgery as detected via transcranial Doppler ultrasonography (McDaid et al., 1994; Vingerhoets et al., 1996). A correlation between the number of surgical microemboli detected and neuropsychological outcome has been found (Aberg, 1995). A study by Clark and colleagues (Clark et al., 1995) found that the greatest pre- versus post-surgery neuropsychological changes (i.e., > - 3 standard deviations post-surgery) were found in individuals who had more than sixty Doppler-detected microemboli during surgery. Surgical factors other than emboli influence neuropsychological outcomes after CABG also. Body temperature, mean arterial pressure, and jugular bulb oxygen saturation have all been associated with poor neuropsychological outcome (Newman, Croughwell et al., 1995; Townes et al., 1989). For elderly individuals, hypotension *during* surgery, and rapid rewarming *after* surgery, contributes to this risk (Newman, Kramer et al., 1995). Generally speaking, subcortical regions

of the brain are especially vulnerable to the physiological effects of CABG (Harrison, 1995) although there is also evidence that microemboli associated with hypoperfusion tend to gravitate to the right cerebral hemisphere. Specifically, the watershed area of the parietal-occipital cortex appears to be a preferred location for microemboli to lodge (Stump, 1995). This is relevant to the nature of neuropsychological impairments that may be seen. The parietal-occipital cortex mediates a variety of visual functions (Lezak, 1995).

As might be expected based on the areas of the brain most readily affected by CABG surgery, the nature of neuropsychological problems are in many ways, similar to those seen in hypertension, MI, and CA. Memory and various forms of executive control are especially vulnerable in CABG surgery and the risks for post-surgical depression and anxiety are high also (Byrne, 1990; Townes et al., 1989; Vingerhoets, DeSoete, & Jannes, 1995). Short-term memory impairments and a constrained ability to learn new verbal information are common problems in the early months of post-CABG recovery. Post-CABG impairments improve over time although there is some debate about how quickly and to what extent.

### 2.2.4. Diabetes Mellitus and Cardiovascular Disease

Diabetes mellitus is one of the most frequently occurring, attendant diseases in the cardiovascular population. Due to how the vascular system of the body is disrupted by aberrations in glucose metabolism, the presence of diabetes is a specific risk factor for the development and progression of cardiovascular diseases (Rodriguez-Saldana et al., 2002). Let us first examine the neuropsychological risks associated with diabetes alone, followed by the risks of having both diabetes and cardiovascular disease.

Most studies have shown that both age and blood glucose levels moderate the nature and severity of neuropsychological impairments in diabetic individuals. In general, younger diabetics have well preserved memory and learning abilities, even in the face of substantial elevations of blood glucose levels. Hypoglycemic states produce more deleterious neuropsychological effects, especially in men (Draelos et al., 1995; Ryan & Geckle, 2000). However, several studies have documented a specific risk for neuropsychological impairment in older diabetics involving verbal learning and memory. Ryan and Geckle explain these problems in terms of the synergistic effects of the metabolic disruptions associated with diabetes and the structural and functional changes associated with aging.

Beyond middle age, the risks for neuropsychological impairments are significantly increased in individuals with diabetes, especially if they also suffer from cardiovascular disease. An especially high risk for progressive cognitive decline has been found in older diabetics who have hypertension (Knopman et al., 2001; Posner, Tang, Luchsinger, Lantigua, Stern, & Mayeux, 2002). Also, there are heightened neuropsychological risks associated with cardiopulmonary bypass surgeries in older diabetics with cardiovascular disease. These individuals have greater difficulties autoregulating cerebral blood flow and most likely, this is the major cause of post-operative neuropsychological impairments in this population (Pallas & Larson, 1996).

There is an exhaustive literature dealing with the neuropsychological impairments associated with diabetes although it is beyond the scope of this literature review to explore this in further detail. In the context of this study, it is most important to recognize that the increased incidence of diabetes in the cardiovascular population carries with it an increased risk for neuropsychological impairments, particularly for individuals beyond middle age.

### 2.2.5. Summary

The prevalence and physiologic bases of cardiac-based neuropsychological deficits are well documented in the literature. These vary as a function of age, education, and the severity and type of cardiac disease, although certain neuropsychological impairments are seen with regularity. Impairments of memory are an essential given, although the nature of memory problems can vary as a function of disease type and surgical factors. The most frequently occurring problems involve, but are not limited to, aspects of explicit memory and working memory. Various visual-spatial impairments can be seen and these may be particularly prominent in the elderly and those who have multiple medical problems and/or more lengthy surgeries. Many of these problems, as well as other shortcomings (e.g., specific types of memory, cognitive efficiency, and difficulties with novel problem solving) may in part, reflect a primary problem with executive control. These neuropsychological problems appear to relate to the pathophysiologic changes in circulatory perfusion and damage to small vasculature. While many areas of the brain can be affected by these changes, the white matter of the brain and particularly, connections between the frontal system and subcortex, seem to be highly susceptible to compromise. Mesial-temporal, frontal and more posterior (i.e., right parietal-occipital) regions of the cerebral hemisphere appear to be selectively vulnerable also.

As will be reviewed in greater detail at a later point in this literature review, emotional disturbances such as depression, are equally pervasive across the spectrum of cardiac diseases and surgeries and these can be potentiated by the neurologic changes (Newman & Sweet, 1992). This is relevant because the areas of the brain most likely to be compromised by cardiac disease

not only regulate cognitive learning processes but also, aspects of mood, behavior, and emotion. While the relationship between emotional symptoms and organic consequences is not straightforward, the more important point is that both emotional and cognitive limitations have the potential to directly influence learning in fundamental ways. However, these neuropsychological problems are unlikely to be recognized by the clinical practitioners working with individuals attempting to make lifestyle changes to manage their cardiovascular disease.

## 2.3. Prevalence versus Recognition of Neuropsychological Deficits

While neuropsychological impairments frequently accompany cardiac diseases and are significant enough to interfere with everyday functioning, these are rarely diagnosed. Only those individuals with obvious symptoms (e.g., dementia, paralysis, and/or aphasia) are readily recognized as impaired. This is because the neuropsychological impairments associated with cardiovascular disease are not usually recognized in the context of routine clinical care. A related problem is that these less than obvious symptoms are easily mistaken for fatigue, physical debilitation, and/or medication effects. Despite their covert nature, neuropsychological problems may be integrally interfering with individuals' response to lifestyle intervention programs.

### 2.3.1. The Frequency of Under-Diagnosis

Two studies provide examples of how serious neuropsychological deficits can be present but go undetected in individuals with cardiovascular disease. In 1984, Garcia and colleagues (Garcia, Tweedy, & Blass, 1984) administered two tests of intellectual functioning to one-

hundred individuals who were consecutively admitted to a *rehabilitation* hospital; this facility served individuals with various types of physical disabilities, not only those with heart disease. Twenty-five percent of these individuals were impaired on these tests. When these patients' medical records were reviewed, it was discovered that 84% of those having cognitive impairments had some form of cardiovascular disease. The second study is even more relevant, as it specifically addressed the frequency of undetected neurological impairments in individuals participating in a structured cardiac rehabilitation program. Barclay and colleagues (Barclay, Weiss, Mattis, Bond, & Blass, 1988) drew a sample of twenty subjects who had been classified as normal on routine neurological exams. They were careful to exclude from the study *all* individuals with known neurological impairments or other diseases causing cognitive impairments (e.g., stroke, dementia, alcoholism, chronic pulmonary disease, metabolic encephalopathy, etc.). These twenty subjects were then given more thorough neurological exams. Only one of the twenty performed normally on the more comprehensive examination. The majority (15/20) exhibited *multiple* neurological abnormalities judged to be related to multi-focal brain damage caused by acute and chronic hypoxia. Results of neuropsychological testing conducted with these individuals were most interesting. All but one subject exhibited neuropsychological impairments that were significant enough to be detected on cursory screening measures. In terms of functional significance, 35% of them were experiencing difficulties with medication adherence.

The significance of these studies is threefold. First, neuropsychological impairments occur with regularity in individuals with cardiac disease and have the potential to negatively impact adherence. Second, these problems are usually *not* obvious enough to be detected by

skilled hospital staff providing clinical care. Third, these problems usually go undetected unless standardized neuropsychological evaluations are administered.

### 2.3.2. The Belief that Neuropsychological Aberrations are Temporary

Even when neuropsychological vulnerabilities are recognized and diagnosed in cardiac individuals, a popular opinion is that these are transient, related to factors such as the acute nature of the cardiac event, medication effects, and/or cardiovascular inefficiency (Byrne, 1996). In the case of CABG surgery for example, a common belief is that cognitive and emotional difficulties will be short-lived. While some longitudinal studies support this (Townes et al., 1989; Vingerhoets et al., 1996), there is equal evidence that residual problems can be unremitting and in some cases, progressive. One year after surgery, Newman and colleagues (Newman, Croughwell et al., 1995, p. 1326) found persistent impairments in 35% of their CABG individuals. The worst long-term prognoses were found in individuals who were the most impaired in early post-CABG evaluations (i.e., 10 days post-surgery). Another study revealed that two to three years post-CABG, complaints of memory problems and cognitive inefficiency continued to be self-reported by individuals (Kareken et al., 1992). In a study conducted five years post-CABG, individuals' whose initial neuropsychological impairments were severe continued to have greater impairments than less impaired counterparts (Sotaniemi, Mononen, & Hokkanem, 1986). In addition to the chronicity of neuropsychological problems in post-CABG individuals, these individuals are also at risk for acquiring new deficits during their recovery due to their vulnerable cardio- and cerebro-vascular systems (Bruggemans, Vandijk, & Huysmans, 1995; Stump, 1995).

### 2.3.3. The Problem of Selective Attrition

A third problem impeding the recognition of neuropsychological impairments in cardiac individuals relates to how selective attrition influences sample characteristics and limits empirical research. Selective attrition is especially problematic for longitudinal studies because the most impaired individuals are lost to follow-up due to both mortality and neuropsychological impairment severity. Regarding the latter, cardiac individuals who drop out of research and treatment studies typically have greater neuropsychological impairments than those who remain active participants (Blumenthal et al., 1995; Vingerhoets et al., 1996). Therefore, the level of chronic impairment, particularly in the post-surgery population, may actually be *underestimated* in the existing body of research because the most impaired members withdrew from treatment and were lost to follow-up.

## 2.4. The Many Faces of Depression in Cardiac Disease

The emotional problems accompanying cardiac diseases have thus far, been linked with the same neurological substrate causing cognitive problems. Stated simply, subcortical and frontal systems are vulnerable to vascular and oxygen disturbances and these areas not only regulate cognitive functions but also, mood, emotions, and temperament (Newman & Sweet, 1992).

There is a substantial body of literature addressing how frequently depressive disorders pre-date the onset of coronary symptoms. Compelling arguments have been made regarding how

depressive symptoms may be prodromal of the more pervasive neuropsychological impairments to follow (Coffey et al., 1990; Nussbaum et al., 1995). However, there is an equally sizeable literature exploring how depression influences lifestyle choices and the natural progression of disease. In general, the research indicates that a depressive state may inhibit the individual's ability to make the adaptive changes needed to comply with behavioral prescriptions (Sykes, 1994). These complex relationships cannot be reduced to simple, linear dichotomies such as depression causes heart disease or heart disease causes depression. It is most likely that the biologic and psychosocial mechanisms linking both conditions are interrelated in synergistic ways. It is beyond the scope of this literature review to explore the epidemiology of depressive illness in the context of heart disease in detail; a comprehensive review can be found in Dew (1998). Certain foundational matters are relevant to the current study, however, such as basic prevalence rates, symptomatic course, and typical treatment responses. Also, it is important to recognize that depression is already known to be powerful predictor of a host of negative medical and behavioral outcomes in cardiovascular diseases.

### 2.4.1. Prevalence of Symptoms

Symptoms of psychological distress accompany many chronic diseases. For cardiovascular disorders, depression is the most common problem (Byrne, 1990; Sykes, 1994). A meta-analysis of relevant studies in this area was conducted by Dew (1998) and showed a 17% prevalence rate of depression in cardiovascular disease. These symptoms occur across the spectrum of cardiovascular diseases, including relatively minor expressions of disease. Depression has been reported in those with hypertension (Blumenthal et al., 1993), elevated lipid

levels (Glueck, Kunkel, & Tieger, 1997; Hayward, 1997), myocardial infarction (Robichaud-Ekstrand, 1992; Sykes, 1994), coronary artery bypass graft (Burker et al., 1995; Byrne, 1990; Pimm & Jude, 1990; Vingerhoets et al., 1995), and heart transplantation (Dew et al., 1994). Gender-specific differences are known, although these mirror what is observed in psychiatry and the population at large. Women exhibit (and report) more symptoms of depression than men (American Psychological Association, 2000; Beck, Steer, & Brown, 1996; Burker et al., 1995; Sykes, 1994; Vingerhoets et al., 1995).

### 2.4.2. Symptom Evolution, Course, and Response to Cardiac Rehabilitation

Depressive symptoms often pre-date the onset of cardiac problems but these seem to be significantly exacerbated by both the stress and physiology of disease. Unfortunately, symptoms of depression in individuals with cardiovascular disease tend to *increase* rather than decrease over time (Barefoot, Helms et al., 1996; Barefoot & Schroll, 1996; Byrne, 1990; Hazavehei, 1994). The chronicity and progression of symptoms are likely to have the most negative effects on medical adherence in this population.

Sykes (1994) provides a multidimensional conceptualization of how depressive symptoms influence adjustment and prognoses both before and after cardiac events.

> With regard to the presence of a pre-existing depressive state, we know that in many cardiac individuals, the prodromal phase of the illness is characterized by a state of vital exhaustion (Appels & Mulder, 1989; Falger & Schouten, 1992), while not exactly the same as depression (Van Diest & Appels, 1991) nonetheless overlaps considerably with it. Symptoms of exhaustion and fatigue prior to an acute MI have been found to be the best predictors of post-infarction depression by Ladwig, Lehmacher, Roth, Breithard, Budde, and Borggrefe (1992). Furthermore, there is evidence from epidemiological work that non-clinical depression is a risk factor

> for heart disease (Baldwin, 1980; Murphy, Monson, Olivier, Sobol & Leighton, 1987). Baldwin's Oxford Record Linkage Study clearly identified non-depressed or schizophrenic individuals, as being at substantially lower relative risk for diseases of the heart and vascular system. In their meta-analytic review of the psychological literature, Booth-Kewley and Friedman (1987) also identified depression as an independent risk factor for coronary heart disease (CHD). Depression is also associated with coronary artery disease (Freedland, Carney, Lustman, Rich & Jaffe,1992) ... [In summary] ... cardiac individuals may, compared to other individuals, have a pre-existing depressive loading, which would then be exacerbated by a highly negative, unpredictable and uncontrollable cardiac event. (p. 58-59)

Participation in a structured cardiac rehabilitation program can have palliative effects although this does *not* alleviate depressive symptoms entirely. Hazavehei (1994) found that regardless of whether or not individuals participated in a structured program, depressive symptoms increased over time. The difference was that the level of depression was greatest in individuals who chose *not* to participate. Similarly, Robichaud-Ekstrand (1992) found that those with severe depression did not experience symptom reduction after participating in a cardiac rehabilitation program that focused primarily on physical exercise rather than broader lifestyle changes. In the exercise-only programs, the greatest symptomatic improvements were realized when the level of depression was moderate rather than severe.

### 2.4.3. Predictive Value of Depression

The risk for depression in cardiovascular diseases is principally relevant to the predictive model proposed in this research. Not only are these symptoms complexly intertwined with neurological anomalies but more importantly, depression predicts a host of negative outcomes in cardiac disease. As compared with non-depressed cardiac individuals, those who are depressed

are more likely to have recurrent cardiac problems and neurological events and increased mortality risks (Barefoot, Helms et al., 1996; Barefoot & Schroll, 1996; Carney, Rich, & Freedland, 1988). Depression has been identified as an effective predictor of post-myocardial infarction exercise behavior. Depression limits the individual's ability to begin and follow-through with an exercise program (Ziegelstein et al., 2000) as well as the tolerance of physical exercise intensity, particularly in women (Marchionni et al., 2000).

## 2.5. Other Psychological Variables

Depression is the psychological variable receiving the most attention in relation to medical adherence. However, there are a host of other psychological variables that influence the development and prognosis of cardiovascular disease as well as adherence. These can be broadly classified into three categories: (a) environmental demands and perceived stress, (b) social support, and (c) hostility.

### 2.5.1. Environmental Demands and Perceived Stress

Specific aspects of lifestyle and environment – namely, how busy the individual is – may negatively impact adherence. Park and colleagues (Park et al., 1999) hypothesized that busyness could influence adherence in two opposing ways. One possibility was that stimulating and diverse environments better equip the individual with the cognitive skills needed to incorporate medically-necessary activities into their lives, particularly in older adults. Another alternative was that chronic overstimulation and overcommittment may result in considerable forgetfulness

for adherence activities (Martin and Park, 2003). Two findings from this area of research are most important to the current study. First, middle-aged individuals had greater problems with adherence due to heightened environmental demands (i.e., busyness). Second, individuals with high levels of routine in their daily lives – even those who were older and had significant cognitive impairments – had better adherence.

### 2.5.2. Social Support

A great deal of adherence research has examined the important role that social support plays in relation to medical adherence (Leslie and Schuster, 1991; Norbeck, 1981). Not surprisingly, adherence outcomes are enhanced by the support of caring loved ones. The more intriguing findings are that love, intimacy, and social connectedness are now known to play critical, moderating roles in the reversal of cardiovascular disease and increased longevity. Components of the Ornish program (i.e., group support, aspects of stress management) are specifically included to help participants improve their social connectedness. Ornish (1998) provides a comprehensive review of this body of literature in his book, *Love and survival: Eight pathways to intimacy and health.*

### 2.5.3. Hostility

While social connectedness provides a buffer in cardiovascular disease, hostility and social isolation can open the floodgates and hasten the progression of cardiovascular disease and related mortality. Historically, the Type A personality – one that is highly driven, competitive,

achievement-oriented, and hostile – has been associated with an increased risk for cardiovascular disease. More recent research has shown that only the hostile facet of the Type A personality may be deleterious to health and longevity (Dembroski & Costa, 1987 and Williams & Barefoot, 1988 as cited in Steinberg & Jorgensen, 1996).

The Cook-Medley Hostility Scale (Cook & Medley, 1954) is the most widely used instrument to quantify hostility in this area of research. The weight of empirical evidence indicates a strong relationship between scores on the Cook-Medley and increased risk for cardiovascular disease (Barefoot, Dahlstrom, & Williams, 1983). Moreover, scores on the Cook-Medley not only predict cardiac morbidity but also, mortality of *all* causes (Barefoot et al., 1983; Barefoot, Dodge, Peterson, Dahlstrom, & Williams, 1989; Barefoot, Larsen, Von de Lieth, & Scholl, 1995).

## 2.6. Significance of Neuropsychological Impairments to Cardiac Rehabilitation

### 2.6.1. The Dr. Dean Ornish Program for Reversing Heart Disease

#### 2.6.1.1. General Description

The Ornish program is an intensive lifestyle intervention that addresses the physical, mental, emotional, and spiritual aspects of human health. It is the only program offering scientific evidence that the severity of cardiovascular disease can be reversed through rigorous lifestyle changes. Participants follow a low-fat, vegetarian diet, perform regular aerobic exercise, practice daily stress management techniques, and participate in twice-weekly group support sessions. Participants are asked to not miss more than two sessions during the initial

twelve-weeks of the program. At the end of 12 weeks, participants transition to Phase II of the program; there are four tracts of the Phase II program, each of which varies in program intensity level. Stratification decisions are based on each participant's individual cardiac risk factors and his/her demonstrated adherence across the four components of the program throughout the first twelve weeks.

Prior to beginning the program, each participant undergoes a physical examination with his/her primary physician that includes blood tests to assess lipid levels. A graded exercise stress test is completed to detect any cardiac complication that would prevent program participation. A variety of questionnaires are completed including tests assessing participants' expectations and beliefs about health behaviors as well as assessments of mood, feelings of hostility, and their perceptions of their quality of life, degree of social support, and stress levels. All of these – blood lipid testing, exercise stress test, and questionnaires – are readministered at the end of the twelve weeks and after one year of program participation.

#### 2.6.1.2. Components of the Ornish Program

Participants attend a hospital-based Ornish program two days weekly for a total of ten hours per week. Each day of program participation includes exercise, stress management, an informative lecture, group support, and a group meal. A professional chef prepares the meal and the nutritionist dines with the group and is available to answer questions about food preparation and the nutritional composition of each meal.

Each program day includes at least one hour of formal education, often involving a lecture with visual aids or interactive components. Often, these lectures are provided during or

immediately after the meal. These lectures address heart-healthy lifestyle issues such as menu planning and shopping tips and relevant information about cardiac disease, stress management, group support, and exercise. Less formal educational activities occur throughout the program, including individual interactions with staff and other participants and a field trip to a local supermarket to learn about reading nutritional labels and the availability of Ornish-friendly food products. For a comprehensive review of the Ornish program, the reader is referred to *Dr. Dean Ornish's program for reversing heart disease* (Ornish, 1996). Presented below is a brief overview of the four major components of the Ornish program.

***Dietary guidelines.*** The Ornish eating plan is a low-fat, vegetarian diet that emphasizes eating plant-based, whole foods in abundance including the daily intake of soybean products. The eating plan has no caloric restrictions but the intake of certain foods is limited. These foods include fat-free dairy products, refined carbohydrates, sugars, and alcohol. Other than limited intake of nonfat dairy products, no animal or fish products are consumed. Specific fruits and vegetables – such as coconut and avocado – are not permitted due to their high fat content. The same is true for all nuts and seeds other than dry-roasted soy nuts. No caffeine is permitted. With strict adherence to these guidelines, the diet provides less than 10 mg of dietary cholesterol per day. Each participant is required to complete daily food diaries. These are submitted to the nutritionist on a weekly basis and percentage scores are computed that represent each participant's dietary adherence for the week.

***Exercise guidelines.*** In the initial days of the program, each participant meets with the exercise physiologist who designs an exercise prescription based on his/her age, pre-program EKG results, and physical capabilities. Participants are encouraged to exercise more days of the week than not, and a minimum of three hours weekly. Each participant is responsible for

completing a daily exercise diary to record the amount and type of exercise completed each day. These diaries are forwarded to the exercise physiologist on a weekly basis who computes percentage scores that reflect weekly exercise adherence. On the two days participants attend the program, nurse managers and exercise physiologists monitor the exercise sessions. Program staff monitor and record weight, pulse, blood pressure levels, and cardiovascular response to exercise during these program-hosted exercise sessions.

***Stress management.*** Each participant is required to engage in one hour of stress management per day. In the Ornish program, a variety of stress management techniques are taught, including a combination of yoga and other techniques such as stretching, breathing, meditation, imagery/healing visualization, and progressive relaxation. On the days participants attend the program, stress management sessions are part of daily programming. On the remaining five days, participants practice stress management at home. The diary entries for stress management include the length and type of stress management practiced each day. A weekly percentage score is computed for each participant's adherence to the stress management component of the program.

***Group support.*** Because social isolation is linked with higher risks of death from heart disease and other causes, the Ornish program emphasizes social connectedness and interpersonal intimacy. Program participants attend a one-hour, group support session on a twice-weekly basis. These sessions are led by a licensed professional and provide an opportunity for participants to talk about their experiences and feelings. This aspect of the program provides peer support for the comprehensive lifestyle changes each participant is making and also, an opportunity to discuss feelings and experiences beyond their program participation. Weekly adherence to group support is quantified in a different way than the other three components of

the Ornish program. Ratings are provided by both the participant and case manager to reflect the participant's active involvement in the group support process.

### 2.6.2. Ornish Program versus Conventional Cardiac Rehabilitation Programs

Conventional cardiac rehabilitation programs primarily focus on changes in diet and exercise that are qualitatively similar to, but less intense than, the Ornish program. For example, while caffeine consumption may be discouraged in conventional programs, it is typically not prohibited as in the Ornish program. Dietary fat consumption in conventional programs is usually twice as much as permitted in the Ornish program. Also, vegetarian diets are not mandatory in most conventional cardiac rehabilitation programs.

Beyond the more rigorous nature of the dietary changes in the Ornish program, the encompassing and comprehensive lifestyle changes required by the program are beyond most conventional cardiac rehabilitation programs. For example, while smoking is discouraged in conventional programs, it is prohibited in the Ornish program. Also, the Ornish program requires the daily practice of stress management techniques and twice-weekly participation in structured group support sessions. While conventional cardiac rehabilitation programs may offer qualitatively similar programming and supports, typically, these are optional rather than mandatory and not at the level of intensity prescribed in the Ornish program.

Each of the four components of the Ornish program is supported by structured clinical education activities and extensive participant record keeping. The level of active learning required by the Ornish program is substantially greater than in most conventional programs. Clearly, meeting the basic requirements of the Ornish program requires a much higher level of

self-discipline, time management, cognitive learning, and strategic planning than conventional cardiac rehabilitation programs.

## 2.7. What Kind of Learning Problems Are Anticipated in the Ornish Program?

### 2.7.1. Knowledge Acquisition

The depth and breadth of new learning required by participants in the Ornish program places an intense burden on more "effortful" aspects of cognitive processing. Consistent with the supply-demand hypothesis advanced in this research, these more effortful aspects of cognitive processing are highly vulnerable in these individuals by virtue of their cardiovascular disease as well as advanced age. These processes – and especially, verbal working memory – are important building blocks of learning due to the role they play in transferring newly acquired information into long-term memory (Park, Lautenschlager, Hedden, Davidson, Smith, & Smith, 2002; Park et al., 1996). For more than a decade, Park and colleagues have been exploring how cognitive impairments interfere with individuals' acquisition of the kind of medical information that supports adherence. While their entire body of research provides an important foundation for this research, some of their recent studies are more specifically relevant to the kind of knowledge acquisition explored in this research.

A study by Brown and Park (2002) examined the learning of familiar and unfamiliar medical information in young and old adults and two findings are especially relevant to the current study. First, older adults consistently learned less than younger adults, regardless of whether they were learning about diseases that were familiar or unfamiliar to them. The second

finding was more novel – both young and old adults demonstrated better learning for an unfamiliar disease rather than a familiar one. The authors offered two alternate explanations of this phenomenon. One explanation was that prior knowledge can hinder learning new information on the same topic. They conceptualized this finding using a "schema-copy plus tag" model (Graesser & Nakamura, 1982 as cited in Brown & Park, 2002). In this model, information that is not wholly consistent with the existing schema is attached with a "tag." Because this newly acquired "tag" decays more quickly than the old learning encapsulated in the schema, when learners are asked to recall this information, they revert to the original schema rather than the newly-acquired tag. An alternate explanation of why learning unfamiliar information was superior to familiar information was offered also. This related to the reduced room for growth when a topic is familiar; "….in other words, the rate of learning may be proportional to the material that is yet to be learned (e.g., Sagiv, 1979)" (Brown & Park, 2002, p. 707).

One of the most recently published studies from these researchers investigated cognitive processing capacity and knowledge in relation to individuals' performances on verbal memory tasks (Hedden, Lautenschlager, & Park, 2005). Structural equation modeling was used to show that working memory had the strongest direct path to free verbal recall. In addition, this research showed that individuals' existing verbal knowledge funds can be used to support memory if appropriate retrieval cues are present – this most often occurs with tasks requiring recognition memory rather than free recall. These findings demonstrate that working memory contributed the most to tasks requiring free recall and the least to tasks requiring recognition memory. In terms of age-related differences, these were greatest for the recall tasks and least for recognition tasks.

These scientific studies are relevant to the kind of information processing deficits clinicians typically observe in intervention programs such as cardiac rehabilitation. Even if practitioners do not recognize the breadth and significance of cardiac-based neuropsychological impairments, clearly, they observe problems that are readily framed in this context. A common complaint among health educators is that individuals have difficulties learning essential facts about their illnesses. The breadth and depth of this problem is illuminated through a large study completed by Plous and colleagues (Plous, Chesne, & McDowell, 1995). Six hundred and six cardiac individuals were given a brief exam covering the content of heart-healthy written materials they had been given in a previous visit. Their poor performance was staggering. Less than one-third (30.5%) understood the information. The average test score for this sizeable sample was lower than chance. Similar findings are described in other studies. Glanz and colleagues (Glanz, Brekke, Hoffman, & Admire, 1990) report that individuals receiving counseling for cholesterol reduction frequently exhibit poor recall of nutritional facts and personal medical information (e.g., one's own lipid levels, behavioral goals, need for dietary changes, etc.). Schuster and colleagues sought to determine whether self-efficacy (i.e., one's confidence in his/her ability to master the task at hand) could explain these problems – it did not (Leslie and Schuster, 1991). The best predictor of knowledge acquisition in their study was the type of educational intervention used. One-on-one contingency contracting seemed to be the best for helping individuals learn relevant nutritional and exercise facts. Also, participation in the structured cardiac rehabilitation program (rather than a home-based program) appeared to promote better knowledge acquisition for males. Regardless of intervention type, female cardiac individuals acquired less factual knowledge than males (Schuster & Waldron, 1991).

### 2.7.2. Combining Facts and Procedures

Another observation made by clinical educators is that individuals have difficulties with an aspect of the educational intervention that combines explicit memory and procedural learning – keeping accurate food diaries. These are a mainstay of nutritional interventions despite the fact that food diaries are often inaccurate, incomplete, and unreliable (Howat et al., 1994).

While problems with diary accuracy have never been framed in a neuropsychological context, Dwyer, Kroll, and Coleman (1987) discuss how diary-keeping is mediated by specific information processing skills. Their article was written as a primer for clinical educators (and primarily, for nurses and nutritionists) who are non-experts in cognitive science. Dwyer and colleagues provide specific examples of how different types of memory are needed for diary keeping and cite the need for empirical investigations into the relationship between diary accuracy and memory function. Eighteen years later, there is no evidence that such research has ever been undertaken. A number of other studies describe diary-keeping problems that can be readily assimilated into an information-processing paradigm. In addition to factual (i.e., explicit memory) problems, it appears as though individuals sometimes struggle with *procedural* aspects of these diaries (Lansky & Brownell, 1982; Streit, et al., 1991). Hypothetically, these kinds of procedural problems could relate to the way executive control functions (such as strategic planning, working memory, and prospective memory) stand to be compromised by cardiac disease.

If self-report diaries are inaccurate and unreliable, why do health educators continue to use them? Regardless of whether food diaries are *reliable,* these are indeed *valid* predictors of

dietary outcomes (Streit et al., 1991). The procedural act of completing the diaries – regardless of factual accuracy – seems to play an important role in mediating adherence. When framed in neuropsychological and information-processing perspectives, it can be argued that hand-written diaries directly impact adherence because this type of self-generated language moderates learning and self-regulation (see Vygotsky, 1962; 1978; see also Luria, 1973). Not yet known is whether diaries have the same self-regulatory function at all levels of cognitive function. This raises several questions. Do diaries enhance learning when individuals have more severe impairments of memory and executive control? Are the expert-novice instructional methods used to help individuals improve diary-keeping effective for more impaired individuals? One may expect diary-keeping to promote adherence in more greatly impaired individuals because these provide an external support for the internal executive control that is lacking. However, the very nature of their executive control impairments may inhibit their ability to benefit from verbal feedback of any type. This means that attempts to convince more impaired individuals to keep diaries may be unfruitful. Moreover, their ability to reap the learning and adherence benefits of their own hand-written diaries may be inferior to those whose executive control functions are better preserved.

### 2.7.3. Summary

Clinical educators have observed problems with memory and learning in individuals with cardiovascular disease. Specific educational and psychosocial supports appear to lessen the impact of these problems in some individuals, but an essential paucity of research specific to cardiac-based learning problems remains. Given the neuropathology of cardiac disease and how

this directly affects memory, learning, and executive control, combining the methods of clinical neuropsychology and information processing theories of learning may help us better understand these problems.

## 2.8. Building and Testing the Predictive Models

### 2.8.1. Hypothesis: Neuropsychological Supply – Information Processing Demand

Specific areas of the brain are more vulnerable than others to disruptions of blood and oxygen transport associated with cardiovascular diseases. This selective vulnerability results in a relatively consistent pattern of neuropsychological impairments. Across the cardiovascular disease spectrum, specific problems with information processing and emotional regulation occur regularly. Hypothetically, the cognitive processes most likely to be disrupted by cardiac disease are the same skills needed for adherence-based learning in the Ornish program. This is the premise of the *neuropsychological supply – information processing demand* predictive model, hereafter referred to as the *NIP*. To be determined is whether measurements of one's neuropsychological supply can be used to predict the mastery of specific kinds of adherence having distinct information processing demands. Examples of the content and adherence expectations of the Ornish program elucidate this further.

The content of the Ornish program is such that various types of verbal memory (i.e., explicit and working memory) must be accessed in order for the individual to benefit from one-on-one counseling, lectures, and informational handouts. Likewise, many levels of visual-spatial processing must be brought to bear. Visual aids commonly accompany verbal instruction (e.g.,

viewing educational films, slides, food pyramids, and food models used to teach portion control, levels of saturated fat, etc.). In fact, some aspects of instruction, such as demonstrations of exercise routines and exercise equipment, are almost exclusively based in visual-motor modeling. If, for example, one wanted to predict how well exercise routines would be mastered, tests of visual-spatial functions may rank higher than tests of verbal memory in the prediction equation for that outcome. The opposite may be true when predicting the learning of heart-healthy facts. This simplified example demonstrates how the relative strength of NIP predictors is expected to vary as a function of the type of adherence being predicted. By the same token, some predictors are expected to rank high in the prediction equations for the majority of the adherence and learning outcomes. Most notably, this is expected to be true for measures of memory and executive control. These neuropsychological processes are expected to be key for most of the lifestyle changes taught in the Ornish program. Memory and executive control functions are expected to be important to adherence-based learning because these functions modulate the ability to strategically plan, initiate, and maintain goal-directed behaviors (Denckla, 1996a).

### 2.8.2. Neuropsychological Methods Predict Everyday Behavior

A substantial and growing literature demonstrates that neuropsychological tests can be used to predict everyday behaviors. Early research in this area focused on predicting employment and vocational success (Heaton, Chelune, & Lehman, 1978; Newman, Heaton, & Lehman, 1978). In recent years, a popular focus has been the prediction of activities of daily living (ADLs), particularly for more elderly individuals who suffer from dementia. Certain

neuropsychological tests appear to be more effective than others for predictions of this type. Providentially, tests measuring the neuropsychological impairments of interest in this study are the best predictors of ADLs. Specifically, tests of visual-spatial, memory, and executive control offer the best predictions of ADLs, particularly for older adults (McCue, Rogers, & Goldstein, 1990; Nadler, Richardson, Malloy, Marran, & Hostetler-Brinson, 1993; Richardson et al., 1995; Snowdon et al., 1989). Additionally, specific tests are already known to predict ADLs that are important for the management of heart disease; i.e., tests of memory, visual-spatial, and executive control effectively predict independence in living, cooking, medication management, and long-term exercise adherence (Bell-McGinty, Podell, Franzen, Baird, & Williams, 2002; Emery et al. 1992; Richardson et al. 1995).

### 2.8.3. Predicting Specific Outcomes of the Cardiac Rehabilitation Intervention

There are no studies in the literature that use neuropsychological tests to predict specific adherence and learning outcomes in cardiac rehabilitation programs. As previously reviewed, Park and colleagues have conducted important work examining knowledge acquisition and the impact of memory capacity and environmental supports across the lifespan. Their related work involving medical adherence research is principally relevant also. Their models of adherence are multidimensional but cognitive aging models are strongly represented therein. Emphasis is placed on those cognitive processes that decline with age such as speed of information processing, inhibition, and most notably, working memory. These studies are relevant to the current study for several reasons. The majority of participants in cardiac rehabilitation programs are middle-aged and older and expected to have these decrements of cognitive functioning.

Moreover, these older participants as well as younger cohorts may have accentuated risks for problems in these aspects of cognitive processing due to how the cardiovascular disease process impacts the areas of the brain mediating these functions.

While most of the adherence studies conducted by Park and colleagues have addressed unidimensional aspects of adherence (i.e., medication adherence; glucose testing in nondiabetic populations), their work has explored the role of vulnerable cognition in relation to adherence. Their research has shown that factors other than impaired cognition play equally (and sometimes more) important roles in mediating adherence, such as the nature of environmental demands facing the individual and other contextual and psychosocial supports. Across studies, the most direct paths between cognitive impairments and poor adherence have been found in "old-old" subjects who had the greatest cognitive deficits. While some research conducted by Park and colleagues has explored these problems in populations at risk for neuropsychological compromise (e.g, hypertension) a majority of their populations have a low risk for cognitive compromise aside from the risk associated with advanced age. Also, while their work in this area has made very important contributions, most of their studies have not included comprehensive neuropsychological evaluations designed to capture the more subtle processing deficits characteristic of specific disease processes (see Brown and Park, 2002 for an overview of studies). It is likely that populations with greater risks for neuropsychological compromise *and* advanced age – as is found in the cardiac rehabilitation population – will show the more potent influences of cognitive factors on adherence, particularly when evaluated with a comprehensive assessment battery including measures that are specifically sensitive to the neuropsychological problems commonly associated with cardiovascular disease.

Studies relating to exercise adherence and outcomes in other types of intervention programs are also relevant to the current research. Several correlational studies have examined the relationship between physical fitness and neuropsychological status. Numerous studies have documented a positive correlation between physical fitness and neuropsychological test performance and also, various aspects of cognition and emotion can be improved through exercise. While the latter is intriguing (and important for future studies), it is not principally relevant to the current study. Of greater importance is the relationship between neuropsychological test performance and long-term exercise adherence. Two studies have explored this relationship using the same or comparable methods included in the NIP model.

Shay and Roth (1992) compared the neuropsychological profiles of extremely fit and less fit elderly males. Their study included a broad-based neuropsychological assessment battery although between-group differences emerged in only one area. Extremely fit males were superior to less fit counterparts only on tests of visual-spatial processes (Hooper Visual Organization Test and the Rey-Osterreith Complex Figure Drawing). These findings were interpreted in a cognitive reserve context; i.e., visual-spatial processes that typically decline as a part of normal aging are better preserved in those who are extremely fit. After examining the relationships between age, fitness levels, visual-spatial processing, and executive control, Libon and colleagues (Libon et al., 1994) arrived at a cognitive reserve interpretation also.

While there are no relevant predictive studies in cardiac rehabilitation that can be cited as a precedent for the current study, alcohol treatment programs have conducted predictive intervention studies (i.e., identifying individuals who may have difficulty mastering the skills most critical to long-term adherence at the outset of treatment). The qualitative similarities between the neuropsychological impairments attributed to alcohol abuse and cardiovascular

disease merit mention. As is true in cardiovascular disease, impairments of executive control, memory, and visual-spatial processing are common among chronic alcohol abusers and researchers in this area have linked these problems to poor outcomes.

A previous dissertation study used scores from the California Verbal Learning Test (CVLT) to predict how well detoxified alcoholics could retain information from a lecture on alcoholism. Zimbelman (1990 as cited in Delis, Kaplan, Kramer, & Ober, 2000, pp.126-127) found that two CVLT indices, Total Recall for Trials 1-5 and Semantic Clustering, were able to predict the retention of lecture material. A similar study conducted by Smith and McCrady (1991) verified the relationship between the Trials 1-5 index and in-program learning. Using pre- and post-program tests of factual knowledge, Smith and McCrady computed difference scores to quantify a factual *learning quotient*. These learning quotients were positively correlated with the CVLT Trials 1-5 index, verifying the relationship between CVLT test performance and the amount of factual information learned and remembered in the program.

A number of studies have examined the relationship between neuropsychological measures and treatment adherence and as expected, positive correlations are usually found. Fals-Stewart (1993) found that the individuals who were least compliant in forensic intervention programs were also those having the greatest neuropsychological impairments. Selective attrition has been problematic in alcohol intervention studies also; those with more severe impairments are less likely to continue on with alcohol aftercare programs (Smith & McCrady, 1991). Several studies address the specific role of executive control functions in relation to adherence. Miller (1991) provides an overview of this literature and concludes that impairment of executive functioning (e.g., difficulties with metacognition, problem solving, complex

memory) seems to be associated with the worst treatment adherence in most alcohol intervention studies.

### 2.8.4. Components of the Predictive Models

#### 2.8.4.1. Practical Considerations

***Outpatient sample.*** Participation in this study is expected to be less burdensome than most neuropsychological studies conducted with cardiac populations because subjects are not recruited during acute stages of illness or recovery. Subjects are recruited on an outpatient (not inpatient) basis, and appointments are scheduled at their convenience.

***Time.*** Results of a national professional practice survey indicate the average time needed to complete a standard neuropsychological evaluation is 6.5 hours with a standard deviation of 2.3 hours (Putnam & Deluca, 1990). Because this is an inordinate time demand for research study volunteers, Newman (1995) and Stump (1995) offer specific recommendations regarding appropriate time parameters. For cardiac studies involving acutely ill patients who are hospitalized and awaiting surgery, they recommend that each test session be limited to approximately one hour. It is important to recognize, however, that the longitudinal design of most of those studies involve frequent re-evaluations. Individuals undergo testing before cardiopulmonary surgery, have follow-up sessions within one week and one month after surgery, and have intermittent re-evaluations in subsequent years. This means that over the course of six-weeks, most individuals enrolled in cardiac-based neuropsychological investigations are spending three to four hours completing standardized tests, and they are acutely ill during some of this testing. The NIP model involved approximately three hours of testing over a twelve-week

period. This is less than *half* the time required for most studies of this type and the average, outpatient neuropsychological evaluation.

***Number of tests.*** The average number of tests included in most outpatient neuropsychological evaluations can be as many as twenty-five or more. For studies conducted with acutely ill, cardiac individuals, Stump (1995) recommends that the research protocol be limited to ten tests (p. 1352). A total of eleven measures are included in this research protocol and more than half require five minutes or less to complete.

***Access to data routinely collected in the Ornish program.*** The ability to streamline this research protocol was made possible by the fact that comprehensive data are already being collected through the Ornish program. These include tests assessing relevant psychological factors such as depression, quality of life, feelings of hostility, and perceptions of stress and social support. With the permission of each host Ornish program (and in accord with HIPAA statutes), these data were included as potential predictors alongside the neuropsychological data. Only those aspects of the neuropsychological protocol being administered by the investigator are reviewed below.

#### 2.8.4.2. Neuropsychological Components

Specific tests of baseline intelligence/cognitive reserve, visual-spatial processing, various types of memory, and executive control are included as possible predictors for the model developed for each outcome. These measures, and the rationale for their inclusion, are briefly described below. The review of the technical and psychometric properties of these test measures is reserved for the Instrumentation section of Chapter 3.

***Baseline intelligence/cognitive reserve.*** The importance of including an empirical estimate of baseline intelligence in cardiac research studies is demonstrated through the work of McDaid and colleagues (McDaid et al., 1994). Using one of the most popular measures of this type, the National Adult Reading Test (NART), they found that the NART was a powerful predictor of the other neuropsychological tests in their research protocol, both before and after CABG surgery. Before surgery, the NART was the best predictor of performances on verbal, visual-spatial, and memory measures. Together with age, the NART was also a strong predictor of psychomotor speed both before and after surgery. As indicated through this and other studies, the NART appears to capture some meaningful aspect of educationally-driven cognitive reserve. This is important because this type of cognitive reserve may temper the expression and severity of neuropsychological impairments observed in cardiac individuals. Because such cognitive reserve factors could moderate some (but not all) learning and adherence outcomes, a representative measure must be included in the pool of potential predictors.

***Visual-spatial processing and memory.*** Visual-spatial problems have been associated with essentially all forms of cardiac disease and are a part of normal aging. Older individuals with cardiovascular disease, and especially those who have had CABG surgery, may be exceptionally vulnerable to visual-spatial problems because embolic lesions tend to gravitate to the right parietal-occipital lobe (Stump, 1995). The Hooper Visual Organization Test (VOT) is an ideal measure to assess visual-spatial problems in the cardiac population because the VOT is sensitive to bilateral and diffuse brain damage and specifically, damage to the right parietal lobe (Boyd, 1981 and Wang, 1977 in Western Psychological Services, 1983, p.1; Fitz, Conrad, Hom, & Sarf, 1992 as in Nadler, Grace, White, Butters, & Malloy, 1996, p. 224). Also, the VOT is a powerful predictor of various ADLs in geriatric populations (Richardson, et al., 1995) and

discriminates between seniors who are physically fit and those who are not (Shay & Roth, 1992). In addition to the Hooper VOT, the Rey-Osterreith Complex Figure Drawing (ROCFD) is also included in the research protocol. The ROCFD provides an additional measure of visual-spatial integrity as well as an assessment of immediate and delayed memory (Rey, 1964). The ROCFD is known to be sensitive to the level of exercise fitness in the elderly (Shay & Roth, 1992).

***Memory and executive control.*** Memory and executive control are expected to be potent predictors of a majority of outcomes for two reasons. First, the areas of the brain most vulnerable to cardiac-based damage regulate these aspects of neuropsychological function. Second, because memory and executive functions are potent predictors of ADLs, these are expected to predict the subcomponent learning and adherence skills supporting these ADLs.

One of the most frequently used measures of executive control, the Wisconsin Card Sort Test (WCST), is included in the predictive model. The WCST has predictive power for specific aspects of memory and learning, thus making its inclusion in the model especially valuable. The WCST appears to be sensitive to working memory (see Ragland et al., 1997 for references of seminal studies) and also, can be used to predict various types of explicit, source, and contextual memory (Spencer & Raz, 1994). However, the WCST has *not* been used with any regularity in cardiac research. No cardiac studies have attempted to predict specific learning outcomes using the WCST. In large part, this may relate to the focus and design of previous studies. For a majority of past studies, data collection began when individuals were acutely ill and hospitalized. Administering a more challenging measure such as the WCST may have been contraindicated by the physical debilitation of those individuals and time constraints imposed by the inpatient hospital environment.

Tests of memory have been well represented in essentially all past neuropsychological studies involving cardiac populations. A study by O'Brien and colleagues (O'Brien et al., 1992) merits special attention – this influenced the selection of one of the principal memory measures used in this research. O'Brien et al. (1992) compared individuals' performances on 19 different memory tests to determine which offered the best characterization of post-CABG memory problems. Many tests were effective; as compared with normal controls, CABG individuals performed worse on 10 of the 19 memory tests. The California Verbal Learning Test (CVLT) provided the best detection of memory problems in CABG individuals. The reason for its superiority was postulated to be the heightened sensitivity of the CVLT to executive control functions.

> The CVLT, in particular, places significant demand on attentional and organizational resources, since it requires the subject to memorize an unorganized list of shopping items that greatly exceeds the immediate memory span. [Other memory measures] may require less organizational capacity, since the subject can benefit from the inherently organized nature of the to-be-learned information (i.e., prose passages and simple geometric figures, respectively). (p. 1123)

Subsequent research has confirmed that the CVLT is sensitive to important aspects of executive control and in the newest version of the CVLT, the CVLT II, it is now possible to compute a specific CVLT-II index score for subcortical-frontal memory dysfunction (Delis et al., 2000). Also, a number of studies have shown correlations between the CVLT and the primary executive control measure included in this study, the WCST (Nathaniel-James, Brown, & Ron, 1996 as cited in Delis et al., 2000, pp. 113-114; Vanderploeg, Schinka, & Retzlaff, 1994). Therefore, including both the CVLT and the WCST in the predictive model is important, not

only because both measure important aspects of executive control but also, because both are predictive of a variety of memory and behavioral outcomes of interest.

An additionally desirable feature of the CVLT is the availability of normative data for various clinical groups. Many of these normative studies have focused on how memory disturbances vary between cortical and subcortical neurological disorders and the similarities/differences found in the CVLT performances of elderly depressives (Delis et al., 2000; Delis, Massman, & Salmon, 1991; Massman, Delis, Butters, & Dupont, 1992; Massman, Delis, Butters, & Levin, 1990; Otto, Bruder, Fava, Delis, Quitkin, & Rosenbaum, 1994). Subgroups of individuals with depression show significant deficits on the CVLT and as stated by the test author in the administration manual of the CVLT-II, "This general pattern, indicative of retrieval deficits as the major contributor to poor performance, is also seen in [a variety of] subcortical [disorders]… (Delis et al., 2000, p. 118)." Given that cardiac-based leukoaraiosis may negatively impact the frontal and subcortical systems of the brain, normative data from these past CVLT studies may be valuable for descriptive and discriminative function data analyses. In addition to the CVLT-II, a variety of other memory measures are included in the research protocol. These are briefly reviewed here and the technical information for these measures is found in the Instrumentation section of Chapter 3.

Two additional measures of verbal memory are included in the research protocol, the Four-Word Short Term Memory Test (FWSTM) (Ryan and Butters, 1980 a, b; Morrow and Ryan, 2002) and the Logical Memory subtest from the Wechsler Memory Scale – Third Edition (WMS-III) (Wechsler, 1997 b; The Psychological Corporation, 1997b). The Logical Memory test has been widely used in cardiac studies (O'Brien et al., 1992). It assesses the individual's ability to remember contextual verbal information presented aloud, much like participants

encounter in the lecture portions of the intervention program. The Four Word Short-Term Memory Test (FWSTM) is an adaptation of the Brown-Peterson technique, a method commonly used in clinical neuropsychology to assess working memory and executive control. The Brown-Peterson technique uses a distractor task to prevent the individual from rehearsing material he/she is holding in memory for short-term retention testing. This technique has been found to be especially sensitive to divided attention, working memory, and one's susceptibility to proactive interference. Research studies with Brown-Peterson techniques have found that these are specifically sensitive to the neuropsychological impairments associated with cardio- and cerebro-vascular diseases (Boone et al., 1992; Boone, 1999; C.M. Ryan, personal communication, April 12, 2002). Also, working memory is one of the more "effortful" aspects of learning that declines with age and has been comprehensively investigated in relation to medication adherence and the learning of novel medical information by Park and colleagues (Brown and Park, 2003 provide an overview of relevant studies.)

Two measures of prospective memory are included in the research protocol. These tests assess how well the individual "remembers to remember;" in other words, the ability to carry out planned actions at an appropriate time. In the context of disease management, this type of memory is required for activities such as taking medications as prescribed, getting the weekly allotment of exercise, and daily diary keeping. Prospective memory involves the retrieval on an intention to act that has been stored in long-term memory. An important aspect of this type of memory is that one is typically engaged in another type of action or ongoing cognitive activity at the point when prospective memory is required (Park, Hertzog, Kidder, Morrell, & Mayhorn, 1997). Two types of prospective memory – event-based and time-based – are recognized. There is some evidence that event-based prospective memory requires less mental effort and self-

initiated processing than time-based prospective memory. To drive this point home, Park and colleagues use an illustrative example of medication taking – for example, if one's heart begins to race (i.e., event) this reminds the individual to take the heart medication, and requires less self-initiated memory than remembering to take the medication at a specific time when physical symptoms are absent.

Finally, also included in the research protocol was the Digit Symbol (DS) subtest of the Wechsler Adult Intelligence Scale - Third Revision (The Psychological Corporation, 1997a,b). The DS is sensitive to a variety of memory and learning factors and often, is one of the first tests to show impairment in nascent conditions such as dementia (Storandt & Hill, 1989 as cited in Lezak, 1995, p. 378). The DS has been used extensively in previous neuropsychological investigations in cardiac diseases, including a recent study involving participants in a traditional cardiac rehabilitation program. Moser et al. (1999) found that the DS was significantly more impaired in participants having both hypertension and low ejection fraction (i.e., inefficiency of heart function). Not only is this test commonly impaired in cardiac populations but also, improvements have been found on the DS when cardiovascular disease is brought under better control. Improved DS scores have been found in previously sedentary elderly persons after four months of regular aerobic exercise (Dustman et al., 1984 in Lezak, p. 378) as well as in medically-treated hypertensives (Miller, 1984 as cited in Lezak, p. 378). Therefore, including the DS in the pool of predictors is valuable for the current study as well as for future analyses that will examine longitudinal neuropsychological changes in program participants over time.

#### 2.8.4.3. Noncognitive and Psychological Components

The majority of psychological variables included in the predictive model are drawn from data already being collected through the routine practices of the Ornish program. These include measures of depression, hostility, perceived stress, preferred support, and general quality of life. The single exception was that the investigator also included an assessment of each participant's perception of his/her own level of busyness.

***Busyness and environmental demands.*** Research conducted by Park and colleagues has revealed that specific aspects of lifestyle and environment had a greater impact on a specific type of adherence (i.e., medication) than cognition. Namely, the amount of routine in one's daily life can be a protective buffer and enhance adherence even in older individuals with greater cognitive impairments. By contrast, individuals who are very busy and have somewhat chaotic schedules may be at greatest risk for poor compliance (Park et al., 1999). To assess these problems, they developed and standardized the Martin and Park Environmental Demand (MPED) Questionnaire (Martin and Park, 2003) which has been used in adults ranging from ages 35 through 84. Due to the substantial time commitment required for success in the Ornish program and the fact that many participants remain employed on a full-time basis, busyness is an especially important variable to include in the pool of potential predictors.

#### 2.8.4.4. Subject Attributes

Individual differences such as age, gender, education, race, marital status, and disease type and severity could influence some aspects of adherence in the Ornish program. It is unlikely that all of these variables will be key predictors in each regression model although disease variables, along with age, gender, and education, have the potential to be important predictors in some models. The moderating influences of disease variables have been carefully explored through this literature review, although the possible impact of age, gender, and education need further explanation.

Across cardiac disease types, one of the strongest predictors of neuropsychological impairment is age (Mills, 1995; Schmidt et al., 1995; Tuman et al., 1992). The predictive potency of age could be influenced by many converging factors such as the cumulative effects of chronic cardiac problems, other co-morbid diseases, and the effects of normal aging.

Education is an effective predictor of a host of behavioral, emotional, cognitive, and medical outcomes in the population at large. The work of Garrison and colleagues (Garrison, Gold, Wilson, & Kannel, 1993) demonstrates the integral relationship between education and cardiovascular outcomes. As part of the renowned Framingham Heart Study, an epidemiological investigation of the natural history of heart disease, longitudinal studies are being conducted on a large sample (>2500 subjects) to determine coronary risk factors. Thus far, their findings indicate that with the exception of cholesterol levels, the least educated subjects have the highest coronary risks in all behavioral areas and these risks result in more devastating medical outcomes. Like age, education could rank high in some predictive models.

A number of studies point to female gender as an independent risk factor for higher rates of attrition, poor attendance, poor adherence, impaired learning, dementia, and other adverse medical outcomes in cardiovascular disease. Also, some of the neuropsychological tests included in the model are differentially affected by gender. Therefore, because differential gender risks exist for both predictor and outcome variables, gender may be an important moderating variable in some of the predictive models.

### 2.8.5. Selection of Outcome Variables

All but two of the outcomes predicted in this study are extracted from participant program records. The exceptions are the brief rating scales completed by program staff and participants' performances on the factual knowledge questionnaire; these will be reviewed below. Three kinds of outcomes are predicted: (1) Behavioral Prescription Adherence, (2) Cognitive Learning: Documented and Perceived, and (3) Phase II Stratification.

#### 2.8.5.1. Behavioral Prescription Adherence

This outcome relates to how well the participant complied with the four major components of the Ornish program – dietary, exercise, group support, and stress management. Primarily, this is assessed through the structured diaries kept by the participant for each of these four components of the program. The exception is that adherence to the Group Support component of the program is assessed through a combination of these self-report diaries and staff ratings.

#### 2.8.5.2. Cognitive Learning: Documented and Perceived

The Documented Learning outcomes include comparisons of pre- and post-program scores on the Ornish Knowledge Test and the accuracy of participants' food diaries. The amount of specific factual knowledge each participant learns in the Ornish program is of specific interest for two reasons. First, well-documented in the literature is that individuals' knowledge about their disease and its management is an important predictor of long-term medical adherence and health outcomes (Kirscht & Rosenstock, 1977; Lin, Ko, Tsai, & Chen, 1995; Winkleby et al., 1994). Second, this critical mediator of adherence and health is expected to be quite vulnerable in program participants due to the impairments of verbal learning that have been consistently documented in cardiac populations (Glanz et al., 1990; Leslie & Schuster, 1991; O'Brien et al., 1992; Plous et al., 1995; Schuster, Wright, & Tomich, 1995; Schuster &Waldron, 1991). Therefore, if participants cannot successfully learn key factual information about his/her disease and the Ornish program, the prognoses for adherence and medical well-being are poor. In addition to assessing the acquisition of program-specific factual information, another way knowledge and learning are assessed is through quantitative analyses of participants' food diaries. While a majority of food diary research has focused on completion rates and reliability rather than factual accuracy, examining the factual accuracy of diaries is important in the current study. This "daily homework" assignment provides another valuable index of factual learning. Various information processing skills – mostly self-directed – must be brought to bear in order for food diaries to be accurate. One must remember what and how much was eaten, the nutritional profile of each food, and how to record these facts in the diary. Some nutrition facts

are already committed to memory but others must be found in the reference materials they have been given. Self-directed recall, visual search, and graphic recording skills all influence the accuracy of the food diary. Therefore, a variety of neuropsychological processes are expected to moderate the factual accuracy of food diaries, including explicit and working memory skills and aspects of executive control such as procedural learning.

The Perceived Learning outcomes examine how well staff can identify participant learning problems without having access to neuropsychological test results. Program staff spend approximately 120 hours with each Ornish participant during the first twelve weeks. This affords them ample opportunity to formulate impressions regarding these individuals' learning and adherence abilities. Even with this extensive one-on-one contact, the insidious nature of cardiac-based neuropsychological impairments makes it difficult for staff to recognize these problems and their significance to learning and adherence (Barclay, et al., 1988; Garcia, et al., 1984). To validate this phenomenon, two staff members are asked to complete brief questionnaires at the end of the twelve-week program that assess their perception of participants' in-program learning. This aspect of the research is expected to underscore the value of completing neuropsychological evaluations at the time of program enrollment so in the future, staff can receive information about participants' learning abilities that are useful for day-to-day clinical care.

### 2.8.6. Phase II Stratification

At the end of the first twelve weeks of the program, staff must determine the level of program intensity that best suits each participant's needs in order to be successful with the

Ornish lifestyle. These decisions are based on specified minimum adherence guidelines along with specific criteria regarding coronary risk factors. If it is possible to accurately identify individuals who are most likely to need more intensive (and costly) programming at the end of Phase I, it may be possible to provide additional instructional supports to further promote adherence and coronary risk reductions during the first twelve weeks.

## 2.9. Summary of Literature Review

Neuropsychological impairments occur with regularity in all types of cardiovascular disease. The most serious impairments are found among those having more advanced disease, other health problems, and/or complicated cardiac surgeries. An exceptionally high risk for neuropsychological impairment is associated with cardiopulmonary bypass surgery, particularly for older individuals, those with already compromised neurological functioning, and specific co-morbidities (i.e., hypertension and low ejection fraction; diabetes). While neuropsychological impairments are the rule rather than exception in cardiovascular disease, their significance to medical adherence is not yet known. In large part, this relates to the phenomenology of the problem.

Individuals having the greatest neuropsychological impairments are more likely to withdraw from treatments and research studies that would bring these problems to the fore. Hypothetically, this selective attrition has limited patient care, scientific investigations of the problem, and the understanding of gender-specific risks. Those who *do* participate in treatment typically have less severe impairments that go unnoticed by health care staff. While mild and rarely recognized, these problems may directly affect individuals' ability to benefit from

treatments that would help them sustain long-term medical adherence due to how the brain has been compromised by cardiovascular disease and its treatments.

Certain areas of the brain are more vulnerable than others to the blood and oxygen transport problems that accompany cardiovascular disease(s) and corrective cardiac surgeries. This selective vulnerability leads to neuropsychological impairments that diminish learning capacity and emotional resilience. Hypothetically, the neuropsychological resources most likely to be disrupted by cardiovascular disease are also those most essential for adherence. Therefore, it may be possible to predict adherence based on the availability of these neuropsychological resources. This tenet is the foundation of the proposed predictive model, the *neuropsychological supply – information processing demand* model, or *NIP*. The purpose of the NIP is to provide a pragmatic way to conceptualize, quantify, and scientifically investigate the impact of neuropsychological impairments on adherence-based learning. This research is expected to show that because information-processing factors have been largely unaccounted for in past research, this has directly limited the predictive potency of other models. The most significant contribution expected from this research is its pragmatic utility and foundation for future research. If neuropsychological factors – and cognitive learning in particular – prove to be missing pieces of the adherence puzzle, this has far reaching significance. The direct contribution to structured intervention programs is clear. The NIP can be administered when individuals begin the program to determine who may need more than routine levels of support and instruction. Because the development of the NIP was guided by information processing theories of learning, it will be possible to develop and validate specific instructional methods grounded in these theories. Therefore, scientific validation of the NIP provides both a pragmatic

tool for identifying individuals at greatest risk for poor adherence and a theoretical foundation that will guide improvements in the educational methods used in cardiac intervention programs.

# 3. METHOD

## 3.1. Participants

Subjects were recruited from three hospitals offering the *Dr. Dean Ornish Program for Reversing Heart Disease* in Western Pennsylvania including Allegheny General, Mon-Valley, and Westmoreland Regional Hospitals. Letters of support from the Associate Director of Research for Dr. Dean Ornish and the Preventive Medicine Research Institute and hospital program directors are found in Appendix A. Approval letters from the governing Institutional Review Boards (IRB) are found in Appendix B.

Recruitment for this study was incorporated into the routine intake process at the three hospital sites. Potential subjects included all new participants enrolling in the program at those sites from May of 2003 through January of 2004. These included both men and women, most of whom were middle-aged or older. The only exclusionary criteria were those who were non-English speaking and/or had previously participated in a site-sponsored Ornish program. There were no exclusionary criteria based on disease type, age, gender, education, race, or ethnic characteristics. The intake case manager informed each participant of the opportunity to volunteer for the research study. Each participant was asked if he/she was willing to be contacted by the investigator to learn more about the research study. The case manager asked interested participants to review and sign the consent form permitting investigator-initiated

contact; a sample of this consent form, the "Authorization for the Sharing of Health Information Related to Possible Participation in a Research Study" is found in Appendix C. Originals of this consent form were retained by the host program and filed in patient medical records and copies were forwarded to the investigator. Participants who granted this consent were contacted by the investigator by phone and a brief description of the research was provided. For those who chose to participate, the investigator arranged to meet him/her on a date, time, and location of his/her choosing. Most often, a private meeting room was reserved at the host hospital or a community public library. At the outset of that meeting, prospective subjects reviewed the consent form with the investigator; it was the sole responsibility of the investigator to obtain the informed consent of each subject. The nature of informed consent included agreeing to complete the procedures and permitting the investigator to examine specific portions of his/her Ornish program records. A copy of the "Consent to Act as a Subject in a Research Study" is found in Appendix C.

Subjects incurred no costs for participating in the research and there was no billing of insurance providers. Subjects were paid twenty dollars for their participation. The only risk was any momentary frustration or anxiety he/she experienced when attempting to answer test questions. Participants were permitted to withdraw from the study at any time. Neither the participant nor program staff working with him/her was given specific information about his/her test performances. All participant information was handled in a confidential manner and in accord with HIPAA statutes.

## 3.2. Procedures

### 3.2.1. General Overview

Enrollment in this research study required each subject to participate in a ninety-minute test session prior to beginning the program (Week 0) and at the end of twelve weeks (Week 12). The only post-test results addressed in this study are Week 12 scores on the Ornish Knowledge Test. Pre- and post-program comparisons of neuropsychological test performances are reserved for a subsequent study. Appointments were scheduled at the time and location most convenient for each participant (i.e., hospital site, community public library, etc.). The protocol included investigator-administered tests of memory and thinking and two participant-completed questionnaires. One questionnaire assessed participants' specific knowledge of the Ornish program and more general knowledge about heart-healthy living. The busyness and environmental demands of each participant's daily life was assessed through the other.

At the end of Week 12, program staff were asked to rate their perception of how well each participant was able to learn various components of the program. This aspect of the research protocol was not disclosed to participants or program staff. Keeping subjects and staff blind to this aspect of the research protocol was important. This avoided priming the staff to look for participant learning problems and ensured that participants' in-program behaviors were not influenced by knowing that program staff would be rating their learning. At the end of twelve weeks, the case manager and nutritionist who worked closely with program participants

during the first twelve weeks completed these brief rating scales. The nutritionist rated participants' learning of the dietary component of the program. Because the case manager accompanies the participant to all other aspects of the program, this individual was in the best position to rate participants learning in the stress management, exercise, and group support components of the program.

In addition to the research protocol, participant information gathered through routine program practices was included in the data collection process. This included demographic and medical information along with weekly adherence percentage scores of each of the four components of the Ornish program. In addition, data from some of the questionnaires routinely administered to participants at Week 0 by the Ornish program were included in statistical analyses. These included data from tests assessing depression, hostility, self-perceived stress, social support, and quality of life. All but two of the outcomes predicted in this study were extracted from participant program records. The exceptions were the brief rating scales completed by program staff and participants' performances on a test assessing factual information presented in the Ornish program (Ornish Knowledge Test).

### 3.2.2. Data Collection: Individual Testing

The following test battery was administered in fixed order to all participants.

1. Instructions for time- and event-based prospective memory tasks*
2. National Adult Reading Test - Revised **
3. (a) Wechsler Logical Memory Test (Immediate Recall)
4. (a) Rey-Osterrieth Complex Figure Drawing (Copy)
4. (b) Rey-Osterrieth Complex Figure Drawing (Immediate Recall)
5. (a) California Verbal Learning Test-II (Immediate Recall)
3. (b) Wechsler Logical Memory Test (Delayed Recall/Recognition)
4. (c) Rey-Osterrieth Complex Figure Drawing (Delayed Recall/Recognition)
6. Digit Symbol (with incidental and free recall)
7. Hooper Visual Organization Test
5. (b) California Verbal Learning Test-II (Delayed Recall/Recognition)
8. Wisconsin Card Sorting Test
9. Ornish Knowledge Test
10. Martin and Park Environmental Demands Questionnaire
11. Four Word Short-Term Memory Test

***** The prospective memory tasks are ongoing tasks completed by the subject throughout the test session. The time-based task requires the subject to notify the examiner of every ten-minute increment that has passed. The event-based task requires the subject to keep a running tally (i.e., making a cross on a sheet of paper) each time a new test is administered, by listening for a specific cue from the examiner (i.e., "Let's do the next test.").

****** In addition to estimating intelligence, possible reading problems are identified through the National Adult Reading Test – Revised. A cut-off Standard Score of < 80 was established, below which reading problems were expected to invalidate independently completed questionnaires thus necessitating modified administration (i.e., read all questionnaires aloud to participant).

## 3.3. Instrumentation

The majority of tests used in this research have been rigorously standardized. Test selection was guided by three factors. First, only neuropsychological measures having predictive strength for relevant activities of daily living were included in the model (Emery et al., 1992; McCue et al., 1990; Newman et al., 1978; Richardson et al., 1995; Shay & Roth, 1992; Snowdon et al., 1989). Second, some instruments were selected because they have been used successfully in previous cardiac studies and/or because they assess specific types of information-processing important to this research (Comunian, 1989; Delis et al., 2000; Denckla, 1996a,b; Dew, 1998; Godbout & Doyon, 1995; Hazavehei, 1994; Hickey, Owen, & Froman, 1992; Karnath et al., 1991; Libon et al., 1994; McDaid et al., 1994; Moser et al., 1999; Shallice, 1982; Shallice et al., 1994; Spencer & Raz, 1994; Stump, 1995; Vanderploeg et al., 1994). Third, preference was given to those tests having specificity for the frontal/subcortical systems of the brain and valuable normative data (Delis et al., 2000; Delis, Massman et al., 1991; Heaton, 1981; Massman et al., 1990; Massman et al., 1992).

A description of each instrument follows. These are categorically grouped and alphabetically organized within each category. The description of each instrument includes information regarding psychometric properties and the conceptual rationale for its inclusion in the study. Copies of the non-copyright-protected test instruments are found in Appendix D.

### 3.3.1. Neuropsychological Indices

#### 3.3.1.1. Prospective Memory Tasks

Prospective memory refers to how well one can "remember to remember." This is the memory needed to carry out planned actions at a future time. Prospective memory involves the retrieval on an *intention* to act that has been stored in long-term memory. An important aspect of this type of memory is that one is typically engaged in another type of action or ongoing cognitive activity at the point when prospective memory is required (Park et al., 1997). In the context of cardiac disease management, this type of memory is very important for activities such as taking medications as prescribed or remembering about the planned trip to the gym or grocery.

Two types of prospective memory – event-based and time-based – are recognized. Event-based prospective memory requires less mental effort and self-initiated processing than time-based prospective memory; for example, if one feels thirsty and this reminds the individual that he/she hasn't begun to drink the water quota for the day, this requires less self-initiated memory than remembering to begin drinking the water without being prompted by thirst. The two prospective memory tasks used in this study were developed by Bisiacchi and colleagues (1996, p. 309). The time-based task requires the subject to inform the examiner each time ten minutes have passed in the test session. Subjects are asked to remove his or her watch at the beginning of the test session and these are placed out of view. A clock is placed behind the subject in the testing room, and he/she may turn around to check this at any time throughout the session. The event-based task requires subjects to write a cross on a list kept by his/her side after each test is completed. The cue for making this cross is the phrase "Let's do the next test."

These instructions are given at the beginning of the test session and never mentioned again. Two scores were computed: percent of correct time estimates and percent of correct event cueing. The research with time- and event-based prospective memory reveals age differences (Bisiacchi, 1996; Park, et al., 1997) as well as interactions with how busy the individual is with competing activities (Park & Kidder, 1996). Copies of the prospective memory test reporting forms are found in Appendix D.

#### 3.3.1.2. National Adult Reading Test - Revised

With rare exception, vocabulary skills tend to "hold" even in the face of neurological compromise. As such, vocabulary skills are correlated with overall cognitive/intellectual functioning earlier in life. The NART-R provides an empirical estimate of baseline intelligence as well as literacy level. It is especially sensitive to verbal intelligence (Blair & Spreen, 1989; see also Crawford, Stewart, Parker, Besson, & Cochrane, 1989; Gladsjo et al., 1999; Lezak, 1995, pp. 103-106; 551-553; Nelson & Willison, 1991; Schwartz & Saffran, 1987). The NART-R requires the subject to read 61 low-frequency words that have irregular pronunciations. (See Appendix D for a copy of the test administration form.) Average test completion time is approximately five minutes. Psychometric studies have consistently demonstrated high split-half reliability and excellent validity for the NART-R. A coefficient of .83 has been reported when the NART-R has been used to predict Wechsler Verbal IQ scores (Blair & Spreen, 1989). Also, a previous study with cardiac surgery patients demonstrated that the NART-R accounts for a significant proportion of variance in other neuropsychological measures (McDaid et al., 1994).

#### 3.3.1.3. Rey-Osterrieth Complex Figure Drawing

The ROCFD measures various aspects of perceptual organization, visual memory, and executive control functions (Osterrieth, 1944 and Rey, 1941 as found in Lezak, 1995; Rey, 1964). Subjects are first asked to copy the complex figure on a blank sheet of letter-sized paper. They are not forewarned that after copying the figure, they will be asked to draw this same figure from memory two more times. An immediate recall trial is conducted three minutes after the copy is completed. The delayed recall trial occurs one-half hour later. There do not appear to be any primary age effects on ROCFD performance, although there are gender effects. Lezak (1995, p. 576) provides an overview of this literature which shows that men tend to score higher than women on the ROCFD. Also, the ROCFD has been correlated with level of exercise fitness in the elderly (Shay & Roth, 1992). More than fifty years of research has been conducted with the ROCFD including many studies examining qualitative and quantitative differences based on disease types and areas of brain dysfunction. These normative data are available in Mitrushina, Boone, and D'Elia (1998).

#### 3.3.1.4. Wechsler Logical Memory Test

The Wechsler Logical Memory test is a component of the Wechsler Memory Scale – Third Edition (WMS-III) (Wechsler, 1997 b; see also The Psychological Corporation, 1997b). The Logical Memory tests are auditory verbal recall tests. Two brief stories, each approximately five lines in length, are read aloud by the examiner. Immediately after hearing each story, the

subject is asked to retell as much of the story as he/she can. The second story is read aloud a second time and the subject's recall is reassessed. After approximately thirty minutes, the subject is asked to again recite all that can be remembered from each story without hearing either again. Test development, scoring, and normative data for the WMS-III include national standardization and specific disease groups of interest to this study. Split-half internal consistency methods were used to estimate the reliability coefficients for 13 age bands. For the Immediate Recall subtest, reliability coefficients span .81 through .91 with an average coefficient of .88. For the Delayed Recall subtest, reliability coefficients range from .71 to .87 with an average coefficient of .79. Test-retest reliability is .77. Interscorer reliability has been reported as greater than .90.

#### 3.3.1.5. California Verbal Learning Test – Second Edition

The CVLT-II is a verbal memory test designed to measure aspects of information processing that are key to learning (Delis et al., 2000). These include working memory, recognition, and various types of recall (e.g., immediate recall, short- and long-delay, and free and cued recall, etc.). Learning strategy, the effects of interference, and general learning curve characteristics are all assessed with the CVLT-II. On average, the CVLT-II requires seventeen minutes to administer (Delis et al., 2000, p. 7). Originally published in 1987, the California Verbal Learning Test (CVLT) was one of the first clinical instruments incorporating principles from cognitive science to quantify multiple components of learning and memory. The newest edition, the CVLT-II, is the first major revision of the instrument and was chosen for this

research due to the many psychometric improvements that have been made. The test authors provide the best and most succinct description of the CVLT-II in the test administration manual.

> The CVLT-II measures both recall and recognition of two lists of words over a number of immediate- and delayed-memory trials. In the first five trials, the examinee is asked to recall words from List A immediately after each presentation of the list. List A includes 16 words, four words from each of four semantic categories. Words from the same category are never presented consecutively, which affords an assessment of semantic clustering, the most effective strategy for learning unstructured verbal information. An interference list (List B) of 16 words is then presented for one trial. The interference trial is followed by short-delay free-recall and short-delay cued-recall trials of List A. A 20-minute delay occurs next, during which nonverbal testing takes place. After the nonverbal testing, long-delay free-recall, long-delay cued-recall, and yes/no recognition trials of List A are administered. The CVLT-II ends with a forced-choice recognition trial administered approximately 10 minutes after the yes/no recognition trial. The CVLT-II quantifies numerous parameters of learning and memory, including:
>
> - levels of total recall and recognition on all trials
> - different learning strategies (e.g., semantic clustering, serial clustering, subjective clustering)
> - primacy-recency effects in recall
> - rate of new learning per trial
> - consistency of item recall across trials
> - degeree of vulnerability to proactive and retroactive interference
> - retention of information over short and longer delays
> - enhancement of recall performance by category cueing and recognition testing
> - breakdown of recognition performance (discriminability and response bias) derived from signal-detection theory
> - indices reflecting the relative integrity of encoding, storage, and retrieval processes
> - analysis of intrusion-error types in recall (e.g., semantically related, semantically unrelated, or across-list intrusions)
> - repetition errors in recall
> - analysis of false-positive types in recognition testing

- new measures of test-taking effort in memory assessment (Delis et al., 2000, pp. 2-3)

A number of pragmatic improvements have been realized with the CVLT-II. This newer version is easier to administer and better tolerated by examinees. The words included on the lists are easier to understand and state-of-the-art scoring software is available that automatically computes multiple raw and standardized scores. Improvements in the standardization sample and normative database developed for the CVLT-II are significant also. The standardization sample essentially mirrors the population census statistics for 1999. A total of 1087 adults were included and their ages ranged from 16 through 89 and the sample matched census statistics for race, gender, and geographical stratification. Also included in the standardization process were studies using the neuropsychiatric populations likely to be administered the CVLT-II. These are substantial improvements over the first edition of the CVLT. The norms for the first edition were derived from a non-clinical reference group consisting of only 273 adults who had an average education level of fourteen years and lived in one of four cities in the United States. Split-half reliability estimates for the total CVLT-II sample are very high ($r$ = .94) and within age groups, these generally exceed .90. Split-half reliabilities are even higher when the CVLT-II is administered to individuals with various types of brain dysfunction ($r$ = .96). Finally, the construct validity of the CVLT-II and its sensitivity to the kinds of memory problems seen in cardiac populations has been substantiated through the voluminous research that has been conducted with the first edition of the test (Nussbaum, Allender, & Copeland as cited in Delis et al., 2000; O'Brien et al., 1992).

#### 3.3.1.6. Four Word Short-Term Memory Test

The Four Word Short-Term Memory Test (FWSTM) is an adaptation of the Brown-Peterson technique, an assessment method commonly used in clinical neuropsychology to evaluate working memory and central executive capacity (Ryan & Butters, 1980 a, b). The Brown-Peterson technique uses a distractor task to prevent the individual from rehearsing material he/she is holding in memory for short-term retention testing. In the FWSTM, the words are read aloud to the subject followed by a different three-digit number for each trial. The individual is asked to count backwards from the number, subtracting by threes for varying time intervals (i.e., 5, 15, or 30 seconds). After this serial subtraction exercise, he/she is asked to recall the four words. A copy of the FWSTM test form is found in Appendix D.

Morrow and Ryan (2002) have compiled normative data for the FWSTM using a large group of subjects ($N = 350$) spanning ages 18 through 65. The normative data are stratified by age and education and include percentile rankings. Both age and education are correlated with performance on the FWSTM.

#### 3.3.1.7. Wechsler Digit Symbol Subtest

The Digit Symbol (DS) subtest of the Wechsler Adult Intelligence Scale – Third Edition is a speeded symbol substitution task (The Psychological Corporation, 1997a). The DS is administered using the three-subtest adaptation first developed by Kaplan and colleagues (Kaplan, Fein, Morris, & Delis, 1991 as cited in Lezak, 1995, P. 463). This includes the Coding

subtest and two Incidental Learning subtests, the Paired and Free Recall subtests. The administration time for all of the three DS subtests requires approximately three minutes.

The Coding subtest is comprised of a series of numbers, each of which is paired with a hieroglyphic-like symbol. Using a key, the subject works his/her way through several rows of numbers transcribing as many of the symbols as possible within two minutes (The Psychological Corporation, 1997a). The average test-retest stability coefficient is high (.84), although this is even higher for the age cohort used in this study. Standardization studies reveal that the highest DS stability coefficients are found in age groups 55 to 74 and 75 to 89 (.86 and .87, respectively). Also, the DS has mild to moderate correlations with several of the other tests used as neuropsychological predictors in the NIP model (CVLT, ROCFD, and WCST) (The Psychological Corporation, 1997b).

The two Incidental Learning subtests are administered immediately after the Coding subtest. These subtests are included to help identify reasons for low scores on the Coding subtest. The first of the two Incidental Learning subtests is the Pairing Subtest. This measures subjects' ability to recall the hieroglyphic-like symbols from memory. Two rows of numbers are presented, this time without the number-symbol key. The Pairing subtest measures examinees' ability to attend to, process, and remember the symbols. The second Incidental Learning subtest is the Free Recall subtest which requires the subject of recall as many symbols as possible, independent of the numbers. This subtest provides a measure of the degradation of symbolic memory (The Psychological Corporation, 1997a, pp. 15-16).

The DS has been long regarded as a sensitive indicator of brain damage and a number of studies support its inclusion in the current research. In addition to providing a measure of information processing speed, the DS assesses motor coordination, short-term memory, visual

perception, and clerical speed and accuracy. The DS is known to be sensitive to a number of cognitive factors having to do with memory and learning. It is often one of the first tests to evidence impairment in insidious conditions such as dementia (Storandt & Hill, 1989 as cited in Lezak, 1995, p. 378). Most importantly, the DS has been used extensively in various studies involving cardiac rehabilitation (CR) participants. Individuals participating in CR who have both hypertension and low ejection fraction earn significantly lower scores than those CR participants who do not have these problems (Moser et al., 1999). Not only have impairments been identified on the DS in these groups but also, improvements on the DS are seen when cardiovascular disease is brought under better control. Improved DS scores have been found in medically-treated hypertensives (Miller, 1984 as cited in Lezak, p. 378) and previously sedentary elderly persons after four months of regular aerobic exercise (Dustman et al., 1984 as cited in Lezak, p. 378). Therefore, including this subtest is warranted not only for the current study but also, for follow-up studies that will examine longitudinal changes in patients who continue to participate in cardiac rehabilitation.

#### 3.3.1.8. Wisconsin Card Sorting Test

The WCST was developed to assess abstract reasoning ability and the ability to shift cognitive strategies in response to changing environmental contingencies. It requires the subject to correctly sort a deck of cards to one of four key cards relying only on simple verbal feedback (i.e., right or wrong) from the examiner. The examiner systematically changes the sorting rule without telling the subject, requiring the subject to inhibit previous problem solving strategies and generate new ones (Heaton, 1981; Heaton et al., 1993; Ragland et al., 1997).

Historically, the WCST has been categorized as a test of executive control that is specifically sensitive to brain injuries directly or indirectly involving the frontal lobe (Lezak, 1995, p. 623). More recent studies have found that the WCST is sensitive to other regions of the brain (i.e., hippocampi and temporal lobe) and other kinds of information processing. At least three cognitive factors can be identified in the WCST, each of which are differentially sensitive to frontal and temporal lobe damage (Dehaene & Changeux, 1991; see Ragland et al., 1997 for citations on Eslinger & Grattan, 1993, Owen, Roberts, Polkey, Sahakian, & Robbins, and Sullivan et al., 1993). These findings, as well as the work of Ragland and colleagues (Ragland et al., 1997), suggest that the WCST may measure important aspects of both explicit and working memory in addition to executive control.

Regarding psychometric development, the WCST has undergone extensive standardization and normative studies with both normal and clinical populations. Normative data are available for young through old (ages 6.5 through 89) with educational corrections available for adults. The reliability and validity of the WCST are well-established. Inter- and intra-scorer reliabilities are high, ranging from .88 to .96. The literature addressing the construct validity of the WCST is voluminous. In relation to the current study, several findings are noteworthy. Factor analytic studies have revealed that the number of categories achieved and error scores load on both complex intelligence and planning-organization and -flexibility factors (Daigneault, Braun et al., 1988 as cited in Lezak, 1995, p. 623). The demonstrated sensitivity of the WCST to working and explicit forms of memory, as well as the cerebral substrate mediating these processes (Ragland et al., 1997), make it an optimal fit for the current study. There are established precedents for using the WCST to predict cognitive and behavioral outcomes (Foster, Hillbrand, & Silverstein, 1993; Spencer & Raz, 1994). The study by Spencer and Raz is

especially relevant; they found that the number of perseverative errors observed on the WCST was inversely related to performances on both factual and contextual memory tests.

#### 3.3.1.9. Hooper Visual Organization Test

The VOT measures one's perception and organization of visual stimuli. Average test completion times range from five to ten minutes. The VOT consists of 30 line drawings depicting simple objects that have been cut into pieces and disparately arranged. The subject is asked to identify what each object would be if the pieces were put back together correctly. The test is based on the assumption that deficits observed on the VOT reflect underlying difficulties in neurological functioning (Hooper, 1958; Western Psychological Services, 1983).

The VOT is commonly included in neuropsychological test batteries. It is sensitive to neurological damage of both the right- and left-hemispheres and has specificity for focal right parietal lesions (Fitz, Conrad, Hom, & Sarf, 1992 as in Nadler, Grace et al., 1996, p. 224; Wang, 1977 as in Western Psychological Services, 1983, p. 1). Including the VOT in this study is important for two reasons. Based on past research, there is evidence that microemboli occurring during CABG surgery frequently lodge in the right parietal-occipital cortex (Stump, 1995). Second, the VOT is sensitive to a number of relevant activities of daily living that involve self-care such as dependence in cooking ($r$ = .70), medication administration ($r$ = .73), and money management ($r$ = .73) (Richardson et al., 1995). Therefore, subjects' VOT performances may be strong predictors of many aspects of behavioral adherence.

Regarding technical information, the total raw score on the VOT is obtained by adding the number of correct responses. Partial credit is given for certain responses that occur with

moderate frequency in a non-impaired population. More than fifty years of research has been devoted to the VOT including the development of various norms that are expected to be valuable for this research (see Mitrushina et al., 1998). The reliability of the VOT has been examined in both clinical and nonclinical populations. In the original standardization studies, Hooper found a split-half correlation coefficient of .82. In a second study (Hooper, 1958), a split-half correlation of .78 was found. A third reliability study (Gerson, 1974 as in Western Psychological Services, 1983, p. 12) revealed a split-half reliability of .80. The VOT has appropriate test-retest reliability (.86) also (Lezak, 1995, p. 410).

### 3.3.2. Other Indices

#### 3.3.2.1. Ornish Knowledge Test

The Ornish Knowledge Test is a 20-item (54-point), short-answer test that was developed by the investigator for this research project. The content of this test covers factual information presented in the first twelve weeks of the Ornish program. The Ornish Knowledge Test is administered at Week 0 and Week 12 to obtain a difference score that reflects each participant's explicit factual learning in the program. Copies of the pre- and post-test versions (Weeks 0 and 12, respectively) of the Ornish Knowledge Test are found in Appendix D; the only difference between these two versions is the introductory paragraph. Otherwise, the actual content of the test is the same at Weeks 0 and 12.

#### 3.3.2.2. Martin and Park Environmental Demands Questionnaire

The Martin and Park Environmental Demands Questionnaire (MPED) is used to measure environmental demands and busyness in adults (Martin & Park, 2003). The normative studies with the MPED have included a broad age range – ages 35 through 84. The MPED is a 13-item scale using likert ratings. Psychometric analyses of the MPED revealed two dimensions: (1) Busyness – the density of obligations and (2) Routine – the predictability of events independent of density. A copy of the MPED is included in Appendix D for review. The items in each scale are essentially, independent of one another ($r$ = .13). The internal validity of the scale using Cronbach's alpha was $\alpha$ = .88 for the Busyness scale and $\alpha$ = .74 for the Routine scale although the latter may be an underestimate because this scale only has four items. External validity was established by correlating factor scores with external criterion variables.

### 3.3.3. Ornish Program Indices

All Ornish participants complete a battery of questionnaires prior to beginning the program. Five of these indices are included in the statistical analyses dealing with model testing and development.

#### 3.3.3.1. Center for Epidemiologic Studies Depression Scale

The Center for Epidemiologic Studies Depression Scale, CES-D, is a 20-item test frequently used as a screening for depression in clinical research studies (Radloff, 1977). Each item uses a four-point likert rating scale (0-3), where zero indicates the absence of symptoms and 3 indicates a severe level of symptoms. Items 4, 8, 12, and 16 are reverse scored. The CES-D total score ranges from 0 through 60, with higher scores indicating higher levels of depression. Using a cutoff score of 16, the CES-D has a sensitivity of 73% and specificity of 84% for detecting depression in hospitalized patients, the medically ill, and the elderly. Scores between 17 and 22 indicate "possible" symptoms of depression and scores exceeding 23 indicate "probable" symptoms of depression (Radloff & Teri, 1986). The internal consistency values for the CES-D, as measured by Cronbach's alpha (α), range from .84 to .90 for the general population and patient population samples. Test-retest reliability coefficients were .32 for the 3-month retest to .54 for the 6-month retest. In terms of construct validity, the CES-D has high correlations with other self-report depression screening measures such as the Beck Depression Inventory and the Hamilton Depression Rating Scale (Radloff, 1977).

#### 3.3.3.2. Modified Cook-Medley Hostility Scale

Hostility is a significant psychological risk factor for cardiovascular morbidity and mortality. The most widely used measurement of hostility in health research studies, the 50-item Cook-Medley Hostility Scale (Cook & Medley, 1954), is part of the Minnesota Multiphasic

Personality Inventory. The Cook-Medley has excellent stability over time with correlations of .85, .84, and .74 for one-, four-, and ten-year test-retest intervals (Barefoot et al., 1983, 1989; Shekelle, Gale, Ostfeld, & Oglesby, 1983). Barefoot and colleagues analyzed the items on the Cook-Medley and found five factors (cynicism, hostile attribution, aggressive responding, hostile affect, and social avoidance). Three of these factors – cynicism, hostile affect, and aggressive responding – were found to be the most sensitive to health outcomes. The modified version of the Cook-Medley Hostility Scale is comprised of the 27 test items that make up these factors. The single summary score of these 27 items offers better prediction of the health outcomes than the full 50-item version (Barefoot et al., 1989; Helmers et al., 1993).

#### 3.3.3.3. SF-12 Health Survey

The SF-12 is a survey of general health that is widely used in medical outcome studies. The SF-12 is an abbreviated version of the SF-36, a multidimensional assessment instrument designed to assess the quality of physical and mental aspects of life. Both the SF-12 and the SF-36 assess eight health constructs: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health (Ware, 1993). While most of the research conducted with the SF-36 has been conducted with medically-compromised individuals, norms have been compiled using a sample of 2,000 healthy individuals. Test-retest reliability and content, construct, and criterion-related validity for both the SF-12 and SF-36 are all within acceptable parameters. The majority of reliability coefficients exceed .70 for most samples and across studies, the coefficients for the Physical Functioning factor is the highest

(Stewart, 1989; Ware, 1993). When predicting the SF-36 from the SF-12, coefficients exceeded .90 (Ware, 1992).

#### 3.3.3.4. Perceived Stress Scale

The Perceived Stress Scale (PSS-10) assesses participants' perceptions of their stress levels over the preceding month (Cohen, Kamarck, & Mermelstein, 1983). This 10-item test uses a 5-point likert rating scale. Responses range from 0 for "never" to 4 for "very often." The initial PSS consisted of 14 items. The four items that loaded least on factor analyses were eliminated, resulting in improved internal reliability (Cohen & Williamson, 1988). Test-retest reliability of the PSS-10 ranges from .55 to .85, and internal consistency is .78. Construct validity coefficients range from .21 to .47.

#### 3.3.3.5. Preferred Support Profile

The Preferred Support Profile is a 36-item test that assesses specific types of social support. Four-point likert scales are used to rate both the importance and the availability of each aspect of support represented on the test. With both clinical and nonclinical groups, the Preferred Support Profile has internal consistency (.92 to .96), as well as appropriate reliability and validity (Pettengill, 1992, 1996 as cited in Greenwood, 1999).

## 3.4. Research Questions

Do neuropsychological variables significantly improve the prediction of cardiac rehabilitation outcomes beyond what is accounted for by program knowledge, demographic, disease, and psychological variables?

How much variance in each outcome is accounted for by a combination of top-ranking neuropsychological and non-neuropsychological predictors?

Which of the non-neuropsychological variables are important to include in the predictive models?

Which of the neuropsychological tests commonly used to identify cognitive impairments in cardiovascular disease are the best predictors of specific learning and adherence outcomes?

## 3.5. Data Analyses

Nine program outcomes, each classified into one of three categories, were analyzed. These categories included: (1) Behavioral Prescription Adherence, (2) Cognitive Learning: Documented and Perceived, and (3) Phase II Stratification. For each outcome, the correlation matrices computed for demographic, disease, psychological, and neuropsychological variables were reviewed. For all but one outcome, variables were selected as potential predictors for each

regression model if they correlated with the outcome at $p < .10$. The exception was the Phase II Stratification outcome where a more stringent cut-off of $p < .05$ was used. Each variable in the pool of qualifying predictors belonged to one of four predictor categories – program-specific knowledge, demographic/disease, psychological, and neuropsychological. The program-specific knowledge category had one variable, the pre-test (Week 0) of the Ornish Knowledge Test. For the remaining categories, the "best" three predictors were selected. The "best" predictors were defined as those having the highest correlations with outcomes and lowest correlations with the other qualifying variables from the same predictor category. The maximum number of predictors that could qualify for inclusion in the regression model was ten – the Ornish Knowledge Test and three variables from each of the three predictor categories. However, correlations at $p < .10$ were not always found between the outcomes and the predictors in each category. The actual number of predictors included in the initial (unrefined) regression models ranged from 4 to 8.

Data were analyzed through two studies. The aims of the first study were model justification and building. Hierarchical linear regression was the primary statistical analysis used in the first study to demonstrate the substantive contribution that neuropsychological predictors make to each regression model when other predictors (i.e., demographic, disease, psychological, and pre-existing program knowledge) are statistically controlled for. Logistic regression (with the hierarchical entry of variables) was used to predict Phase II Stratification which reflects overall success in the program and the level of program intensity that will follow for each participant. The aim of the second study was model refinement. This second study provides the final regression model for each of the nine outcomes.

# 4. RESULTS

## 4.1. Sample

Using the recruitment procedures outlined in Chapter 3, sixty-one prospective participants in the *Dr. Dean Ornish Program for Reversing Heart Disease* gave consent for the investigator to contact them to provide information about volunteering for this study. Of these 61 individuals who agreed to this contact, 53 volunteered to participate in the study. The majority of these participants ($n$ = 31) were enrolled in the program at Westmoreland Regional Hospital (WRH). Sixteen subjects were from Allegheny General Hospital (AGH) and six were from Mon-Valley Hospital (MVH). Of these 53 subjects, 7 did not complete the 12-week program thus reducing the sample size to 46 subjects.

Descriptive data for sample demography are found in Table 1. Gender representation was a 2:3 ratio (male: female) and the majority of subjects were Caucasian ($n$ = 43). Two individuals were African-American and one was Icelandic. (Race was not included in the potential predictor pool due to the small number of non-Caucasian subjects in the sample and because exploratory data analyses showed that race did not correlate strongly with any of the program outcomes.) All subjects spoke fluent English. A majority of subjects were married or cohabitating. Of the 18 single subjects, 7 had never married, 1 was separated, 5 were divorced, and 5 were widowed. Most subjects were between the ages of 47 and 78 (78%) and the average

age was 60. Ten subjects were younger than 47 and only 2 of these were younger than 40. The youngest subject was 31.25 and the oldest, 78.42. All but two subjects completed a minimum of high school and a majority completed some college or higher (76%). Almost half of the subjects were working full-time while participating in the program ($n$ = 22; 47.8%). Six subjects were working part-time and 16 were retired. Only two subjects had never worked outside of the home; these were women who had primarily functioned as homemakers throughout adult life. A broad range of income was represented in the sample. Consistent with general population statistics, the income of male subjects exceeded female subjects ($F$ (1, 41) = 7.26, $p$ = .01). There were no other gender- or race-specific differences in age or education. Also, no significant demographic differences were found between the three hospital sites with one exception – subjects from AGH had more education than those from MVH ($M$ = 15.50, $SD$ = 1.79 vs. $M$ = 12.33, $SD$ = 2.58, respectively; $F$ (2, 43) = 4.57, $p$ = .012).

**Table 1 Descriptive statistics for demographic variables**

| *Variable* | *n* | *Variable* | *n* |
|---|---|---|---|
| Gender | | Marital Status Category | |
| Male | 18 | Married | 28 |
| Female | 28 | Unmarried | 18 |
| Race[a] | | Employment Category | |
| Caucasian | 43 | Working | 28 |
| Other | 3 | Not Working | 18 |

| *Variable* | *Mean* | *Range* | *SD* |
|---|---|---|---|
| Age | 59.95 | 31.25 – 78.42 | 10.72 |
| Education (Years) | 14.48 | 9 – 20 | 2.30 |
| Income Category[b] | 35,001 – 50,000 | < 7,500 – > 100,000 | —[b] |

*Note.* $N = 46$

[a] Race was not included in regression models due to the minimal representation of non-Caucasian subjects. Two subjects were African-American and one was Icelandic.

[b]Income is quantified by the Ornish program using ranked intervals; there were 8 possible income intervals and the mean for the sample was 5.05 with a standard deviation of 1.99. The approximate value of this standard deviation is $30,000.

The medical and coronary risk factors represented in the sample are found in Tables 2 and 3. To qualify for enrollment in the program, all prospective participants had more than one coronary risk factor. Table 2 provides an overview of the general cardiac diseases and risk factors in the sample and further disease specification is detailed in Table 3. In addition to the major medical complications cited in Table 3, a number of other health problems were represented in the sample ranging from benign (e.g., arthritis, sensory deficits) to more serious problems such as neurological trauma and disease. Six subjects had one or more neurological complications and of these, two subjects had documented closed head injuries from motor vehicle accidents that had occurred more than twenty years earlier. A majority of subjects were right handed ($n$ = 41); five subjects were left-handed.

**Table 2 Descriptive statistics for demographic variables**

| *Medical and Cardiac Risks (Total #)* | *Mean* | *Range* | *SD* |
|---|---|---|---|
| Medical Problems | 7.46 | 2 – 19 | 3.03 |
| Cardiac Risks | 3.50 | 1 – 6 | 1.3 |
| Cardiac Events | .43 | 0 – 2 | .69 |
| Cardiac Surgery | .43 | 0 – 2 | .54 |
| Physiologic/Heritable Risks | 2.83 | 1 – 5 | .93 |
| Psychiatric Diagnoses | .28 | 0 – 2 | .54 |

*Note.* $N$ = 46

**Table 3 Frequency of specific diseases**

| *Cardiac Events* | *n* | *Physiologic/Heritable* | *n* |
|---|---|---|---|
| Myocardial Infarction | 10 | Congestive Heart Failure[a] | 1 |
| Cardiac Arrest[a] | 0 | Coronary Artery Disease | 28 |
| | | Hyperlipidemia | 35 |
| | | Diabetes | 20 |
| *Cardiac Surgeries* | *n* | Family History of Cardiac Disease | 13 |
| CABG[b] | 9 | Hypertension | 36 |
| PTCA/Stents[c] | 11 | Obesity | 18 |
| | | Other Vascular Problems[a] | 6 |

*Note.* $N = 46$

[a] These variables were not included in the regression models due to minimal representation.

[b] Coronary Artery Bypass Graft

[c] Pericutaneous Transluminal Coronary Angioplasty

The number of medical problems suffered by subjects differed between hospital sites. Subjects from AGH had significantly fewer medical problems ($M = 5.88$, $SD = 1.99$) than either MVH or WRH ($F$ (2, 43) = 8.39, $p = .001$). Subjects from MVH had the most medical problems ($M = 11$, $SD = 4.20$). More importantly, AGH subjects had fewer coronary risk factors and cardiac surgeries than MVH ($F$ (2, 43) = 4.92, $p = .012$; $F$ (2, 43) = 6.02, $p = .005$, respectively). Additionally, stronger representation of diabetes was found in MVH subjects than either WRH or

AGH ($F$ (2, 43) = 5.26, $p$ = .009). Due to these interaction effects, as well as those identified between hospital site and education, the inclusion of hospital site as a potential predictor was important. To do so, the three hospital sites were collapsed into a dichotomous variable. Because the MVH hospital site had the greatest risk, subjects from this hospital were classified into one category, and those from AGH and WRH, into the other.

A majority of subjects in the sample were taking antihypertensive medications ($n$ = 35), some type of lipid-lowering drug ($n$ = 30), and vitamin supplements ($n$ = 29). Of the 20 subjects diagnosed with Diabetes Mellitus, 17 were taking medications to manage this problem. Of the 11 subjects with documented psychiatric diagnoses, only 6 were being pharmacologically treated for these problems. All of these individuals were taking antidepressants and two were taking additional psychotropics. In terms of recreational substance usage, self-reported alcohol intake was low. A majority described themselves as nondrinkers (72%) and the average alcohol consumption for the sample was less than one-half drink per day ($M$ = 0.322, $SD$ = 0.66). Only three individuals reported having more than one drink per day (i.e., 2 - 3 drinks per day). Cigarette smoking was not a critical concern; active smokers are not permitted to enroll in the Ornish program. Of those who were previous smokers, most had quit several years earlier. One subject had quit smoking just two months prior to beginning the program.

### 4.2. Psychological and Neuropsychological Test Results

Table 4 provides the descriptive statistics for the psychological tests administered to participants before they began the Ornish program. All but one of these tests, the Martin and

Park Environmental Demands (MPED) scale, are routinely administered as part of the Ornish program. On average, participants' scores on self-report measures of depression, hostility, and perceived stress were not significantly different from the general population. The mean score on the depression screening measure (CESD: $M = 12.72$, $SD = 10.5$) was modestly higher than the norm for healthy adults who are free from significant depressive features ($M = 10.5$, $SD = 7.8$) but as a group, the score was not indicative of clear-cut depressive symptoms (i.e., mild to moderate symptoms of depression (16-22); cut-off score for clinical depression = 23; Radloff, 1977). As a group, feelings of hostility were not pathologically high. The mean score for the sample was significantly below than the lower end of the cut-off used by the Ornish program to indicate significant problems with hostility (i.e., females > 16.5; males >18). The mean score on the Perceived Stress Scale ($M = 14.48$, $SD = 8.06$) approached, but did not reach, a level indicative of significant stress (>18). Similarly, scores on the SF-36, the Preferred Support Scale, and the Martin and Park Environmental Demands (MPED) scale were largely consistent with norms for the general population and other appropriate normative data. The SF-36 was most noteworthy for modestly low scores on the Vitality and General Health subscales; not unexpected for a sample of individuals with cardiac problems. The Preferred Support Scale indicated that as a group, these individuals had low levels of social support. Finally, scores on the MPED Busyness and Routine subtests were consistent with what has been reported by the test authors in a study examining the relationship between adherence and environmental demands in individuals diagnosed with rheumatoid arthritis.

**Table 4 Descriptive statistics for psychological predictors (N = 46)**

| *Psychological Measures* | *Mean* | *Range* | *SD* |
|---|---|---|---|
| *Depression, Hostility, and Stress* | | | |
| CESD Total Score | 12.72 | 0 – 34 | 10.05 |
| Cook-Medley Hostility Scale | 6.83 | 0 – 9 | 4.25 |
| Perceived Stress Scale | 14.48 | 2 – 32 | 8.06 |
| *SF – 36* | | | |
| Physical Functioning | 73.33 | 5 – 100 | 25.89 |
| Role-Physical | 67.78 | 0 – 100 | 42.18 |
| Bodily Pain | 68.42 | 12 – 100 | 23.32 |
| General Health | 59.00 | 0 – 97 | 23.20 |
| Vitality | 49.49 | 0 – 100 | 25.30 |
| Social Functioning | 64.58 | 0 – 100 | 29.59 |
| Role-Emotional | 71.84 | 0 – 100 | 34.85 |
| Mental Health | 70.76 | 28 – 100 | 18.50 |
| *Social Support* | | | |
| Preferred Support Profile | 52.22 | 1.20 – 100 | 41.47 |
| *Environmental Demands*[a] | | | |
| MPED Busyness[a] | 20.56 | 9 – 34 | 5.70 |
| MPED Routine[a] | 12.80 | 6 – 19 | 3.61 |

[a] The Martin and Park Environmental Demands (MPED) test was the only psychological measure specifically administered as part of this research study. All other psychological measures are routinely administered by the Ornish program.

The descriptive statistics for the neuropsychological tests administered in the pre-test session are found in Table 5. The majority of neuropsychological data used in the predictive models were raw scores. The exceptions were some percentage scores (e.g., prospective memory tests; Logical Memory % Retention) and one standard score representing the estimated level of verbal intelligence (i.e., NART-R). While raw scores were preferred for statistical analyses, these are not the best for characterizing the sample. Norm-referenced scores are preferred for this purpose because these provide relevant statistical corrections for age and education to determine whether each participant's score is within or outside of average and expected performance levels. Descriptive statistics were used to summarize norm-referenced scores for the purpose of sample characterization. These data are not presented here but rather, briefly summarized. As a group, subjects were free from significant neuropsychological impairment. Higher than average levels of verbal intelligence were estimated through the NART-R; scores spanned the Average through Superior ranges. No participant earned a NART-R Standard Score < 80 and therefore, all self-report questionnaires were independently completed by all participants. Scores on a majority of the verbal and visual-spatial memory measures were within the average range. There were two noteworthy exceptions where the mean scores for the group were one-half standard deviation below average. These included the five-second recall subtest of the Four Word Short-Term Memory Test and the recognition memory subtest of the Rey figure (RCFT Recognition).

**Table 5 Descriptive statistics for neuropsychological predictors (N = 46)**

| *Neuropsychological Measures* | *Mean* | *Range* | *SD* |
|---|---|---|---|
| *Verbal Memory* | | | |
| Logical Memory I[a] | 39.59 | 19 – 59 | 9.66 |
| Logical Memory – 1st Recall[a] | 24.15 | 11 – 39 | 6.37 |
| Logical Memory – Learning Slope[a] | 4.61 | 0 – 10 | 2.28 |
| Logical Memory II[a] | 23.30 | 3 – 38 | 7.64 |
| Logical Memory % Retention[a] | 80.65 | 16 – 112 | 16.75 |
| Logical Memory Recognition[a] | 25.87 | 20 – 30 | 2.52 |
| CVLT Trials 1-5 Total[b] | 52.70 | 23 – 74 | 10.96 |
| CVLT List B[b] | 5.87 | 2 – 11 | 2.09 |
| CVLT Short Delay Free Recall[b] | 10.96 | 3 – 16 | 3.15 |
| CVLT Short Delay Cued Recall[b] | 12.09 | 4 – 16 | 2.89 |
| CVLT Long Delay Free Recall [b] | 11.72 | 0 – 16 | 3.64 |
| CVLT Long Delay Cued Recall[b] | 12.33 | 4 – 16 | 3.05 |
| CVLT Total Learning Slope (Trials 1-5) [b] | 1.46 | .40 – 2.30 | .50 |
| CVLT Yes/No Recognition[b] | 14.98 | 11 – 16 | 1.27 |
| CVLT Forced Choice Recognition (% Recall)[b] | 99.87 | 94 – 100 | .88 |
| *Working Memory* | | | |
| Four-Word Short-Term Memory – 5" | 13.44 | 5 – 18 | 3.15 |
| Four-Word Short-Term Memory – 15" | 10.53 | 4 – 20 | 3.60 |
| Four-Word Short-Term Memory – 30" | 9.13 | 0 – 18 | 3.92 |
| Four-Word Short-Term Memory – Total | 33.11 | 15 – 56 | 8.92 |
| *Incidental Memory* | | | |
| Digit Symbol Paired Associate Cued Recall | 9.98 | 2 – 18 | 5.00 |
| Digit Symbol Free Recall | 4.80 | 0 – 9 | 2.46 |

[a] Wechsler Memory Scale –3rd Edition [b] California Verbal Learning Test –2nd Edition

*Table 5, continued*

| *Neuropsychological Measures* | *Mean* | *Range* | *SD* |
|---|---|---|---|
| *Prospective Memory* | | | |
| Time-Based (% Correct) | 72.22 | 0 – 100 | 29.21 |
| Event-Based (% Correct) | 78.26 | 0 – 100 | 27.19 |
| *Visual-Spatial Processing and Memory* | | | |
| Hooper Visual Orientation Test (Total) | 26.34 | 17.50 – 30 | 2.57 |
| RCFT Copy[c] | 30.99 | 8 – 36 | 5.04 |
| RCFT Immediate[c] | 16.30 | 7 – 30 | 6.13 |
| RCFT Delay[c] | 16.64 | 4.5 – 29 | 6.24 |
| RCFT Recognition[c] | 19.48 | 14 – 23 | 1.78 |
| *Executive Control* | | | |
| WCST Correct[d] | 70.78 | 31 – 104 | 12.38 |
| WCST Errors[d] | 34.02 | 6 – 97 | 24.08 |
| WCST Perseverative Responses[d] | 22.46 | 3 – 62 | 17.32 |
| WCST Perseverative Errors[d] | 19.15 | 3 – 50 | 14.10 |
| WCST Nonperseverative Errors[d] | 14.87 | 2 – 47 | 11.20 |
| WCST Trials to Complete 1st Category[d] | 16.85 | 10 – 129 | 19.33 |
| WCST % Conceptual Level Responses[d] | 62.26 | 2 – 91 | 22.91 |
| WCST Failure to Maintain Set[d] | .91 | 0 – 7 | 1.40 |
| WCST Learning to Learn[d] | -4.18 | -15.91 – 6.17 | 5.68 |
| *Miscellaneous* | | | |
| Ornish Knowledge Test (Total = 54) | 13.30 | 3 – 32 | 6.46 |
| NART-R (estimated Verbal IQ)[e] | 110.51 | 93.10 – 124.25 | 7.29 |
| Digit Symbol (Total Raw) | 62.78 | 32 – 96 | 14.70 |

[a] Wechsler Memory Scale –3rd Edition

[b] California Verbal Learning Test –2nd Edition

[c] Rey-Osterreith Complex Figure Test

[d] Wisconsin Card Sorting Test

[e] National Adult Reading Test - Revised

### 4.3. Studies 1 and 2: General Rationale and Preliminary Data Analyses

Study 1 primarily addresses the first research question – Do neuropsychological variables significantly improve the prediction of cardiac rehabilitation outcomes beyond what is accounted for by program knowledge, demographic, disease, and psychological variables? Minimal attention is given to interpreting the qualitative and clinical significance of the predictor variables in Study 1; this is largely reserved for Study 2 and the Discussion section (Chapter 5). Study 2 addresses the next two research questions which relate to model refinement – Which neuropsychological and non-neuropsychological variables are most important to include in the model and how much variance in each outcome is explained through these multidimensional models? The fourth research question – Which of the neuropsychological tests commonly used to identify cognitive impairments in cardiovascular disease are the best predictors of specific learning and adherence outcomes? – is explored through both Studies 1 and 2 and the Discussion section (Chapter 5).

Potential predictors for each outcome were selected by reviewing the correlation matrices and identifying variables that correlated with the outcome at $p < .10$. Additional selection rules were employed to limit collinearity problems. Within each predictor category (i.e., demography/disease, psychological, neuropsychological), intercorrelation matrices were inspected to determine if any bivariate correlations exceeded .70. Most often, this occurred between different subtests of the same psychological or neuropsychological test (e.g., Wisconsin Card Sorting Test; SF-36) and tests measuring the same construct (e.g., measures of verbal memory; the psychological screening measures). When this occurred, only the variable having the highest correlation with the outcome was included. This allowed the variable with the next

highest qualifying correlation – usually representing a different construct than the highly correlated variables – to be included in the model.

The regression models revealed no problems with multicollinearity when compared against rule-of-thumb benchmarks (Garson, 2005) for Tolerance and VIF (Tolerance > .2 or VIF < 4). For the linear regression models developed in Study 1, Tolerance values ranged from .360 through 1.000 and VIF values spanned 1.007 through 2.776. A more careful review of collinearity diagnostics, including consideration of condition indices and variance proportions, is reserved for Study 2 which addresses model refinement.

Scatterplots, boxplots, and linear regression plots were used to evaluate assumptions about normality, linearity, and equality of variances. For each model, casewise diagnostics were performed to identify any data outliers exceeding 3.3 standard deviations. One outlier was found for the Food Diary Learning Slope outcome and this was eliminated from the data set. The residual errors for each regression model were evaluated by reviewing the scatterplots and histograms. No serious violations of homoscedasticity were identified through the residual scatterplots and in general, the histograms of residual errors were normally distributed. Finally, normal probability plots were used to depict the regression line and validate the linear relationship between each predicted value and residuals. In short, no major violations of regression model assumptions were identified.

Linear regression was used to predict all but one outcome. The exception was that logistic regression was used to predict Phase II Stratification; the scaling of this outcome was dichotomous rather than continuous. A hierarchical method of variable entry was used for both the linear and logistic regression models. To evaluate the unique contribution made by neuropsychological variables, these were the last to enter each regression model. The sequence

for entering qualifying variables was as follows: Step 1: Ornish Knowledge Test, Step 2: demographic/disease, Step 3: psychological, and Step 4: neuropsychological.

## 4.4. Study 1: Model Building

### 4.4.1. Behavioral Prescription Adherence

Four outcomes were assessed to determine Behavioral Prescription Adherence. These included participants' adherence to: 1) an extremely low fat, vegetarian food plan, 2) more than three hours of exercise per week, 3) twice-weekly participation in group support sessions, and 4) the daily practice of stress management, primarily in the form of yoga, relaxation, and meditation techniques. As part of routine program practices, participants' adherence to these four components of the program for the first twelve weeks are quantified through their completion of highly structured diary reporting forms. (See Appendix E for samples of food diary and Personal Awareness Log (PAL) forms.) Program staff review these diaries and compute percentage scores that reflect weekly adherence to each program component. In addition to these diaries, program staff rate participants' involvement in the Group Support component of the program and these staff ratings contribute to the computation of the percentage score for the Group Support adherence outcome. For each of the four Behavioral Prescription Adherence outcomes reviewed in this study, an average adherence percentage for the twelve weeks was computed. These Behavioral Prescription Adherence outcomes include Dietary, Exercise, Group Support, and Stress Management.

#### 4.4.1.1. Dietary Adherence

Five predictors qualified for inclusion in the regression model used to predict Dietary Adherence. The descriptive statistics, including intercorrelations between this outcome and potential predictors, are found in Tables 6 and 7. Only one demographic/disease variable (Income Category) and one psychological (Perceived Stress Scale) variable qualified for inclusion in the model and these variables were weakly correlated with Dietary Adherence at $p < .10$. By contrast, two of the three neuropsychological predictors were strongly correlated with this outcome at $p < .01$ (WCST Perseverative Responses and WCST Trials to Complete 1st Category). The other neuropsychological variable (Four-Word Short Term Memory – Total), was correlated with Dietary Adherence at $p < .05$.

**Table 6 Descriptive statistics for Dietary Adherence and predictor variables**

| *Variables* | *Mean* | *Range* | *SD* |
|---|---|---|---|
| Dietary Adherence (%) | 92.50 | 77.36 – 98.75 | 5.20 |
| Income Category[a] | 5.05 | 1 – 8 | 1.99 |
| Perceived Stress Scale | 14.48 | 2 – 32 | 8.06 |
| WCST Perseverative Responses | 22.46 | 3 – 62 | 17.32 |
| WCST Trials to Complete 1st Category | 16.85 | 10 – 129 | 19.33 |
| Four-Word Short-Term Memory – Total | 33.11 | 15 – 56 | 8.92 |

[a] 1 = < 7,500 2 = 7,501 – 15,000 3 = 15,0001 – 25,000 4 = 25,001 – 35,000
5 = 35,001 – 50,000 6 = 50,001 – 75,000 7 = 75,001 – 100,000 8 ≥ 100,001

**Table 7 Intercorrelations between Dietary Adherence and predictor variables**

| *Variables* | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|
| 1. Dietary Adherence (%) | — | .288 | -.253 | -.389** | -.482** | .348* |
| 2. Income Category | | — | -.160 | -.462** | -.168 | .168 |
| 3. Perceived Stress Scale | | | — | .304* | .138 | .076 |
| 4. WCST Perseverative Responses | | | | — | .428** | -.308* |
| 5. WCST Trials to Complete 1st Category | | | | | — | -.075 |
| 6. Four-Word Short-Term Memory –Total | | | | | | — |

* $p < .05$. ** $p < .01$.

The hierarchical regression model for Dietary Adherence is found in Table 8. Neither the demographic predictor (Income Category) nor the psychological predictor (Perceived Stress Scale) explained a statistically significant amount of variance in Dietary Adherence ($F(1,40) = 3.630$, $p = .064$, $F(2,39) = 2.837$, $p = .071$, respectively). Only when the neuropsychological predictors were introduced did the regression model reach statistical significance ($F$ (5, 36) = 4.685, $p = .002$). The model as a whole was statistically significant, explaining approximately one-third of the variance in Dietary Adherence ($R^2 = .394$, adjusted $R^2 = .310$). With all variables entered, only two of the three neuropsychological variables – WCST Trials to Complete 1st Category and Four Word Short-Term Memory (Total Score) – made statistically-significant contributions to the model ($\beta = -.411$, $t = -2.853$, $p = .007$ and $\beta = .312$, $t = 2.240$, $p = .031$, respectively). The lion share of explained variance (26.7% of 39.4%) is attributed to the

neuropsychological predictors when demography, disease, and scores on psychological measures are statistically controlled ($\Delta F(3,36) = 5.293$, $p = .004$).

**Table 8 Hierarchical regression for Dietary Adherence**

| *Model* | *Variables* | *B* | *SE B* | β | $R^2$ | $\Delta R^2$ |
|---|---|---|---|---|---|---|
| Step 1 | | | | | .083[a] | |
| | Income Category | .755 | .396 | .288 | | |
| Step 2 | | | | | .127[b] | .044 |
| | Income Category | .666 | .397 | .254 | | |
| | Perceived Stress Scale | -.137 | .098 | -.212 | | |
| Step 3 | | | | | .394[c]** | .267** |
| | Income Category | .361 | .384 | .138 | | |
| | Perceived Stress Scale | -.129 | .089 | -.200 | | |
| | WCST Perseverative Responses | .002 | .052 | .006 | | |
| | WCST Trials to Complete 1st Category | -.111 | .039 | -.411** | | |
| | Four-Word Short-Term Memory – Total | .182 | .081 | .312* | | |

[a] adjusted $R^2 = .060$ [b] adjusted $R^2 = .082$ [c] adjusted $R^2 = .310$

* $p < .05$. ** $p < .01$.

#### 4.4.1.2. Exercise Adherence

On average, participants' total time spent in exercise each week exceeded the minimum level specified by their exercise prescription (i.e., 180 minutes per week = 100%) although considerable variability was evident across participants. Also, a broad range of demographic/disease, psychological, and neuropsychological variables qualified as predictors for the Exercise Adherence regression model. The descriptive statistics for this outcome and the eight qualifying predictor variables are found in Table 9 followed by the intercorrelation matrix in Table 10. All but one of the predictors correlated with Exercise Adherence at $p < .05$; the exception was one of the two neuropsychological variables, CVLT List B ($r = .267$, $p < .10$). Not surprising was that participants' perception of their own physical vitality at the time of program entry bore the strongest zero-order correlation with Exercise Adherence (SF-36: Vitality: $r = .436$, $p < .01$).

Table 11 reveals that each category of predictors made a significant contribution to the prediction of Exercise Adherence. Using demographic/disease predictors only, between 26% and 31% of the variance in Exercise Adherence is explained ($F(3,41) = 6.068$, $p = .002$). When the psychological predictors are entered, the model remains statistically significant ($F(6,38) = 4.540$, $p = .001$) although the inclusion of these variables did not improve the model. The additional 11% of explained variance was not accompanied by a significant change in the $F$ statistic ($\Delta F(3,38) = 2.393$, $p = .084$). By contrast, the inclusion of neuropsychological predictors did significantly improve the model ($\Delta F(2,36) = 7.541$, $p = .002$), explaining an additional 17 % of the variance. As a whole, the model is highly significant ($F(8,36) = 6.462$, $p < .0005$) and explains approximately half of the variance in Exercise Adherence ($R^2 = .590$,

adjusted $R^2$ = .498). Both of the qualifying neuropsychological predictors made statistically significant contributions to composite model and one of these, WCST Perseverative Responses, made the greatest contribution (β = -.402, $t$ = -2.964, $p$ = .005). Also figuring prominently in the model were disease factors (Coronary Artery Disease), feelings of physical vitality (SF-36 Vitality), environmental demands (MPED Busyness), and the cognitive ability to focus on the task at hand, despite interfering stimuli (CVLT List B).

**Table 9 Descriptive statistics for Exercise Adherence and predictor variables**

| *Variables* | *Mean* | *Range* | *SD* |
|---|---|---|---|
| Exercise Adherence (%) | 111.15 | 63.88 – 181.25 | 25.90 |
| Employment Category[a] | .61 | 0 – 1 | .49 |
| Coronary Artery Disease[b] | .61 | 0 – 1 | .49 |
| Diabetes[b] | .43 | 0 – 1 | .50 |
| SF-36: Vitality | 49.49 | 0 – 100 | 25.30 |
| Perceived Stress Scale | 14.48 | 2 – 32 | 8.06 |
| MPED Busyness | 20.56 | 9 – 34 | 5.70 |
| CVLT List B | 5.87 | 2 – 11 | 2.09 |
| WCST Perseverative Responses | 22.46 | 3 – 62 | 17.32 |

[a] not working = 0, currently working = 1

[b] absent = 0, present = 1

**Table 10 Intercorrelations between Exercise Adherence and predictor variables**

| *Variables* | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|
| 1. Exercise Adherence (%) | — | -.321* | .360* | -.328* | .436** | -.348* | -.351* | .267 | -.309* |
| 2. Employment Category | | — | -.187 | .074 | -.095 | .531** | .188 | .057 | -.062 |
| 3. Coronary Artery Disease | | | — | .074 | .277 | -.330* | -.192 | .057 | .292* |
| 4. Diabetes | | | | — | -.135 | .106 | -.031 | -.199 | .187 |
| 5. SF-36: Vitality | | | | | — | -.019 | -.543** | -.157 | -.197 |
| 6. MPED Busyness | | | | | | — | .279 | -.027 | -.292* |
| 7. Perceived Stress Scale | | | | | | | — | .100 | .304* |
| 8. CVLT List B | | | | | | | | — | -.080 |
| 9. WCST Perseverative Responses | | | | | | | | | — |

* $p < .05$. ** $p < .01$.

**Table 11 Hierarchical regression for Exercise Adherence**

| *Model* | *Variables* | *B* | *SE B* | β | $R^2$ | $\Delta R^2$ |
|---|---|---|---|---|---|---|
| Step 1 | | | | | .307[a]** | |
| | Employment | -12.176 | 6.971 | -.232 | | |
| | Coronary Artery Disease | 17.919 | 6.971 | .341* | | |
| | Diabetes | -17.370 | 6.762 | -.336* | | |
| Step 2 | | | | | .418 [b]*** | .110 |
| | Employment | -7.444 | 7.705 | -.142 | | |
| | Coronary Artery Disease | 11.364 | 7.317 | .217 | | |
| | Diabetes | -14.857 | 6.692 | -.288* | | |
| | SF-36: Vitality | .266 | .165 | .260 | | |
| | MPED Busyness | -.610 | .737 | -.134 | | |
| | Perceived Stress Scale | -.363 | .509 | -.113 | | |
| Step 3 | | | | | .590[c]**** | .172** |
| | Employment | -6.230 | 6.713 | -.119 | | |
| | Coronary Artery Disease | 14.488 | 6.636 | .276* | | |
| | Diabetes | -7.198 | 6.104 | -.139 | | |
| | SF-36: Vitality | .333 | .145 | .325* | | |
| | MPED Busyness | -1.392 | .687 | -.307* | | |
| | Perceived Stress Scale | .259 | .483 | .081 | | |
| | CVLT List B | 2.884 | 1.406 | .233* | | |
| | WCST Perseverative Responses | -.601 | .203 | -.402** | | |

[a] adjusted $R^2$ = .257 [b] adjusted $R^2$ = .326 [c] adjusted $R^2$ = .498

*$p \leq .05$. **$p < .01$. ***$p \leq .001$. ****$p < .0005$.

#### 4.4.1.3. Group Support Adherence

Only four variables qualified for inclusion in the regression model for Group Support Adherence. No demographic or disease variables, and only one psychological variable, SF-36: General Health, met inclusion criterion (Table 12). The correlation matrix presented in Table 13 shows weak correlations ($p < .10$) between all but one of the qualifying predictors and Group Support Adherence. The exception was the neuropsychological variable, RCFT Delay, which was negatively correlated ($r = -.355$) with Group Support Adherence at $p < .05$.

**Table 12 Descriptive statistics for Group Support Adherence and predictor variables**

| *Variables* | *Mean* | *Range* | *SD* |
|---|---|---|---|
| Group Support Adherence (%) | 80.94 | 51.42 – 99.08 | 10.64 |
| Ornish Knowledge Test (Week 0)[a] | 13.30 | 3 – 32 | 6.46 |
| SF-36: General Health | 59.00 | 0 – 97 | 23.20 |
| RCFT Delay | 16.64 | 4.5 – 29 | 6.24 |
| WCST Nonperseverative Errors | 14.87 | 2 – 47 | 11.20 |

[a] Week 0 = pretest; highest possible score = 54

**Table 13 Intercorrelations between Group Support Adherence and predictor variables**

| *Variables* | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| 1. Group Support Adherence (%) | — | -.275 | .276 | -.355* | .250 |
| 2. Ornish Knowledge Test (Week 0) | | — | .046 | .399** | -.260 |
| 3. SF-36: General Health | | | — | .198 | -.129 |
| 4. RCFT Delay | | | | — | -.409** |
| 5. WCST Nonperseverative Errors | | | | | — |

* $p < .05$. ** $p < .01$.

Table 14 shows the hierarchical regression model for Group Support Adherence. Entering the Ornish Knowledge Test (Week 0) as the first step in the regression sequence did not result in a statistically significant model ($F(1,43) = 3.527$, $p = .067$). This variable explained only 5% of the variance in Group Support Adherence (adjusted $R^2 = .054$). Adding the single qualifying psychological predictor (SF-36: General Health) boosted the model to a statistically significant level ($F(2, 42) = 3.981$, $p = .026$) although taken together, these two variables only account for approximately 12% of the variance in Group Support Adherence ($R^2 = .159$, adjusted $R^2 = .119$). The inclusion of neuropsychological predictors resulted in a significant increment of 12.4% in the amount of explained variance ($\Delta F(2, 40) = 3.451$, $p = .041$). With all variables entered, the model was significant ($F(4, 40) = 3.948$, $p = .009$) and accounted for approximately one-fourth of the variance in Group Support Adherence ($R^2 = .283$, adjusted $R^2 = .211$). Two variables made significant contributions at $p < .05$. These included the single qualifying psychological predictor, SF-36: General Health ($\beta = .363$, $t = 2.650$, $p = .011$), and one neuropsychological variable, RCFT Delay ($\beta = -.322$, $t = -2.043$, $p = .048$).

**Table 14 Hierarchical regression for Group Support Adherence**

| *Model* | *Variables* | *B* | *SE B* | β | $R^2$ | $\Delta R^2$ |
|---|---|---|---|---|---|---|
| Step 1 | | | | | | |
| | Ornish Knowledge Test (Week 0) | -.453 | .241 | -.275 | .076[a] | |
| Step 2 | | | | | .159[b]* | .084* |
| | Ornish Knowledge Test (Week 0) | -.475 | .233 | -.289* | | |
| | SF-36: General Health | .133 | .065 | .289* | | |
| Step 3 | | | | | .283[c]** | .124* |
| | Ornish Knowledge Test (Week 0) | -.213 | .242 | -.129 | | |
| | SF-36: General Health | .166 | .063 | .363* | | |
| | RCFT Delay | -.549 | .269 | -.322* | | |
| | WCST Nonperseverative Errors | .125 | .141 | .131 | | |

*Note.* No demographic/disease variables met inclusion criterion ($p < .10$) for this regression model.

[a] adjusted $R^2 = .054$ [b] adjusted $R^2 = .119$ [c] adjusted $R^2 = .211$

* $p < .05$. ** $p < .01$.

#### 4.4.1.4. Stress Management Adherence

Participants' adherence to the Stress Management component of the Ornish program was the lowest of the four program components. Table 15 shows that as a group, the average adherence to the Stress Management was approximately 79% and the lowest adherence score was 37.38%. Of the six variables qualifying for inclusion in the Stress Management Adherence model, only one neuropsychological variable met inclusion criterion, the Four-Word Short Term Memory – 15", and this variable was only weakly correlated with Stress Management Adherence at $p < .10$ (Table 16).

**Table 15 Descriptive statistics for Stress Management and predictor variables**

| *Variables* | *Mean* | *Range* | *SD* |
|---|---|---|---|
| Stress Management Adherence (%) | 79.45 | 37.38 – 122.66 | 16.92 |
| Age | 59.95 | 31.25 – 78.42 | 10.72 |
| Coronary Artery Disease[a] | .61 | 0 – 1 | .49 |
| Family History[b] | .28 | 0 – 1 | .46 |
| SF-36: Mental Health | 70.76 | 28 – 100 | 18.50 |
| MPED Busyness | 20.56 | 9 – 34 | 5.70 |
| Four-Word Short-Term Memory – 15" | 10.53 | 4 – 20 | 3.60 |

[a] absent = 0, present = 1

[b] family history of cardiovascular disease: absent = 0, present = 1

**Table 16 Intercorrelations between Stress Management Adherence and predictor variables**

| *Variables* | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|
| 1. Stress Management Adherence | — | .294* | .308* | -.333* | .314* | -.358* | .250 |
| 2. Age | | — | .351 | -.007 | .223 | -.584 | -.074 |
| 3. Coronary Artery Disease | | | — | -.189 | .073 | -.330 | .104 |
| 4. Family History | | | | — | -.203 | .125 | -.068 |
| 5. SF-36: Mental Health | | | | | — | -.240 | -.119 |
| 6. MPED Busyness | | | | | | — | .282 |
| 7. Four-Word Short-Term Memory - 15" | | | | | | | — |

* $p < .05$. ** $p < .01$.

The hierarchical regression model for Stress Management Adherence is found in Table 17. A significant predictive model was obtained by using the demographic/disease predictors alone ($F(3,40) = 3.769$, $p = .018$) which account for 16% of the variance in Stress Management Adherence (adjusted $R^2 = .162$). When the psychological predictors are added, the model remains statistically significant ($F(5,38) = 2.938$, $p = .024$) but the addition of these did not result in a statistically significant increment in the amount of explained variance ($\Delta F(2,38) = 1.538$, $p = .228$). However, including the single qualifying neuropsychological predictor did significantly improve the model ($\Delta F(1,37) = 6.111$, $p = .018$). In fact, despite the weak zero-order correlation between Four Word Short-Term Memory – 15" and Stress Management Adherence, this was the only variable to make a significantly unique contribution when all six of

the qualifying variables were included in the model (β = .345, $t$ = 2.472, $p$ = .018). Taken together, the model as a whole is significant ($F$ (6, 37) = 3.796, $p$ = .005) and accounts for approxiately one-third of the variance in Stress Management Adherence ($R^2$ = .381, adjusted $R^2$ = .281).

**Table 17 Hierarchical regression for Stress Management Adherence**

| *Model* | *Variables* | *B* | *SE B* | β | $R^2$ | $\Delta R^2$ |
|---|---|---|---|---|---|---|
| Step 1 | | | | | .220[a]* | |
| | Age | .367 | .236 | .233 | | |
| | Coronary Artery Disease | 5.809 | 5.219 | .169 | | |
| | Family History | -11.132 | 5.297 | -.299* | | |
| Step 2 | | | | | .279[b]* | .058 |
| | Age | .146 | .278 | .092 | | |
| | Coronary Artery Disease | 5.406 | 5.212 | .158 | | |
| | Family History | -8.996 | 5.372 | -.242 | | |
| | SF-36: Mental Health | .174 | .133 | .190 | | |
| | MPED Busyness | -.521 | .518 | -.176 | | |
| Step 3 | | | | | .381[c]** | .102* |
| | Age | .084 | .262 | .053 | | |
| | Coronary Artery Disease | 3.227 | 4.972 | .094 | | |
| | Family History | -7.722 | 5.070 | -.208 | | |
| | SF-36: Mental Health | .200 | .125 | .218 | | |
| | MPED Busyness | -.932 | .514 | -.314 | | |
| | Four-Word Short-Term Memory – 15" | 1.623 | .656 | .345* | | |

[a] adjusted $R^2$ = .162 [b] adjusted $R^2$ = .184 [c] adjusted $R^2$ = .281

* $p$ < .05. ** $p$ < .01.

#### 4.4.1.5. Summary: Behavioral Adherence Outcomes

Table 18 provides a summary of the Behavioral Adherence Outcomes including $R^2$ and adjusted $R^2$ values and the standardized (β) coefficients for the top-ranking variables in each of the four models. These regression models clearly demonstrate the important contribution made by neuropsychological variables when predicting adherence to behavioral prescriptions. All of these regression models were significantly improved by including neuropsychological predictors. For all but one outcome, neuropsychological predictors made the most unique contribution (i.e., top-ranking standardized (β) coefficients) to each regression model. For the exception, Group Support Adherence, a neuropsychological variable had the second highest standardized (β) coefficient. Tests of memory and especially, verbal working memory, were strongly represented in all four behavioral adherence models – these ranked either first or second in statistical significance in each model. In addition, important contributions were made by measures of executive control in two of the four models. For both Food Diary and Exercise Adherence, the standardized (β) coefficients for subtests from the WCST (Trials to Complete 1st Category and Perseverative Responses) held the top-ranking position in these regression models. In summary, the inclusion of neuropsychological variables in these adherence models boosted the amount of explained variance from a range of 8.2% to 41.8% to a range of 21% to 59%. More importantly, the increment in explained variance for each model was statistically significant and not simply attributed to a reduction in subject to predictor ratio.

**Table 18 Behavioral Prescription Adherence Summary**

| *Outcome* | $R^2$ | adjusted $R^2$ | β | *t* | *p* |
|---|---|---|---|---|---|
| *Dietary Adherence* | *.394* | *.310* | | | *.002* |
| WCST Trials to Complete 1st Category | | | -.411 | -2.853 | .007 |
| Four-Word Short-Term Memory - Total | | | .312 | 2.240 | .031 |
| *Exercise Adherence* | *.590* | *.498* | | | *.002* |
| WCST Perseverative Responses | | | -.402 | -2.964 | .005 |
| SF-36: Vitality | | | .325 | 2.299 | .027 |
| MPED Busyness | | | -.307 | -2.028 | .050 |
| CVLT List B | | | .233 | 2.051 | .048 |
| *Group Support Adherence* | *.283* | *.211* | | | *.009* |
| SF-36: General Health | | | .363 | 2.650 | .011 |
| RCFT Delay | | | -.322 | -2.043 | .048 |
| *Stress Management Adherence* | *.381* | *.281* | | | *.005* |
| Four-Word Short Term Memory – 15” | | | .345 | 2.472 | .018 |
| (MPED Busyness) | | | (-.314) | (-1.813) | (.078) |

*Note.* $R^2$ and adjusted $R^2$ values are for the regression models including all predictors. The Stress Management model had less than 2 predictors significant at $p < .05$. The next predictor closest to reaching statistical significance is included in parentheses.

### 4.4.2. Cognitive Outcomes: Documented and Perceived Learning

#### 4.4.2.1. Documented Learning

The first twelve weeks of the Ornish program includes highly structured lecture series that are uniform across all hospital sites and designed to teach specific facts and procedures that are essential to the Ornish lifestyle. To assess participants' explicit learning of this factual information, the Ornish Knowledge Test was developed while this researcher participated in the Ornish program. At the end of each week, lecture notes and handouts were used to develop questions that reflected the material covered in the program over the course of that week.

Administering the Ornish Knowledge Test to research participants before and after the first twelve weeks of the program was important for two reasons. The first reason was reflected through the behavioral adherence and coronary risk factor models reviewed thus far. To determine if the amount of Ornish-specific knowledge the individual possessed at the time of program entry was important those outcomes, Week 0 scores on the Ornish Knowledge Test were included as the first step in the regression models if these met inclusion criterion ($p < .10$). Second, re-administering the Ornish Knowledge Test at the end of the first twelve weeks of the program made it possible to directly assess explicit learning of Ornish-specific factual information. This permitted the identification of the neuropsychological (and other) factors most important to explicit (factual) learning.

The behavioral adherence and coronary risk factor outcomes reviewed thus far reveal that the amount of Ornish-specific knowledge participants' possessed at the time of program entry did not play a significant role in predicting adherence to the four components of the program or

the reduction of coronary risk factors. Of the four regression models already reviewed, the Ornish Knowledge Test (Week 0) qualified for inclusion in only one model and did not make a significant contribution to that model (Group Support) once all variables were entered. These findings suggest that the kind of learning needed to adhere to behavioral prescriptions is not as greatly impacted by one's existing knowledge base at the time of program entry (i.e., "old" learning) as it is by neuropsychological factors that mediate "new" (i.e., in-program) learning.

The two aspects of "new" learning evaluated in this study are referred to as Documented Learning outcomes. These include Ornish-specific knowledge acquisition (i.e., comparison of Weeks 0 and 12 on the Ornish Knowledge Test) and the application of this factual knowledge and procedural guidelines through the keeping of food diaries.

***Documented Learning: Ornish Knowledge Test (Week 12).*** Table 19 shows that on average, participants scored ten points better on the Ornish Knowledge Test at Week 12 as compared to Week 0. This represents a 77% improvement. However, it was surprising to find the average score for the group after twelve weeks of program participation was 23.86 and the highest score was only 36. Given the highest possible score on this test is 54, this means on average, participants demonstrated only 44.18% mastery of the factual content of the Ornish program by the end of twelve weeks. The highest score indicated only a 67% mastery of the information.

**Table 19 Descriptive statistics for Ornish Knowledge Test (Week 12) and predictor variables**

| *Variables* | *Mean* | *Range* | *SD* |
|---|---|---|---|
| Ornish Knowledge Test – Week 12 | 23.86 | 6 – 36 | 7.22 |
| Ornish Knowledge Test – Week 0 | 13.30 | 3 – 32 | 6.46 |
| Age | 59.95 | 31.25 – 78.42 | 10.72 |
| Cardiac Surgery[a] | .43 | 0 – 2 | .54 |
| Medical Problems (Total #) | 7.46 | 2 – 19 | 3.03 |
| MPED Busyness | 20.56 | 9 – 34 | 5.70 |
| RCFT Delay | 16.64 | 4.5 – 29 | 6.24 |
| CVLT Short Delay Free Recall | 10.96 | 3 – 16 | 3.16 |
| Four-Word Short-Term Memory – 30" | 9.13 | 0 – 18 | 3.92 |

*Note.* The Ornish Knowledge Test assesses participants' learning of specific factual information taught in the first 12-weeks of the Ornish program. This short-answer questionnaire was developed specifically for this research project and administered in both the pre- and post-test sessions (Weeks 0 and 12). The highest possible score on the Ornish Knowledge Test is 54.

[a] total number of cardiac surgeries

The intercorrelations between qualifying predictors and Week 12 scores on the Ornish Knowledge Test are found in Table 20. All but one of the qualifying predictors were strongly correlated with Week 12 scores on the Ornish Knowledge Test at $p < .01$. The single exception,

MPED Busyness, was correlated at $p < .05$. As expected, participants' pre-program scores on the Ornish Knowledge Test (Week 0) were highly correlated with Week 12 scores on this measure ($r = .565$). However, this was not the top-ranking correlation. This was reserved for a test of explicit verbal memory (CVLT Short Delay Free Recall: $r = .658$).

**Table 20 Intercorrelations between the Ornish Knowledge Test (Week 12) and predictor variables**

| *Variables* | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|
| 1. Ornish Knowledge Test (Week 12) | — | .565** | -.389** | -.518** | -.441** | .356* | .534** | .658** | .535** |
| 2. Ornish Knowledge Test (Week 0) | | — | -.173 | -.247 | -.177 | -.018 | 399** | .422** | .225 |
| 3. Age | | | — | .437** | .378** | -.584** | -.327* | -.401** | -.205 |
| 4. Cardiac Surgery[a] | | | | — | .430** | -.454** | -.290 | -.546** | -.464** |
| 5. Medical Problems (Total #) | | | | | — | -.271 | -.355* | -.509** | -.386** |
| 6. MPED Busyness | | | | | | — | .277 | .455** | .439** |
| 7. RCFT Delay | | | | | | | — | .639** | .303* |
| 8. CVLT Short Delay Free Recall | | | | | | | | — | .503** |
| 9. Four-Word Short-Term Memory - 30" | | | | | | | | | — |

* $p < .05$. ** $p < .01$.

Table 21 presents the hierarchical regression model for Week 12 scores on the Ornish Knowledge Test. Pre-program scores (Week 0) on this test account for approximately 30% of the variance in Week 12 scores ($R^2$ = .319, adjusted $R^2$ = .301). The predictive model including only this pre-test is highly significant ($F(1,39) = 18.252$, $p < .0005$). The addition of age and disease variables (number of cardiac surgeries, total number of medical problems) significantly improved the model ($\Delta F(3,36) = 5.183$, $p = .004$) and explained another 20% of the variance. Neither psychological nor neuropsychological variables significantly improved the amount of explained variance ($\Delta F(1,35) = 1.838$, $p = .184$ and $\Delta F(3,32) = 2.210$, $p = .106$, respectively). However, when all variables are entered into the model, the two tests of verbal learning (CVLT Short Delay Recall, Four Word Short-Term Memory – 30") had the highest ranking standardized ($\beta$) coefficients in the model – save only for Week 0 scores on the Ornish Knowledge Test. Taken together, the model as a whole is statistically significant and explains more than half of the variance in participants' Week 12 scores on the Ornish Knowledge Test ($F(8,32) = 6.683$, $p < .0005$).

**Table 21 Hierarchical regression for Ornish Knowledge Test (Week 12)**

| *Model* | *Variables* | *B* | *SE B* | β | $R^2$ | $\Delta R^2$ |
|---|---|---|---|---|---|---|
| Step 1 | | | | | .319[a]**** | |
| | OK Test – Week 0 | .630 | .148 | .565**** | | |
| Step 2 | | | | | .524[b]**** | .205** |
| | OK Test – Week 0 | .493 | .133 | .442**** | | |
| | Age | -.079 | .089 | -.118 | | |
| | Cardiac Surgery[a] | -3.590 | 1.813 | -.270 | | |
| | Medical Problems (Total #) | -.481 | .312 | -.202 | | |
| Step 3 | | | | | .548[c]**** | .024 |
| | OK Test – Week 0 | .532 | .135 | .476**** | | |
| | Age | -.012 | .101 | -.019 | | |
| | Cardiac Surgery[a] | -2.829 | 1.878 | -.213 | | |
| | Medical Problems (Total #) | -.484 | .309 | -.203 | | |
| | MPED Busyness | .255 | .188 | .202 | | |
| Step 4 | | | | | .626[d]**** | .078 |
| | OK Test – Week 0 | .374 | .144 | .335* | | |
| | Age | -.050 | .099 | -.074 | | |
| | Cardiac Surgery[a] | -1.619 | 1.900 | -.122 | | |
| | Medical Problems (Total #) | -.173 | .320 | -.073 | | |
| | MPED Busyness | .041 | .200 | .032 | | |
| | RCFT Delay | .146 | .168 | .126 | | |
| | CVLT Short Delay Free Recall | .409 | .412 | .179 | | |
| | Four-Word Short-Term Memory – 30" | .400 | .256 | .217 | | |

[a] adjusted $R^2$ = .301 [b] adjusted $R^2$ = .471 [c] adjusted $R^2$ = .483 [d] adjusted $R^2$ = .532

* $p < .05$. ** $p < .01$. *** $p \leq .001$. **** $p < .0005$.

***Documented Cogntive Learning: Food Diary Learning Slope.*** While the Ornish Knowledge Test was the primary means of assessing explicit learning of program-specific knowledge, the accuracy of food diaries was also examined. (Samples of uncompleted and completed food diaries, along with an example of feedback provided by the nutritionist, are found in Appendix E.) The accuracy of food diaries reflects the explicit learning and application of dietary guidelines as well as a different type of learning, namely, procedural learning. In addition to nutrition-specific factual learning, diary accuracy also reflects how well the participant has learned the procedures for completing these structured reporting forms. This outcome was not simply evaluated through pre- and post-program comparisons. Rather, the focus was on the rate of diary-keeping mastery across each consecutive week of the program; in other words, the learning slope of diary accuracy. Intuitively, one would expect that higher scores indicate a more favorable learning slope although in this case, the opposite is true – our starting point was the number of errors made at Week 1. We are interested in the reduction of diary-keeping errors across subsequent weeks and therefore, a negative learning slope reflects greater improvements. The Food Diary Learning Slope was computed as follows: (1) Difference scores were computed for the number of food diary errors for each consecutive week, e.g., Week 2 – Week 1, Week 3 – Week 2, Week 4 – Week 3, etc. (2) These difference scores were totaled. (3) An average learning slope score was computed by dividing this total by the number of weeks the diary was kept (with few exceptions, this was usually the entire 12 weeks). Unfortunately, it was possible to compute learning slope indices for only one hospital site, Westmoreland Regional Hospital. This was the only hospital site where the nutritionist was consistent in her method of correcting food diary errors throughout the entire twelve weeks.

The qualifying predictors for the Food Diary Learning Slope outcome are found in Table 22. As a group, the learning slope was negative and indicated a reduction of food diary errors over the course of the program. Learning slope scores spanned -2.50 through 2.72 and this broad range contributed to the minimal learning reflected through the mean score for this outcome (*M* = 0.68, *SD* = 1.07). Of anecdotal interest is that participants' Ornish-specific knowledge at the time of program entry (Ornish Knowledge Test, Week 0) did not qualify as a predictor variable for this outcome. Table 23 shows the intercorrelations between the eight qualifying predictor variables and the Food Diary Learning Slope outcome. All but two of these variables correlated with the outcome at $p < .05$. The exceptions were the relatively weaker correlations found for the demographic predictors (age and income) which only correlated with the outcome at $p < .10$.

**Table 22 Descriptive statistics for Food Diary Learning Slope and predictor variables**

| *Variables* | *Mean* | *Range* | *SD* |
|---|---|---|---|
| Food Diary Learning Slope | -.68 | -2.50 – 2.72 | 1.07 |
| Age | 59.05 | 31.25 – 78.42 | 12.04 |
| Income Category[a] | 4.95 | 1 – 8 | 1.89 |
| Medical Problems (Total #) | 7.63 | 3 – 13 | 2.55 |
| SF-36: Physical Functioning | 77.92 | 25 – 100 | 24.22 |
| Preferred Support Profile | 79.92 | 42 – 100 | 20.12 |
| RCFT Copy | 30.46 | 8 – 36 | 6.02 |
| WCST Trials | 106.46 | 70 – 128 | 23.94 |
| Four-Word Short-Term Memory - 5" | 13.54 | 7 – 18 | 2.90 |

*Note*. $n = 23$

[a] The approximate average income for this subsample was the income interval of $35,001 – 50,000. The approximate standard deviation was $30,000.

**Table 23 Intercorrelations between the Food Diary Learning Slope and predictor variables**

| *Variables* | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|
| 1. Food Diary Learning Slope | — | -.400 | .407 | -.438* | .474* | -.461* | -.429* | -.439* | .508* |
| 2. Age | | — | -.631** | .272 | .103 | .321 | -.016 | .416* | -.026 |
| 3. Income Category[a] | | | — | -.012 | .088 | .136 | -.209 | -.460* | -.103 |
| 4. Medical Problems (Total #) | | | | — | -.217 | .263 | -.192 | .249 | -.476* |
| 5. SF-36: Physical Functioning | | | | | — | -.205 | -.027 | -.459* | .205 |
| 6. Preferred Support Profile | | | | | | — | -.090 | .324 | -.434* |
| 7. RCFT Copy | | | | | | | — | -.181 | .194 |
| 8. WCST Trials | | | | | | | | — | -.162 |
| 9. Four-Word Short-Term Memory - 5" | | | | | | | | | — |

*Note.* $n = 23$

* $p < .05$. ** $p < .01$.

Table 24 shows the hierarchical regression model for the Food Diary Learning Slope outcome. The combination of age, income, and total number of medical problems explained less than 25% of the variance in this outcome ($R^2 = .355$, adjusted $R^2 = .241$). The predictive model

including only these demographic/disease variables was on the cusp of statistical significance ($F(3,17) = 3.120$, $p = .054$). The addition of psychological variables (self-ratings on the SF-36: Physical Functioning scale and the Preferred Support Profile) substantially improved the overall significance of the model ($F(5,15) = 4.816$, $p = .008$). The inclusion of these psychological variables explained another 25% of the variance and this increment was significant ($\Delta F(2,15) = 5.102$, $p = .020$). The addition of neuropsychological variables further improved the model by explaining another 28% of the variance ($\Delta F(3,12) = 10.620$, $p = .001$). With these measures of spatial construction and verbal memory included, the model is highly significant ($F(8,12) = 12.784$, $p < .0005$). As a whole, the model explains more than 80% of the variance in the Food Diary Learning Slope ($R^2 = .895$, adjusted $R^2 = .825$). However, it is important to recognize that due to the low subject to predictor ratio (3:1), the amount of explained variance may be artificially inflated in this preliminary model and substantially lowered when the model is refined in the subsequent study. The more important point for this initial study is the substantial magnitude of the standardized (β) coefficients for these two neuropsychological variables and their apparent contribution to diary-keeping accuracy. These variables, RCFT Copy and the Four Word Short-Term Memory – 5", were the highest ranking of all the eight predictors in the model and made the most unique contributions to the composite model ($\beta = -.528$, $t = -4.935$, $p < .0005$, $\beta = .392$, $t = 3.235$, $p = .007$). The negative coefficient for the RCFT Copy suggests that those who performed poorly on a test of spatial and graphomotor accuracy made the greatest improvements in diary-keeping over time; in other words, those who were sloppy, careless, and gave limited attention to detail at the beginning of the program demonstrated the greatest improvements with these more superficial and procedural aspects of diary-keeping. By contrast, the positive coefficient for the Four Word Short-Term Memory – 5" suggests that better scores

on tests of verbal working memory accounted for a substantial proportion of diary-keeping error reduction.

**Table 24 Hierarchical regression for Food Diary Learning Slope (n = 23)**

| *Model* | *Variables* | *B* | *SE B* | β | $R^2$ | $\Delta R^2$ |
|---|---|---|---|---|---|---|
| Step 1 | | | | | .355[a] | |
| | Age | -.005 | .024 | -.054 | | |
| | Income Category[a] | .209 | .146 | .368 | | |
| | Medical Problems (Total #) | -.176 | .087 | -.419 | | |
| Step 2 | | | | | .616[b]** | .261* |
| | Age | .010 | .025 | .114 | | |
| | Income Category[a] | .290 | .146 | .511 | | |
| | Medical Problems (Total #) | -.122 | .075 | -.291 | | |
| | SF-36: Physical Functioning | .012 | .008 | .265 | | |
| | Preferred Support Profile | -.023 | .011 | -.436* | | |
| Step 3 | | | | | .895[c]**** | .279*** |
| | Age | -.014 | .015 | -.152 | | |
| | Income Category[a] | .113 | .098 | .198 | | |
| | Medical Problems (Total #) | -.076 | .050 | -.182 | | |
| | SF-36: Physical Functioning | .011 | .005 | .257 | | |
| | Preferred Support Profile | -.010 | .008 | -.185 | | |
| | RCFT Copy | -.094 | .019 | -.528**** | | |
| | WCST Trials | -.004 | .006 | -.094 | | |
| | Four-Word Short-Term Memory - 5" | .145 | .045 | .392** | | |

[a] adjusted $R^2$ = .241 [b] adjusted $R^2$ = .488 [c] adjusted $R^2$ = .825

* $p \leq .05$. ** $p < .01$. *** $p \leq .001$. **** $p < .0005$.

***Summary of Documented Learning.*** Participants' acquisition of Ornish-specific knowledge was largely contingent upon what they knew at the time of program entry. Neither the addition of psychological nor neuropsychological variables significantly improved the prediction of Week 12 scores on the Ornish Knowledge Test although tests of both verbal working memory and explicit verbal recall approached significance in this unrefined model. (After removing a number of variables that contributed minimally to the model, the importance of these variables will become evident when the refined model is reviewed in the subsequent study.) As for the learning demonstrated through the reduction of diary-keeping errors, the contribution of neuropsychological variables was more straightforward. Tests of verbal working memory and graphomotor and spatial accuracy made the greatest contributions to the model, supporting the notion that verbal learning and procedural accuracy contribute to this learning outcome. As expected, the regression models predicting these cognitive outcomes performed better than those developed for the behavioral adherence outcomes. Between 53% and 90% of the variance is explained through the regression models developed for the cognitive outcomes while the explained variance for behavioral adherence outcomes ranged from 21% through 59%.

The inclusion of neuropsychological variables in the Food Diary Learning Slope regression model resulted in a very significant increase in the amount of explained variance – $R^2$ rose from 60% to 90%. Verbal working memory, along with spatial and graphomotor accuracy, figured prominently in this model. When predicting Week 12 scores on the Ornish Knowledge Test, the increment in explained variance was not statistically significant owing to the fact that the Week 0 score on this measure was such a potent predictor. After this predictor, two tests of verbal learning (CVLT Short-Delay Free Recall and Four Word Short-Term Memory) were the highest ranking standardized (β) coefficients in the model.

#### 4.4.2.2. Perceived Learning

It was no great revelation that neuropsychological variables contributed in a substantial way to the acquisition of program-specific knowledge and procedures reviewed through the Documented Learning outcomes. However, the more important question is this: Can program staff working with participants accurately identify these problems without having access to neuropsychological test results? This question was explored by asking two members of the program staff at each hospital site who have the most contact with participants to complete brief likert rating scales at the end of 12 weeks. These staff included the nutritionist who is responsible for all aspects of nutrition education and food diary review and the case manager who accompanies participants to the other three components of the program (i.e., exercise, group support, and stress management) and is responsible for reviewing the diaries for those components. (See Appendix E for a sample of these "Personal Awareness (PAL)" reporting forms.)

The rating scales for the nutritionist and the case manager were parallel measures and included brief statements reflecting specific memory and learning constructs. Each included the same four statements whose content reflected aspects of executive control and working, explicit, and prospective memory: 1. Confusion or difficulties paying attention (working memory), 2. Trouble remembering specific facts (explicit memory), 3. Trouble understanding the importance of lifestyle changes to the management of his/her disease (executive control and more specifically, self-insight and reflection), 4. Difficulties with self-reflection, poor organization, or anticipation of future problems interfere with learning (executive control and

more specifically, prospective memory). Program-specific, qualitative examples of these problems accompanied each statement to stimulate further thought and clarification about the nature of learning problems being targeted. A five-point likert scale was used to rate each of these four aspects of memory, learning, and executive ranging from "none" to "profound" problems. If staff recognized these problems, significant negative correlations would be found between their ratings on these scales and the neuropsychological tests; in other words, low scores on neuropsychological measures indicate impairment whereas the reverse is true for the staff rating scales. High scores on the perceived learning scales indicate impairment. Given that extant research has shown that professional staff are not able to detect neuropsychological deficits through routine clinical contact, it was expected that neuropsychological variables would contribute minimally (if at all) to the regression models predicting scores on these scales.

***Nutritionist perceived learning.*** Tables 25 and 26 provide the descriptive statistics and intercorrelations between the qualifying predictor variables and the Nutritionist Perceived Learning outcome. Noteworthy is that the nutritionist from one hospital site was unable to provide these ratings, thereby reducing the sample size for this outcome to $n = 30$. Only four predictor variables qualified for inclusion in the regression model and two of these were weak correlations at the $p < .10$ level. The variable having the strongest correlation was the Ornish Knowledge Test (Week 0: $r = .488$) followed by the RCFT Copy ($r = -.396$).

**Table 25 Descriptive statistics for Nutritionist Perceived Learning and predictors (n = 30)**

| *Variables* | *Mean* | *Range* | *SD* |
|---|---|---|---|
| Nutritionist Perceived Learning | 6.40 | 4 – 14 | 2.93 |
| Ornish Knowledge Test (Week 0) | 13.43 | 3 – 23 | 5.69 |
| Cook-Medley | 7.00 | 0 – 19 | 4.83 |
| RCFT Copy | 30.08 | 8 – 36 | 5.64 |
| RCFT Immediate | 14.65 | 7 – 26 | 4.96 |

*Note.* High scores indicate that the nutritionist perceived learning problems; the highest possible score is 16. A subsample ($n$ = 30) was used for these analyses due to missing data from one hospital site.

**Table 26 Intercorrelations between Nutritionist Perceived Learning and predictor variables**

| *Variables* | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| 1. Nutritionist Perceived Learning | — | -.488** | .348 | -.396* | -.357 |
| 2. Ornish Knowledge Test (Week 0) | | — | -.291 | .254 | .347 |
| 3. Cook-Medley | | | — | -.087 | -.273 |
| 4. RCFT Copy | | | | — | .542** |
| 5. RCFT Immediate | | | | | — |

* $p < .05$. ** $p < .01$.

The hierarchical regression model for Nutritionist Perceived Learning is found in Table 27. Using the Ornish Knowledge Test (Week 0) alone resulted in a statistically significant model that explained approximately 21% of the variance in Nutritionist Perceived Learning ($F(1,28) = 8.763$, $p = .006$; $R^2 = .238$, adjusted $R^2 = .211$). The addition of psychological and neurosychological predictors did not significantly improve the model ($\Delta F(1,27) = 1.755$, $p = .196$, $\Delta F(2,25) = 1.538$, $p = .234$, respectively). As a whole, the model is significant ($F(1,25) = 3.565$, $p = .020$) and explains approximately 26% of the variance in Nutritionist Perceived Learning ($R^2 = .363$, adjusted $R^2 = .261$). Review of the standardized (β) coefficients for the model revealed that none of the four variables were significant at $p < .05$ although the Ornish Knowledge Test (Week 0) approached this level of significance ($\beta = -.345$, $t = -1.971$, $p = .060$). The next highest coefficient was RCFT Copy ($\beta = -.274$, $t = -1.430$, $p = .165$). These findings are noteworthy for two reasons. First, the strongest contributor was participants' fund of program-specific knowledge at the time of program entry (Ornish Knowledge Test – Week 0) rather than the tests of verbal memory that facilitate this kind of program-specific knowledge acquisition. Despite the fact that verbal working memory played an instrumental role in the regression model examining error reductions for diaries reviewed by this nutritionist, relative strengths and weaknesses in participants' verbal working memory capacity were not perceived by the nutritionist. Second, the negative correlation between RCFT Copy and Nutritionist Perceived Learning is relevant. This showed that the nutritionist was able to accurately identify the sloppiness marker that was documented as significant to food diary error reduction. Taken together, these findings suggest that without access to formal neuropsychological testing, the nutritionist was able to identify specific shortcomings in more procedural aspects of program learning (neatness/sloppiness in diary-keeping procedures) but not the verbal memory functions

that are key to overcoming these difficulties and facilitating Ornish-specific knowledge acquisition.

**Table 27 Hierarchical regression for Nutritionist Perceived Learning (n = 30)**

| *Model* | *Variables* | *B* | *SE B* | β | $R^2$ | $\Delta R^2$ |
|---|---|---|---|---|---|---|
| Step 1 | | | | | .238[a]** | |
| | Ornish Knowledge Test (Week 0) | -.251 | .085 | -.488** | | |
| Step 2 | | | | | .285[b]* | .046 |
| | Ornish Knowledge Test (Week 0) | -.218 | .088 | -.423* | | |
| | Cook-Medley | .137 | .103 | .225 | | |
| Step 3 | | | | | .363[c]* | .078 |
| | Ornish Knowledge Test (Week 0) | -.178 | .090 | -.345 | | |
| | Cook-Medley | .131 | .104 | .216 | | |
| | RCFT Copy | -.142 | .100 | -.274 | | |
| | RCFT Immediate | -.018 | .119 | -.030 | | |

*Note.* No demographic/disease variables met statistical criterion for inclusion in this regression model.

[a] adjusted $R^2$ = .211 [b] adjusted $R^2$ = .232 [c] adjusted $R^2$ = .261

*$p$ < .05. **$p$ < .01.

***Case manager perceived learning.*** Case managers from all three hospital sites completed the likert rating scales for this outcome. The descriptive statistics for the qualifying predictors and this outcome are found in Table 28 followed by the intercorrelation matrix in Table 29. The mean scores and standard deviations for the learning perceived by the case manager and the nutritionist were quite similar as were the variables that qualified for inclusion (see Tables 25 and 28). All four of the variables that qualified as predictors for Nutritionist Perceived Learning also qualified for Case Manager Perceived Learning along with additional variables. These included two other quality of life (psychological) variables from the SF-36 (Role Physical, Bodily Pain) and one more neuropsychological variable (WCST Trials). Four of the variables correlated with the Case Manager Perceived Learning outcome at $p < .05$ and the other three, at $p < .10$ (Table 29).

**Table 28 Descriptive statistics for Case Manager Perceived Learning and predictor variables**

| *Variables* | *Mean* | *Range* | *SD* |
|---|---|---|---|
| Case Manager Perceived Learning | 6.00 | 4 – 15 | 3.06 |
| Ornish Knowledge Test (Week 0) | 13.30 | 3 – 32 | 6.46 |
| SF-36: Role-Physical | 67.78 | 0 – 100 | 42.18 |
| SF-36: Bodily Pain | 68.42 | 12 – 100 | 23.32 |
| Cook-Medley | 6.83 | 0 – 19 | 4.25 |
| RCFT Copy | 30.99 | 8 – 36 | 5.04 |
| RCFT Immediate | 16.30 | 7 – 30 | 6.13 |
| WCST Trials | 104.80 | 68 – 128 | 23.93 |

*Note.* $N = 46$. High scores indicate that the case manager perceived learning problems; the highest possible score is 16.

**Table 29 Intercorrelations between the Case Manager Perceived Learning and predictor variables**

| *Variables* | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
|---|---|---|---|---|---|---|---|---|
| 1. Case Manager Perceived Learning Knowledge Test - Week 12 | — | -.250 | -.304* | -.261 | .285 | -.338* | -.319* | .332* |
| 2. Ornish Knowledge Test (Week 0) | | — | -.003 | -.102 | -.224 | .267 | .356* | -.315* |
| 3. SF-36: Role-Physical | | | — | .550** | -.115 | -.011 | .250 | -.331* |
| 4. SF-36: Bodily Pain | | | | — | -.054 | .117 | .264 | -.213 |
| 5. Cook-Medley | | | | | — | -.102 | -.201 | .141 |
| 6. RCFT Copy | | | | | | — | .539** | -.310** |
| 7. RCFT Immediate | | | | | | | — | -.314* |
| 8. WCST Trials | | | | | | | | — |

* $p < .05$. ** $p < .01$.

Table 30 shows the hierarchical regression model for Case Manager Perceived Learning. Entering the Ornish Knowledge Test – Week 0 as the first step did not result in a statistically-significant model. This explained less than 5% of the variance in Case Manager Perceived Learning ($R^2 = .063$, adjusted $R^2 = .041$; $F(1,43) = 2.876$, $p = .097$). The inclusion of three

qualifying psychological predictors bumped the model to a level of significance ($F(4,40) = 2.743$, $p = .042$) but adding these variables did not explain a significantly greater proportion of variance in the outcome. The increment in explained variance approached, but did not achieve, statistical significance ($\Delta F(3,40) = 2.592$, $p = .066$). The model was no longer statistically significant when neuropsychological variables were entered ($F(7,37) = 2.133$, $p = .064$). Taken together, the model as a whole explained only 15% of the variance in Case Manager Perceived Learning ($R^2 = .288$, adjusted $R^2 = .153$). With all variables entered, no standardized ($\beta$) coefficient was significant at $p < .05$. Variables approaching significance were the "sloppiness" marker (i.e., negative coefficient for RCFT Copy) and self-reported feelings of hostility (Cook-Medley). The latter is of anecdotal interest. For both the Nutritionist and Case Manager Perceived Learning models, hostile attitudes at the time of program entry were more strongly correlated with staff-rated learning impairments than neuropsychological measures of verbal memory and learning. No measure of verbal memory qualified for inclusion in the predictive models for staff-perceived learning although the Cook-Medley qualified as a predictor for both models. In other words, participants were more likely to be identified as having memory/learning problems if they entered the program with higher levels of hostility rather than neuropsychological impairments. Therefore, it is possible that the manifestation of these hostile attitudes may have caused rater bias.

**Table 30 Hierarchical regression for Case Manager Perceived Learning**

| *Model* | *Variables* | *B* | *SE B* | β | $R^2$ | $\Delta R^2$ |
|---|---|---|---|---|---|---|
| Step 1 | | | | | .063[a] | |
| | OK Test – Week 0 | -.119 | .070 | -.250 | | |
| Step 2 | | | | | .215[b]* | .153 |
| | OK Test – Week 0 | -.105 | .069 | -.222 | | |
| | SF-36: Role-Physical | -.014 | .012 | -.187 | | |
| | SF-36: Bodily Pain | -.022 | .022 | -.170 | | |
| | Cook-Medley | .148 | .104 | .205 | | |
| Step 3 | | | | | .288[c] | .072 |
| | OK Test – Week 0 | -.058 | .076 | -.122 | | |
| | SF-36: Role-Physical | -.014 | .013 | -.192 | | |
| | SF-36: Bodily Pain | -.014 | .023 | -.108 | | |
| | Cook-Medley | .138 | .104 | .191 | | |
| | RCFT Copy | -.148 | .105 | -.244 | | |
| | RCFT Immediate | .002 | .091 | .004 | | |
| | WCST Trials | .013 | .021 | .105 | | |

*Note.* No demographic/disease variables met inclusion criterion for this regression model.

[a] adjusted $R^2$ = .041 [b] adjusted $R^2$ = .137 [c] adjusted $R^2$ = .153

*$p < .05$.

***Summary of perceived learning.*** As anticipated, the inclusion of neuropsychological variables did not significantly improve the staff-perceived learning models. In fact, the neuropsychological variables having utility in the prediction of the specific learning outcomes predicted through the Documented Learning models did not qualify for inclusion in these models. Program-specific knowledge at the time of program entry (Ornish Knowledge Test – Week 0) figured prominently in predicting Nutritionist Perceived Learning although none of the subcomponent neuropsychological skills that support in-program knowledge acquisition qualified for inclusion in the models predicting staff-perceived learning. Specifically, neither explicit verbal memory nor verbal working memory tests (that have documented importance to Ornish-specific knowledge acquisition and improvements in diary-keeping) qualified for inclusion in these models. Both the nutritionist and the case manager were able to accurately perceive the "sloppiness" marker (i.e., negative correlation between RCFT Copy and staff-perceived ratings of learning) but not the verbal learning skills that facilitate improvements in knowledge acquisition and diary-keeping. Finally, of anecdotal interest is that both the nutritionist and case manager were more likely to rate participants as having learning problems if these individuals self-reported higher levels of hostility at the time of program entry, thus raising the possibility of contamination by way of rater bias.

#### 4.4.2.3. Summary: Cognitive Learning Outcomes

Table 31 provides a summary of the learning outcomes predicted in this study. As expected, neuropsychological predictors made highly significant contributions to the Documented Learning regression models where the total amount of explained variance ranged

from 53% to 90%. Without these, the amount of explained variance in the Documented Learning drops to a range of 48.3% to 61.3%. Also anticipated was that program staff would not be able to recognize the strengths and weaknesses most important to program-specific knowledge acquisition and diary-keeping improvements. Both the nutritionist and the case manager were able to accurately recognize the relevance of the sloppiness marker – the neuropsychological variable sensitive to spatial and graphomotor accuracy (RCFT copy). These findings suggest that program staff recognized improvements in neatness and procedural mastery, along with participants' general fund of Ornish-specific information, as the primary manifestations of learning but not the verbal memory skills that facilitated improvements in those areas. Another noteworthy aspect was that participants' self-ratings of hostility at the time of program entry qualified for each regression model. This suggests that staff appraisals of learning could have been more greatly influenced by rater bias in response to the personality attributes (i.e., hostility) of participants rather than their actual learning/memory abilities.

Finally, of the nine regression models developed in Study 1, the models for staff-perceived learning were among the weakest (as defined the composite $R^2$ of the model with all qualifying variables entered). The only exception was Group Support Adherence – this outcome joined the staff appraisal models as one of the three weakest models. This is relevant for two reasons. First, Group Support Adherence is the only outcome reviewed thus far which includes staff appraisals in the computation of this adherence outcome. Second, the ratings provided by staff and participants for this adherence outcome are highly subjective. In essence, both parties simply provide their perception of involvement in the group support process. This is unlike any of the other outcomes, even the other behavioral adherence outcomes that rely on diary self-report to determine adherence. For the dietary, exercise, and stress management components of

the program, there are highly structured reporting guidelines and specific quantitative and qualitative benchmarks specified in the behavioral prescriptions that must be met and reflected through diary entries.

**Table 31 Summary of Documented and Perceived Learning Outcomes**

| *Outcome* | $R^2$ | adjusted $R^2$ | β | *t* | *p* |
|---|---|---|---|---|---|
| *Documented Learning* | | | | | |
| *Ornish Knowledge Test (Week 12)* | *.626* | *.532* | | | *<.0005* |
| Ornish Knowledge Test (Week 0) | | | .335 | 2.590 | .014 |
| (Four-Word Short-Term Memory – 30") | | | (.217) | (1.566) | (.127) |
| *Food Diary Learning Slope* | *.895* | *.825* | | | *<.0005* |
| RCFT Copy | | | -.528 | -4.935 | .0005 |
| Four-Word Short-Term Memory – 5" | | | .392 | 3.235 | .007 |
| *Perceived Learning* | | | | | |
| *Nutritionist* | *.363* | *.261* | | | *.020* |
| (Ornish Knowledge Test (Week 0) | | | (-.345) | (-1.971) | (.060) |
| (RCFT Copy) | | | (-.274) | (-1.430) | (.165) |
| *Case Manager* | *.288* | *.153* | | | *.064* |
| (RCFT Copy) | | | (-.244) | (-1.413) | (.166) |
| (Cook-Medley) | | | (.191) | (1.323) | (.194) |

*Note.* $R^2$ and adjusted $R^2$ values are for the regression models including all predictors. For any model having less than 2 predictors significant at the $p < .05$ level, the predictors closest to reaching statistical significance are included in parentheses.

The next and final outcome, Stratification to Phase II, also relies on staff appraisals although this stratification is governed by decision-tree pathways with specific qualitative and quantitative cut-off criteria. Phase II stratification is the level of program intensity recommended for each participant based on his/her adherence and the coronary risk reductions realized during the first twelve weeks of the program. In addition to highly specific selection criteria related to the nature and severity of disease factors, adherence levels are also considered (i.e., minimum behavioral prescription adherence levels) in the context of this stratification.

### 4.4.3. Stratification to Phase II

At the end of twelve weeks, Ornish program participants are stratified into one of four levels of program intensity. From least to most intensive, these include the Self-Directed Community (SDC) and Phases IIA, IIB, and IIC. The Self-Directed Community (SDC) is a network of community-based groups in suburban neighborhoods that is governed by other program participants. The content of these programs vary by location, although most offer weekly group support, related group activities such as potluck dinners and/or restaurant outings, and some include structured sessions of stress management. Only those individuals with minimal cardiac risk factors and/or the best adherence during the first twelve weeks are stratified directly into the SDC. The nature of cardiac risks in most Ornish program participants are such that the majority of participants are stratified into one of three Phase II tracks. Phase IIA is the least intensive of the Phase II programs. This provides continuation of the program-based Group Support and Stress Management for an additional twelve weeks after which participants enter the SDC. More intensive programming is found in Phases IIB and IIC. Phase IIB extends Group

Support and Stress Management for six months. Phase IIC is the most rigorous, providing structured exercise sessions, group support, stress management, and a group meal for an additional nine months. For each participant, these stratification decisions are made not only on the basis of cardiac risk factors but also, specific minimum adherence guidelines for each of the four components of the program and psychosocial factors (such as levels of depressive symptoms and social support) reported at Week 12.

In this sample of 46 participants, only one participant was stratified directly into the Self-Directed Community (SDC). A majority ($n$ = 24) were stratified to Phase IIA. Seventeen participants were stratified to Phase IIB and three, to Phase IIC. One participant was not stratified into any of the Phase II groups; this individual chose to drop out of the program at the end of twelve weeks. For this study, these four stratification groups were collapsed into two groups. Group A included the Self-Directed Community (SDC) and Phase IIA ($n$ = 25) and Group B, Phases IIB and IIC ($n$ = 20). Due to missing data for some of the qualifying predictors, the sample size was reduced to 43 subjects (Group A: $n$ = 24, Group B: $n$ = 19). Binary logistic regression was used to predict stratification to Groups A and B. The same predictor categories used for the other regression models were used for this model. The only exception was that the hospital site predictor (Site 1, 2) was not included in this regression model; it was already known that all participants from Mon-Valley Hospital (Site 2) were stratified into Group B (Phases IIB or IIC). Another deviation was that a more stringent selection criterion was used ($p < .05$). The reason for doing so was to increase the subject to predictor ratio. (This dichotomous outcome had only twenty (or slightly more) participants in each of the two outcome groups.) Consistent with the other regression models, the same hierarchical sequence of variable entry described previously was used to construct this model.

Tables 32 and 33 provide the descriptive statistics and intercorrelation matrices for the variables qualifying as predictors for Phase II Stratification. Two disease variables (Diabetes Mellitus and a specific cardiac surgery, PTCA/Stent) qualified for inclusion in this model.

**Table 32 Descriptive statistics for Phase II Stratification and predictor variables (n = 43)**

| *Variables* | *Mean* | *Range* | *SD* |
|---|---|---|---|
| Phase II Stratification[a] | 1.44 | 1 – 2 | .50 |
| PTCA/Stent Surgery[b] | .24 | 0 – 1 | .43 |
| Diabetes[b] | .43 | 0 – 1 | .50 |
| SF – 36: Role Physical | 67.78 | 0 – 100 | 42.18 |
| SF – 36: General Health | 59 | 0 – 97 | 23.20 |
| Cook-Medley Hostility Scale | 6.83 | 0 – 19 | 4.25 |
| WCST Trials | 104.80 | 68 – 128 | 23.93 |
| Four-Word Short-Term Memory – 15” | 10.53 | 4 – 20 | 3.60 |

[a] 1 = Self-Directed Community & Phase IIA; 2 = Phases IIB & IIC

[b] absent = 0, present = 1

**Table 33 Intercorrelations between Phase II Stratification and predictor variables**

| *Variables* | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
|---|---|---|---|---|---|---|---|---|
| 1. Phase II Stratification | — | .382** | .640** | -.356* | -.389** | .429** | .295* | -.425** |
| 2. PTCA/Stent Surgery | | — | .125 | -.366* | -.063 | .302* | .235 | -.143 |
| 3. Diabetes | | | — | -.230 | -.367* | .068 | .183 | -.172 |
| 4. SF – 36: Role Physical | | | | — | .385** | -.115 | -.331* | .083 |
| 5. SF – 36: General Health | | | | | — | -.198 | -.166 | .193 |
| 6. Cook-Medley Hostility Scale | | | | | | — | .141 | -.057 |
| 7. WCST Trials | | | | | | | — | -.205 |
| 8. Four-Word Short-Term Memory – 15” | | | | | | | | — |

* $p < .05$. ** $p < .01$.

Table 34 shows that by using only the disease variables, a reliable and statistically significant predictive model was found ($\chi^2$ (2, $N = 43$) = 23.958, $p < .0005$). These variables explained between 43% and 57% of the stratification decision (Cox & Snell $R^2 = .427$, Nagelkerke $R^2 = .572$). Using these disease variables alone, individuals who were stratified to

the more intensive Group B (Phases II B and II C) were classified with 90% accuracy although a 25% misclassification rate was found for those stratified into the less intensive Group A (SDC and Phase IIA). The overall classification accuracy of the model including only disease variables was 81.4%. Also including the three qualifying psychological variables improved the classification accuracy for Group A from 75% to 91.7% but at the cost of diminishing classification accuracy for Group B from 90% to 73.7%. Including both the disease and psychological predictors resulted in a modest but significant boost in the overall classification rate, raising this from 81.4% to 83.7% ($\Delta\chi^2$ (5, $N$ = 43) = 9.358, $p$ = .025). The amount of variance explained through the combination of disease and psychological predictors ranged from 54% to 72% (Cox & Snell $R^2$ = .539, Nagelkerke $R^2$ = .722). The introduction of the two qualifying neuropsychological variables resulted in a significant increment in explained variance and classification accuracy. The amount of explained variance is increased to an interval of 64% to 85% (Cox & Snell $R^2$ = .637, Nagelkerke $R^2$ = .834). Only one participant stratified to Group A, and two participants stratified to Group B, were misclassified. The overall classification accuracy of the model was 93%. The omnibus tests of model coefficients indicate that the model as a whole is reliable and statistically significant ($\chi^2$ (7, $N$ = 43) = 43.618, $p$ < .0005). With all variables entered, two variables made statistically significant contributions at $p$ < .05 (Diabetes Mellitus: $p$ = .028 and Four Word Short-Term Memory – 15": $p$ = .043). Also, self-reported hostility was on the cusp of significance (Cook-Medley: $p$ = .054).

In summary, coronary risk factors and specifically, the presence/absence of Diabetes Mellitus was a strong predictor of Phase II Stratification. Of all potential predictors, the only other variable that made a statistically significant contribution to the accurate prediction of Phase II Stratification was a measure of verbal working memory. This is no surprise given that this

neuropsychological construct made significantly unique contributions to five of the six of the documented learning and behavioral adherence models.

**Table 34 Hierarchical logistic regression for Phase II Stratification (n = 43)**

| *Model* | *Variables* | *B* | *Wald* | *Cox & Snell $R^2$* | *Nagelkerke $R^2$* | *Odds Ratio* |
|---|---|---|---|---|---|---|
| Step 1 | | | | .427 | .572 | 81.4%[a] |
| | PTCA/Stents | 2.507 | 4.995* | | | |
| | Diabetes | 3.194 | 12.020*** | | | |
| Step 2 | | | | .539 | .722 | 83.7%[b] |
| | PTCA/Stents | 3.251 | 3.311 | | | |
| | Diabetes | 3.648 | 7.223** | | | |
| | SF-36: Role-Physical | -.019 | 1.008 | | | |
| | SF-36: General Health | -.018 | .366 | | | |
| | Cook-Medley | .435 | 4.017* | | | |
| Step 3 | | | | .637 | .854 | 93%[c] |
| | PTCA/Stents | 6.927 | 3.234 | | | |
| | Diabetes | 6.965 | 4.844* | | | |
| | SF-36: Role-Physical | -.050 | 1.744 | | | |
| | SF-36: General Health | .007 | .020 | | | |
| | Cook-Medley | .995 | 3.722* | | | |
| | WCST Trials | -.026 | .488 | | | |
| | Four-Word Short-Term Memory – 15” | -.713 | 4.090* | | | |

[a] 75% for Group A (SDC & Phase IIA); 89.5% for Group B (Phase IIB & IIC)

[b] 91.7% for Group A (SDC & Phase IIA); 73.7% for Group B (Phase IIB & IIC)

[c] 95.8% for Group A (SDC & Phase IIA); 89.5% for Group B (Phase IIB & IIC)

*$p < .05$. **$p < .01$. ***$p \leq .001$.

### 4.4.4. Summary of Study 1: Model Building

Study 1 primarily addressed the first research question – Do neuropsychological variables significantly improve the prediction of cardiac rehabilitation outcomes beyond what is accounted for by program knowledge, demographic, disease, and psychological variables? This question was addressed through the development of nine hierarchical regression models where the neuropsychological variables were the last to enter each model. The cardiac rehabilitation outcomes of interest included adherence to behavioral prescriptions, program-specific learning, and the level of program intensity recommended at the end of 12 weeks (Phase II Stratification). The inclusion of neuropsychological variables made statistically significant contributions to all four adherence outcomes (dietary, exercise, group support, and stress management), one aspect of cognitive learning (i.e., improvements in diary-keeping skills), and Phase II stratification. While the inclusion of neuropsychological predictors did not always improve the amount of explained variance, the standardized (β) coefficients for each of these variables ranked either first or second in each model once all variables were entered. Therefore, results of Study 1 demonstrate that the inclusion of neuropsychological variables significantly improved the amount of explained variance in a majority of these predictive models. Moreover, unique contributions were made by the neuropsychological variables in each of the predictive models after all variables were entered.

## 4.5. Study 2: Model Refinement

The primary purpose of Study 2 was to refine the regression models presented in Study 1 and determine which demographic, disease, psychological, and neuropsychological variables were most important to include in each model. The process of model refinement involved the systematic elimination of variables based on the standardized (β) coefficients and corresponding *p* values. This process involved eliminating the variable that contributed least to each regression model and subsequently, reviewing the model to identify the next weakest predictor to eliminate. This process was repeated until left with those variables making the most substantial and unique contributions to the model as determined by both *p* values and the decrement in adjusted $R^2$ values when these predictors were removed. To remain in the model, a general benchmark of $p < .05$ was used for all variables in the regression equation although for three of the linear models, this was relaxed to $p < .10$. In those cases, a single variable in each equation did not meet the cut-off of $p < .05$ ($p = .056$, $p = .065$, $p = .087$) but its inclusion boosted the adjusted $R^2$ value by $\geq 5\%$. This relaxed benchmark of $p < .10$ was also used for the single logistic regression model (Phase II Stratification). In this case, two of the four predictor variables were not significant at $p < .05$ although eliminating them from the model resulted in a very significant decrement in explained variance and classification accuracy.

For each outcome, the final model is presented along with a review of the viability and stability of each model based on the collinearity diagnostics that were completed. Rule-of-thumb benchmarks for Tolerance, VIF, condition indices, and variance proportions were used to assess problems with multicollinearity (Garson, 2005; Tabachnick & Fidell, 1996, p. 87). For

Tolerance and VIF, values indicating problems with multicollinearity were < .2 and > 4, respectively. Scores on the condition indices were evaluated to determine whether there were possible (≥15) or probable (≥30) problems with multicollinearity. None of the models had condition indices ≥30. For models indicating possible multicollinearity (≥15), this was further explored by reviewing variance proportions. Conservative criteria were used to identify problems with multicollinearity; specifically, multicollinearity was considered problematic if condition indices ≥15 had more than two variance proportions exceeding 0.5 for a given root number. No models met these criteria and therefore, no problems with multicollinearity were identified for any of the regression models.

### 4.5.1. Behavioral Prescription Adherence

#### 4.5.1.1. Dietary Adherence

Table 35 shows the final model for Dietary Adherence is highly significant and explains approximately 30% of the variance in this outcome ($F(2,42) = 10.363$, $p < .0005$). Only two predictors remained in the model and both were neuropsychological variables. One of the executive control predictors (WCST Trials to Complete 1st Category) explained more than 20% of this variance ($F(1,43) = 13.011$, $p < .001$; $R^2 = .232$, adjusted $R^2 = .299$). An additional 8-10% of the variance is explained through the inclusion of a test of verbal working memory, the Four Word Short-Term Memory – Total, and this increment is statistically significantly ($\Delta F$ (1,42) = 6.155, $p = .017$). The Tolerance values for both predictor variables were .994 and the VIF values, 1.006. No problems with multicollinearity were suggested through these values or the condition index of 8.796.

**Table 35 Final regression model for Dietary Adherence**

| *Model* | *Variables* | *B* | *SE B* | β | $R^2$ | $\Delta R^2$ |
|---|---|---|---|---|---|---|
| Step 1 | | | | | .232[a]*** | |
| | WCST Trials to Complete 1st Category | -.130 | .036 | -.482*** | | |
| Step 2 | | | | | .330[b]**** | .098* |
| | WCST Trials to Complete 1st Category | -.123 | .034 | -.458*** | | |
| | Four-Word Short-Term Memory – Total | .183 | .074 | .314* | | |

[a] adjusted $R^2$ = .214 [b] adjusted $R^2$ = .299

* $p < .05$. ** $p < .01$. *** $p \leq .001$. **** $p < .0005$.

#### 4.5.1.2. Exercise Adherence

Table 36 shows that four variables were retained in the final regression model for Exercise Adherence. This regression model was similar to the Dietary Adherence model in two ways. First, the model as a whole was highly significant. Approximately 50% of the variance in Exercise Adherence is accounted for by the model ($F(4,40) = 10.322$, $p < .0005$). Second, the two neuropsychological variables included as predictors were executive control (WCST

Perseverative Responses: β = -.330, $t$ = -2.753, $p$ = .009) and a measure of verbal working memory that assesses one's susceptibility to interference (CVLT List B: β = .294, $t$ = 2.590, $p$ = .013). (*Note.* It is important to highlight the significance of the negative relationship between WCST Perseverative Responses and Exercise Adherence. This shows that those who were less perseverative (i.e., more cognitively flexible) in novel problem solving had better adherence.) While each of these neuropsychological variables contributed significantly to the final model, the contributions made by subjects' self-reported physical vitality (SF-36: Vitality) and environmental demands (MPED Busyness) were relatively greater. This is no surprise. Logically, adherence to the exercise prescription is influence by physical vitality as well as finding the time to exercise each day. The Tolerance and VIF values for these four variables ranged from .858 to .958 and 1.044 to 1.165, respectively, and the condition index was 15.498. While this was at level where multicollinearity was a possibility, inspection of the variance proportions did not support this. For each dimension of the model, the benchmark of possible collinearity problems (i.e., condition index $\geq$ 15; the variance proportions on two or more dimensions exceeding .50) was not found. Therefore, no problems with multicollinearity were identified in the final Exercise Adherence model.

**Table 36 Final regression model for Exercise Adherence**

| *Model* | *Variables* | *B* | *SE B* | β | $R^2$ | $\Delta R^2$ |
|---|---|---|---|---|---|---|
| Step 1 | | | | | .190[a]** | |
| | SF-36: Vitality | .447 | .140 | .436** | | |
| Step 2 | | | | | .306 [b]**** | .115* |
| | SF-36: Vitality | .440 | .132 | .430** | | |
| | MPED Busyness | -1.544 | .584 | -.340* | | |
| Step 3 | | | | | .425[c]**** | .120** |
| | SF-36: Vitality | .363 | .124 | .355** | | |
| | MPED Busyness | -2.042 | .564 | -.450*** | | |
| | WCST Perseverative Responses | -.553 | .189 | -.370** | | |
| Step 4 | | | | | .508[d]**** | .083* |
| | SF-36: Vitality | .419 | .118 | .409*** | | |
| | MPED Busyness | -1.947 | .530 | -.429*** | | |
| | WCST Perseverative Responses | -.493 | .179 | -.330** | | |
| | CVLT List B | 3.632 | 1.402 | .294* | | |

[a] adjusted $R^2$ = .171 [b] adjusted $R^2$ = .273 [c] adjusted $R^2$ = .383 [d] adjusted $R^2$ = .459

* $p < .05$. ** $p < .01$. *** $p \leq .001$. **** $p < .0005$.

#### 4.5.1.3. Group Support Adherence

The amount of explained variance in Group Support Adherence was relatively less than the Dietary and Exercise Adherence outcomes. Nonetheless, Table 37 shows that a significant regression model was found ($F(2,42) = 7.052$, $p < .002$). There were no concerns about collinearity problems in the final Group Support Adherence model. Each of the Tolerance and VIF values were .961 and 1.041, respectively, and the condition index was 7.335.

**Table 37 Final regression model for Group Support Adherence**

| *Model* | *Variables* | *B* | *SE B* | β | $R^2$ | $\Delta R^2$ |
|---|---|---|---|---|---|---|
| Step 1 | | | | | .076[a] | |
| | SF-36: General Health | .127 | .067 | .276 | | |
| Step 2 | | | | | .251[b]** | .175** |
| | SF-36: General Health | .165 | .062 | .361* | | |
| | RCFT Delay | -.728 | .232 | -.427** | | |

[a] adjusted $R^2 = .055$ [b] adjusted $R^2 = .216$

* $p < .05$. ** $p < .01$.

Of the 22% of the variance explained by the model, the majority of this was attributed to the negative relationship between RCFT Delayed Recall and the Group Support outcome. This measure of short-term spatial memory accounted for approximately 17% of the variance in Group Support Adherence ($\Delta F(1,42) = 9.827$, $p < .003$). The other variable which qualified for inclusion in the model was the subjective perception of general health status assessed through

SF-36: General Health. This accounted for approximately 5.5% of the 22% of explained variance and without RCFT Delay Recall, did not produce a statistically significant model ($F(1,43) = 3.548$, $p < .066$).

The clinical significance of the negative relationship between spatial memory (RCFT Delayed Recall) and Group Support Adherence is not definitively known. It is possible that this reflects a subjective reporting bias, directly attributed to the presence of this specific neuropsychological impairment. In other words, those with greater impairments of spatial memory are more likely to erroneously report better participation in the group support process. It is possible that these individuals do not accurately perceive and remember nonverbal forms of social communication. Because they miss this feedback and have poor recall of the group when later completing their diaries, they may erroneously report high levels of Group Support Adherence. In addition, this outcome is further contaminated by the subjective reports provided by staff that also contribute to these adherence scores.

The relevance of the Group Support Adherence model is threefold. First, the nature of how adherence to Group Support is quantified is problematic. The use of entirely subjective reports from both participants and staff was likely a primary cause of the weak predictive model. Second, the subjective reporting from participants could be contaminated by inaccurate nonverbal recall of the actual group session. Third, these findings point to the problems of subjective self-reporting in neuropsychologically-impaired individuals. More structured reporting – as is used for the other components of the Ornish program – is preferred for these individuals.

#### 4.5.1.4. Stress Management Adherence

The final regression model for Stress Management Adherence is found in Table 38. Three variables were retained in the model and these explained approximately 30% of the variance in this outcome ($F(3,40) = 6.477$, $p < .001$). The Tolerance and VIF values for the predictive model ranged from .877 to .940 and 1.064 to 1.140, respectively, and the condition index was 15.260. While this was at a level where multicollinearity was a possibility, review of the variance proportions suggested no such problems. For each dimension of the model, the benchmark of possible collinearity problems (i.e., more than two variance proportions exceeding .50) was not found. Therefore, no problems with multicollinearity were identified in the Stress Management Adherence model.

**Table 38 Final regression model for Stress Management Adherence**

| *Model* | *Variables* | *B* | *SE B* | β | $R^2$ | $\Delta R^2$ |
|---|---|---|---|---|---|---|
| Step 1 | | | | | .098[a]* | |
| | SF-36: Mental Health | .287 | .134 | .314* | | |
| Step 2 | | | | | .183[b]* | .085* |
| | SF-36: Mental Health | .221 | .133 | .242 | | |
| | MPED Busyness | -.889 | .432 | -.300* | | |
| Step 3 | | | | | .327[c]*** | .144** |
| | SF-36: Mental Health | .241 | .122 | .263 | | |
| | MPED Busyness | -1.205 | .411 | -.406** | | |
| | Four-Word Short-Term Memory – 15" | 1.864 | .637 | .396** | | |

[a] adjusted $R^2 = .077$ [b] adjusted $R^2 = .143$ [c] adjusted $R^2 = .276$

* $p < .05$. ** $p < .01$. *** $p \leq .001$.

The two psychological variables included in the final regression model were self-perceived mental health (SF-36: Mental Health) and busyness (MPED Busyness). The contribution made by busyness was relatively greater ($\Delta F(1,42) = 4.583$, $p < .038$ and $F(2,41) = 4.591$, $p < .016$, respectively). These variables have high face validity for predicting Stress Management adherence – individuals with more positive appraisals of their own mental health may be better able to adhere to the stress management techniques taught in the program by virtue of healthy emotional adjustment and perhaps, greater capacities for mental discipline. However, the time demands of adhering to the Stress Management prescription are steep – one full hour per day – in addition to the time devoted to exercise, food preparation, diary completion, and other Ornish lifestyle demands. It is not surprising that self-perceived busyness would be a strong predictor of adherence for this time-challenging aspect of the program and also, that this aspect of the program evidenced the lowest adherence for the sample.

While the busyness factor made a substantial contribution to the Stress Management Adherence model (i.e., higher busyness = lower adherence), the significance of this was superseded by verbal working memory. Adding the Four-Word Short Term Memory – 15" recall subtest resulted in a highly significant $R^2$ increment of 14.4% ($\Delta F(1,40) = 8.577$, $p < .006$) and this variable alone accounted for almost half of the total explained variance in the model. The clinical relevance of this is not entirely clear beyond the role it may play in executing the practice of stress management techniques. For example, verbal working memory may help the participant remember specific directions/instructions and facilitate silent self-cueing in the midst of yoga practice. Also, the executive control aspect of working memory may be engaged to help juggle the competing time demands of a busy day to ensure that the required hour is completed. In addition, the predictive potency of this variable underscores the general importance of

neuropsychological integrity to Stress Management Adherence which presents the greatest challenge to participants.

#### 4.5.1.5. Summary: Final Models for Behavioral Prescription Adherence

Table 39 provides a summary of the final regression models for these outcomes. The amount of explained variance in the adherence to behavioral prescriptions ranged from 22% (Group Support) to 51% (Exercise). In all but one of the models (Exercise Adherence), neuropsychological variables made the most unique and statistically significant contributions. For the exception, Exercise Adherence, a neuropsychological variable ranked third in significance and was superseded only by variables with obvious pragmatic significance to the execution of the exercise prescription (i.e., physical vitality, busyness). Qualitatively, measures of verbal working memory were the most strongly represented of all of the neuropsychological variables, followed by measures of executive control. Tests of verbal working memory were included in three of the four final models and executive control, in two of the four models. While all of the final regression models were significant at $p < .01$, the aspects of behavioral prescription adherence having the strongest final regression models were Dietary and Exercise Adherence ($p < .0005$). For both of these, verbal memory and executive control made very significant contributions. The predictive utility of verbal working memory and environmental demands (i.e., busyness) to Stress Management Adherence are important to underscore given that together, these explain approximately 20% of the variance in this outcome. Because this component of the program shows the lowest adherence ($M = 75.45\%$, $SD = 16.92$), it would be useful to identify these limiting features at the outset of the program. However, neither measures

of busyness nor verbal working memory are currently included in the routine screening measures administered to prospective Ornish program participants.

**Table 39 Summary of final regression models for Behavioral Adherence Outcomes**

| *Outcome* | $R^2$ | adjusted $R^2$ | β | *t* | *p* |
|---|---|---|---|---|---|
| *Dietary Adherence* | *.330* | *.299* | | | *< .0005* |
| WCST Trials to Complete 1st Category | | | -.458 | -3.621 | .001 |
| Four-Word Short-Term Memory - Total | | | . 314 | 2.481 | .017 |
| *Exercise Adherence* | *.508* | *.459* | | | *< .0005* |
| MPED Busyness | | | -.429 | -3.674 | .001 |
| SF-36: Vitality | | | .409 | 3.543 | .001 |
| WCST Perseverative Responses | | | -.330 | -2.753 | .009 |
| CVLT List B | | | .294 | 2.590 | .013 |
| *Group Support Adherence* | *.251* | *.216* | | | *.002* |
| RCFT Delay | | | -.427 | -3.135 | .003 |
| SF-36: General Health | | | .361 | 2.648 | .011 |
| *Stress Management Adherence* | *.327* | *.276* | | | *.001* |
| MPED Busyness | | | -.406 | -2.932 | .006 |
| Four-Word Short Term Memory – 15” | | | .396 | 2.925 | .006 |
| SF-36: Mental Health | | | .263 | 1.969 | .056 |

*Note.* $R^2$ and adjusted $R^2$ values are for the final regression models.

### 4.5.2. Cognitive Learning Outcomes: Documented and Perceived Learning

#### 4.5.2.1. Documented Learning

***Documented Learning: Ornish Knowledge Test (Week 12).*** This predictive model was the most robust of all the predictive models developed in this research ($F(3,37) = 17.472$, $p < .0005$). The strength of the model is further boosted by the absence of any indicators of multicollinearity. The Tolerance and VIF values ranged from .646 to .821 and 1.218 to 1.548, respectively and the condition index was 10.496.

Table 40 shows that more than 55% of the variance in Ornish-specific knowledge acquisition is explained by two forms of verbal memory (explicit and working memory) and the amount of program-specific knowledge participants possessed at the time of program entry. The contribution of explicit verbal memory, as assessed through CVLT Short Delay Free Recall, is vital. When the effects of the other two variables are statistically controlled for, more than 20% of the explained variance is attributed to this measure of explicit verbal memory ($\Delta F(1,38) = 17.420$, $p < .0005$). Verbal working memory, as assessed by the Four Word Short-Term Memory Test, also made a statistically significant, but less unique, contribution to the model. The inclusion of this variable explained an additional 5% of the variance and this increment was significant at $p < .05$ ($\Delta F(1,37) = 4.765$, $p = .035$). With all variables entered into the model, approximately half of the variance is explained by the combination of these two aspects of verbal memory and the other half, the amount of Ornish-specific knowledge participants' possessed at the time of program entry.

**Table 40 Final regression model for Ornish Knowledge Test (Week 12)**

| *Model* | *Variables* | *B* | *SE B* | β | $R^2$ | $\Delta R^2$ |
|---|---|---|---|---|---|---|
| Step 1 | | | | | .319[a]**** | |
| | OK Test – Week 0 | .630 | .148 | .565**** | | |
| Step 2 | | | | | .533[b]**** | .214**** |
| | OK Test – Week 0 | .390 | .137 | .349** | | |
| | CVLT Short Delay Free Recall | 1.168 | .280 | .511**** | | |
| Step 3 | | | | | .586[c]**** | .053* |
| | OK Test – Week 0 | .385 | .130 | .345** | | |
| | CVLT Short Delay Free Recall | .864 | .301 | .378** | | |
| | Four Word Short Term Memory – 30” | .492 | .225 | .267* | | |

[a] adjusted $R^2$ = .301 [b] adjusted $R^2$ = .508 [c] adjusted $R^2$ = .553

*$p$ < .05. **$p$ < .01. ***$p \leq$ .001. ****$p$ < .0005.

***Documented Learning: Food Diary Learning Slope.*** In Study 1, this model explained the greatest amount of variance of all the outcome models ($R^2$ = .895, adjusted $R^2$ = .825). However, that unrefined model was viewed as unstable and unreliable due to the low subject to predictor ratio (3:1). Table 41 shows that the refined model includes only two variables and together, these explain approximately 50% of the variance in food diary error reduction. The statistical significance of the model was high ($F(2,20) = 12.092$, $p$ < .0005) and the subject to predictor ratio was no longer problematic (approximately 12:1). Also, no collinearity problems

were identified. The Tolerance and VIF values for both variables were .962 and 1.039, respectively, and the condition index was 13.761.

**Table 41 Final regression model for Food Diary Learning Slope (n = 23)**

| *Model* | *Variables* | *B* | *SE B* | β | $R^2$ | $\Delta R^2$ |
|---|---|---|---|---|---|---|
| Step 1 | | | | | .184[a]* | |
| | RCFT Copy | -.076 | .035 | -.429* | | |
| Step 2 | | | | | .547[b]**** | .363*** |
| | RCFT Copy | -.098 | .027 | -.549** | | |
| | Four-Word Short-Term Memory 5” | .227 | .057 | .614*** | | |

[a] adjusted $R^2$ = .145 [b] adjusted $R^2$ = .502

*$p$ < .05. **$p$ < .01. ***$p \leq$ .001. ****$p$ < .0005.

The model was comprised of a measure of spatial-constructional accuracy (RCFT Copy) and verbal working memory (Four-Word Short Term Memory – 5”). Approximately two-thirds of the explained variance is attributed to this variable ($\Delta R^2$ = .363; $\Delta F(1,20)$ = 16.042, $p$ = .001). The “sloppiness” marker (i.e., negative standardized (β) coefficient for RCFT Copy) accounts for the other third of the variance in the rate of error reduction in food diaries. The practical interpretation of this is that these more superficial, procedural errors of diary-keeping may be quickly overcome when verbal working memory is intact.

***Summary of Documented Learning Final Regression Models.*** The amount of explained variance in these regression models was among the greatest of all of the models. Clearly, the important role of explicit verbal memory to Ornish-specific knowledge acquisition was demonstrated. The combination of explicit verbal memory and verbal working memory

accounted for as much variance in knowledge acquisition as baseline knowledge; in other words, simply knowing a bit about the Ornish lifestyle when participants enter the program does not mean they will know the most by the end of the twelve weeks. While baseline knowledge accounts for about half of the variance predicted in this aspect of learning, the other half is explained by the integrity of two aspects of verbal learning – explicit verbal recall and verbal working memory. The latter is also critically important to the accuracy of diary keeping and may be the strongest facilitator of overcoming procedural diary keeping problems, such as neatness, organization, and the general mastery of the diary reporting forms.

#### 4.5.2.2. Perceived Learning

***Nutritionist Perceived Learning.*** Table 42 shows that approximately 27% of the variance in Nutritionist Perceived Learning is explained by the model which includes two variables – Week 0 of the Ornish Knowledge Test and RCFT Copy (Table 68). Despite the limited amount of explained variance, the model is statistically significant ($F(2,27) = 6.290$, $p < .006$). No problems with multicollinearity were identified; both variables had Tolerance and VIF values of .936 and 1.069, respectively. The condition index was 13.220.

The reader will remember that high scores on the perceived learning outcomes indicate that staff recognized learning impairments. For Nutritionist Perceived Learning, these ratings of learning impairments seem to be most greatly influenced by the amount of Ornish-specific knowledge the participant possessed at the time of program entry. The nutritionist recognized the "sloppiness" marker although its contribution to the final model was minimal. This explained less than 8% of the variance in perceived learning and the significance of the

standardized (β) coefficient in the final regression model was significant only at $p < .10$ ($\beta = -.291$, $t = -1.773$, $p = .087$). By far, participants' fund of Ornish-specific information at the time of program entry explained the greatest proportion of variance in the learning perceived by the nutritionist (Ornish Knowledge Test – Week 0: $\beta = -.414$, $t = -2.521$, $p = .018$). Conspicuously absent from the model were any of the tests of verbal memory that were demonstrated to be instrumental to the acquisition of additional Ornish knowledge and improving the diaries reviewed by this nutritionist.

**Table 42 Final regression model for Nutritionist Perceived Learning (n = 30)**

| *Model* | *Variables* | *B* | *SE B* | β | $R^2$ | $\Delta R^2$ |
|---|---|---|---|---|---|---|
| Step 1 | | | | | .238[a]** | |
| | Ornish Knowledge Test (Week 0) | -.251 | .085 | -.488** | | |
| Step 2 | | | | | .318[b]** | .046 |
| | Ornish Knowledge Test (Week 0) | -.213 | .085 | -.414* | | |
| | RCFT Copy | -.152 | .085 | -.291 | | |

[a] adjusted $R^2 = .211$ [b] adjusted $R^2 = .267$

*$p < .05$. **$p < .01$.

To further underscore the inability of staff to recognize these problems without access to neuropsychological test results, attempts were made to predict the Nutritionist Perceived Learning outcome using the predictor variables from the refined Food Diary Learning Slope model. The reader will remember that the nutritionist reviews these food diaries on a weekly basis. Not only is he/she responsible for identifying any errors but also, providing the

appropriate guidance and education to resolve any learning problems identified in this area. If the neuropsychological abilities that mediate this kind of learning can be perceived without access to formal test results, the nutritionist is in the best position to do this. The breadth and depth of this individual's involvement in this aspect of the learning process is unparalleled by any other members of the treatment team.

This regression model is found in Table 43 and is referred to as the "Food Diary Model Applied to Nutritionist Perceived Learning." This includes the two variables (RCFT Copy and Four-Word Short Term Memory – 5") that explained more than 50% of the variance in the Food Diary Learning Slope ($F(2,20) = 12.092$, $p < .0005$). When these variables are used to predict Nutritionist Perceived Learning, less than 10% of the variance is explained and essentially, all of this which is attributed to the sloppiness marker (RCFT Copy). The most noteworthy disparity involved the relationship of verbal working memory to Nutritionist Perceived Learning. While the verbal working memory test alone explained more than one-third of the variance in the Food Diary Learning Slope model when paired with the RCFT Copy, verbal working memory explained essentially none of the variance in Nutritionist Perceived Learning ($\Delta R^2 = .001$; $\Delta F(1,27) = .048$, $p = .829$). Moreover, when this variable joined RCFT Copy in the model, this diluted its statistical significance. (Using the RCFT Copy variable only, a significant model is achieved which explains approximately 13% of the variance ($F(1, 28) = 5.222$, $p = .030$) but when the Four Word Short-Term Memory Test – 5" was introduced, the model was no longer significant ($F(2, 27) = 2.546$, $p = .097$)). Results suggest that the nutritionist correctly perceived the sloppiness (RCFT Copy) marker as a learning attribute in the context of improving diary accuracy although she failed to recognize the very important role that verbal working memory played in terms of overcoming this. Moreover, the nutritionist perceived that participants' fund

of Ornish-specific knowledge was relevant to learning (i.e., Week 0 scores of the Ornish Knowledge Test) but failed to accurately identify the neuropsychological processes that support this kind of knowledge acquisition.

**Table 43 Food Diary Model Applied to Nutritionist Perceived Learning (n = 30)**

| *Model* | *Variables* | *B* | *SE B* | β | $R^2$ | $\Delta R^2$ |
|---|---|---|---|---|---|---|
| Step 1 | | | | | .157* | |
| | RCFT Copy | -.206 | .090 | -.396* | | |
| Step 2 | | | | | .159 | .001 |
| | RCFT Copy | -.212 | .096 | -.408* | | |
| | Four-Word Short-Term Memory – 5” | .041 | .186 | .040 | | |

[a] adjusted $R^2$ = .127 [b] adjusted $R^2$ = .096

*$p$ < .05.

***Case Manager Perceived Learning.*** Two predictors remained in the final predictive model for this outcome (Table 44). Like the nutritionist, the case manager recognized the sloppiness marker (RCFT Copy) as an aspect of learning although this was the only neuropsychological variable retained in this refined model. The other predictor was the subjective report of physical well-being (SF-36: Role-Physical). No problems with collinearity were identified. The Tolerance and VIF values for both variables were 1.000 and the condition index was 14.975. The model as a whole was statistically significant ($F(2, 42) = 5.529$, $p = .007$) although of all the regression models developed in this study, the least amount of variance was explained by this model ($R^2 = .208$, adjusted $R^2 = .171$).

**Table 44 Final regression model for Case Manager Perceived Learning**

| *Model* | *Variables* | *B* | *SE B* | β | $R^2$ | $\Delta R^2$ |
|---|---|---|---|---|---|---|
| Step 1 | | | | | .092* | |
| | RCFT Copy | -.022 | .011 | -.304* | | |
| Step 2 | | | | | .208** | .116* |
| | RCFT Copy | -.022 | .010 | -.307* | | |
| | SF-36: Role-Physical | -.207 | .083 | -.341* | | |

[a] adjusted $R^2$ = .071 [b] adjusted $R^2$ = .171

*$p < .05$. **$p < .01$.

It is useful to consider this model relative to the role of the case manager in the context of the Ornish program. The case manager accompanies the participant to all aspects of program activities including educational lectures, stress management, group support, and exercise sessions. The only aspect of program learning and execution this individual is not involved in is the individualized learning that occurs through the nutritionist's review and critique of the food diaries. The case manager reviews diaries for the exercise, group support, and stress management components of the program although this review has more to do with procedural than factual accuracy. Some Ornish-specific instruction is provided in this context (e.g., reiterating specific aspects of the exercise and stress management prescriptions) but substantially less explicit learning is evaluated through these diaries. On the other hand, the case manager is a

much better position to evaluate other avenues of demonstrated learning given the opportunity to observe the participant as he/she engages in a broad range of program activities.

Learning problems perceived by the case manager appear to be most greatly influenced by the sloppiness marker (RCFT Copy) and participants' self-report of physical limitations. While the RCFT Copy variable is likely to be primarily reflected through the sloppiness of diaries for all components of the program, these limitations may also be reflected through any difficulties the participant may have encountered with the spatial demands of these other components of the program, such as spatial-motor accuracy of yoga postures and/or exercise activities. As was true for the nutritionist, the case manager seems to be responding to the end points of learning rather than the subcomponent learning skills that facilitate this learning and move the participant to these end points.

***Summary of Perceived Learning Final Regression Models.*** The models developed for staff-perceived learning explained the least amount of variance of all of the predictive models. The only other model to perform similarly low was the model for Group Support Adherence. Of interest is that this is the only other outcome that includes staff appraisals in the computation of the adherence outcome. None of the memory and executive control processes having demonstrated importance to Ornish-based learning and adherence outcomes were included in the regression models predicting staff-perceived learning. These findings support the extant literature showing that the kind of neuropsychological problems associated with cardiovascular disease are not identified through routine clinical contact.

#### 4.5.2.3. Summary: Final Regression Models for Cognitive Learning Outcomes

A summary of the final regression models for Documented and Perceived Learning is found in Table 45. As compared with all other outcome models developed in this research, the regression models developed for the Documented Learning outcomes explained the most variance and the Perceived Learning outcomes, the least. The finding that staff appraisals do not accurately predict adherence or specific learning outcomes is in no way a criticism of the clinical acumen of the professional staff working with these individuals. This is simply part and parcel of the veiled nature of neuropsychological impairments. The memory, executive control, and other cognitive processes that are paramount to Ornish-specific knowledge acquisition and adherence-based learning cannot be discerned through routine clinical contact. It is only through the administration of highly sensitive neuropsychological assessments that these cognitive facilitators of learning and adherence are identified.

**Table 45 Summary of final regression models for Documented and Perceived Learning Outcomes.**

| *Outcome* | $R^2$ | adjusted $R^2$ | β | *t* | *p* |
|---|---|---|---|---|---|
| *Documented Learning* | | | | | |
| *Ornish Knowledge Test (Week 12)* | *.586* | *.553* | | | *<.0005* |
| Ornish Knowledge Test (Week 0) | | | .345 | 2.956 | .005 |
| CVLT Short Delay Free Recall | | | .378 | 2.871 | .007 |
| Four-Word Short-Term Memory – 30” | | | .267 | 2.183 | .035 |
| *Food Diary Learning Slope*[a] | *.547* | *.502* | | | *<.0005* |
| RCFT Copy | | | -.549 | -3.577 | .002 |
| Four-Word Short-Term Memory – 5” | | | .614 | 4.005 | .001 |
| *Perceived Learning* | | | | | |
| *Food Diary Model Applied to Nutritionist Perceived Learning*[a] | *.159* | *.096* | | | *.097* |
| RCFT Copy | | | -.408 | -2.217 | .035 |
| Four-Word Short-Term Memory – 5” | | | .040 | .218 | .829 |
| *Nutritionist Perceived Learning* | *.318* | *.267* | | | *.006* |
| Ornish Knowledge Test (Week 0) | | | -.414 | -2.521 | .018 |
| RCFT Copy | | | -.291 | -1.773 | .087 |
| *Case Manager Perceived Learning* | *.208* | *.171* | | | *.007* |
| RCFT Copy | | | -.341 | -2.484 | .017 |
| SF-36: Role-Physical | | | -.307 | -2.239 | .031 |

*Note.* $R^2$ and adjusted $R^2$ values are for the final regression models.

[a] The nutritionist reviews participants’ daily food diaries. If the nutritionist can accurately detect learning problems in participants, we would expect these to be the same variables included in the Food Diary Learning Slope model. However, when this model is used to predict the nutritionist’s ratings of perceived learning, it performs poorly.

### 4.5.3. Phase II Stratification: Final Regression Model

The reader will recall that the Phase II Stratification outcome involves dichotomous rather than continuous data which necessitated the use of logistic regression. This model examines the accuracy of using pre-program data to predict whether participants are stratified to less versus more intensive programming at the end of the first twelve weeks (Group A = Self-Directed Community and Phase IIA; Group B = Phases IIB and IIC). The final regression model for Phase II Stratification is found in Table 46. Four predictors were retained in this final regression model, including two physiological variables (Diabetes Mellitus and a specific cardiac surgery, PTCA/Stent), self-reported hostility (Cook-Medley), and a single neuropsychological predictor (Four-Word Short Term Memory – 15"). Using a hierarchical method of variable entry, we find that approximately half of the variance in this outcome is explained by the physiological variables alone and especially, the presence/absence of Diabetes Mellitus (Cox & Snell $R^2$ = .432, Nagelkerke $R^2$ = .578). These disease variables alone can accurately classify 81.8% of the participants although Group B classification is superior (90%) to Group A (75%). The addition of the Cook-Medley improves the overall level of explained variance (Cox & Snell $R^2$ = .524, Nagelkerke $R^2$ = .700) but this does not change classification accuracy (79.5%). Essentially, the addition of the Cook-Medley reverses the characteristics of classification accuracy for Groups A and B. Group A is more accurately classified (87.5%) although Group B classification drops to 70%. Only when the measure of verbal working memory (Four Word Short-Term Memory – 15") is introduced into the model do we observe a significant increment in both explained variance and classification accuracy. Explained variance rises to approximately 75% and overall classification accuracy, 95.5%. Moreover, only two participants

were misclassified using this final regression model for Phase II Stratification which included a measure of verbal working memory.

**Table 46 Final regression model for Phase II Stratification (n = 44)**

| *Model* | *Variables* | *B* | *Wald* | *Cox & Snell $R^2$* | *Nagelkerke $R^2$* | *Odds Ratio* |
|---|---|---|---|---|---|---|
| Step 1 | | | | .432 | .578 | 81.8%[a] |
| | PTCA/Stents | 2.485 | 4.851* | | | |
| | Diabetes | 3.283 | 12.784**** | | | |
| Step 2 | | | | .524 | .700 | 79.5%[b] |
| | PTCA/Stents | 3.157 | 3.716 | | | |
| | Diabetes | 3.940 | 10.436*** | | | |
| | Cook-Medley | .381 | 4.738* | | | |
| Step 3 | | | | .621 | .830 | 95.5%[c] |
| | PTCA/Stents | 5.133 | 3.186 | | | |
| | Diabetes | 6.734 | 5.419* | | | |
| | Cook-Medley | .811 | 3.516 | | | |
| | Four-Word Short-Term Memory – 15” | -.576 | 4.162* | | | |

[a] 75% for Group A (SDC & Phase IIA); 90% for Group B (Phase IIB & IIC)

[b] 87.5% for Group A (SDC & Phase IIA); 70% for Group B (Phase IIB & IIC)

[c] 95.8% for Group A (SDC & Phase IIA); 95% for Group B (Phase IIB & IIC)

*$p < .05$. **$p < .01$. ***$p < .001$. ****$p < .0005$.

### 4.5.4. Summary of Study 2: Model Refinement

Table 47 provides a summary of the final regression models for each of the nine outcomes. Across all models, the amount of explained variance ranged from 17% through 59%. For the Behavioral Prescription Adherence models, the amount of explained variance ranged from approximately 22% to 51%. Neither demographic nor disease variables were retained in these final models and the psychological variables that qualified had readily recognized practical significance. Namely, busyness was an important predictor of the aspects of the program that place the greatest demands on time (exercise and stress management). Quality of life indices, including measures of physical vitality and mental health, made logical contributions to the exercise and stress management models, respectively. Clearly, neuropsychological variables made the strongest contributions to each adherence model. Of the variance explained in these models, the amount attributed to neuropsychological predictors ranged from 40% to 100% and on average, more than half of the explained variance (63%) was attributed to neuropsychological variables. Verbal memory and executive control were the neuropsychological constructs most prominently represented in these models. Most notably, these were especially potent predictors of both Dietary and Exercise Adherence.

The Documented Learning models were also strong in terms of the amount of explained variance. These were comprised entirely of cognitive predictors (i.e., program knowledge and neuropsychological variables. No demographic, disease, or psychological predictors remained in these final regression models. In terms of knowledge acquisition, half of the explained variance is accounted for by program-specific knowledge at the time of program entry and the other half,

to kinds of verbal memory – explicit memory and working memory. Explicit verbal memory was an especially important facilitator of Ornish-specific knowledge acquisition and verbal working memory was vitally important to improving diary-keeping skills. As expected, the Perceived Learning models were weak and the only aspect of neuropsychological ability staff were able to recognize as important to learning was spatial accuracy and neatness – the more procedural aspects of diary-keeping. Staff were not, however, able to recognize the important roles that explicit and working verbal memory played in relation to Ornish-specific knowledge acquisition and improvements in diary-keeping.

Finally, using data collected at the time of program entry, it was possible to predict with 95.5% accuracy the level of program intensity each participant would need at the end of twelve weeks. Along with specific disease and psychological variables having established relationships with the stratification process, scores on a single neuropsychological measure at the time of program entry (Four Word Short-Term Memory – 15"), very significantly enhanced how accurately stratification could be predicted. Without this variable, classification accuracy was only 79.5%. Including this measure of verbal working memory elevated classification accuracy to 95.5% with only two participants misclassified.

**Table 47 Summary of Final Regression Models**

| *Outcome* | *# of predictors* | | $R^2$ | *adjusted* $R^2$ | *p* |
|---|---|---|---|---|---|
| | *Total #* | *NeuroΨ* | | | |
| *Behavioral Prescription Adherence* | | | | | |
| Dietary | 2 | 2 | .330 | .299 | < .0005 |
| Exercise | 4 | 2 | .508 | .459 | < .0005 |
| Group Support | 2 | 1 | .251 | .216 | .002 |
| Stress Management | 3 | 1 | .327 | .276 | .001 |
| *Documented Learning* | | | | | |
| Ornish Knowledge Test (Week 12) | 3 | 2 | .586 | .553 | <.0005 |
| Food Diary Learning Slope[a] | 2 | 2 | .547 | .502 | <.0005 |
| *Perceived Learning* | | | | | |
| Nutritionist[b] | 2 | 1 | .318 | .267 | .006 |
| Case Manager | 2 | 1 | .208 | .171 | .007 |
| | | | *Nagelkerke*[c] $R^2$ | *Cox & Snell*[c] $R^2$ | *Odds Ratio*[c] |
| *Phase II Stratification*[c] *(Group A versus Group B)* *SDC & Phase IIA vs. Phases II B & C* | 4 | 1 | .830 | .621 | 95.5% chance of accurate classification |

*Note.* $N = 46$ except as noted.

[a]$n = 23$ (WRH only) [b]n = 30 (WRH and AGH only) [c]binary logistic regression

# 5. DISCUSSION

Most adherence research with cardiac populations has focused on legitimate psychological and psychosocial concerns as primary mediators of adherence. Studies of applied learning have been conducted but the overwhelming majority of these have been guided by social-cognitive learning theories rather than information processing frameworks of learning. This has limited our understanding of the principal importance of cognitive information-processing in the context of adherence-based learning. Even minor forms of cardiovascular disease can render the brain susceptible to compromise in areas that are vital to memory and learning. The purpose of this research was to examine what impact these memory and learning problems have on various aspects of learning and adherence in individuals with cardiovascular disease. The "supply" of critical learning capacities was quantified through the administration of neuropsychological tests and the "demand" for these skills was illustrated through their predictive utility for specific types of adherence. Most aspects of this neuropsychological supply – information-processing demand (NIP) model were supported through this research.

## 5.1. Answers to Major Research Questions

The first research question – Do neuropsychological variables significantly improve the prediction of cardiac rehabilitation outcomes beyond what is accounted for by program

knowledge, demographic, disease, and psychological variables? – was powerfully supported. The predictive models for five of the six major adherence and learning outcomes were significantly improved by including neuropsychological variables. Moreover, the highest standardized (β) coefficient was a neuropsychological variable for all but one model (Group Support Adherence). This demonstrates that neuropsychological measures offer unique contributions to the prediction of adherence and learning that are not captured through other variables conventionally used for this purpose, such as program-specific knowledge and other human factors such as demography, disease, emotional, psychosocial, and quality of life. The one model that was not substantially improved by the inclusion of neuropsychological variables – Group Support – was no surprise. In fact, this further supports the NIP hypothesis. The other three components of the Ornish program is where the "hard work" is done and Group Support is where participants talk about the hard work. The demand for more effortful cognitive processing in the context of Group Support is not just different, it is substantially less. If subjects so choose, they can contribute minimally (if at all) to the group process and this is unlikely to negatively impact their adherence score for this component of the program because this is quantified by way of subjective report.

Regarding the second research question – How much variance in each outcome is accounted for by a combination of top-ranking neuropsychological and non-neuropsychological predictors? – between 22% and 51% of the variance in adherence outcomes, and 50% to 59% of the variance of in-program learning, was explained by the predictive models. As expected, the models predicting program learning were the strongest in terms of the amount of explained variance, statistical significance, and the representation of information-processing predictors. Essentially half of the variance in program-specific knowledge acquisition and efficient

improvements in diary-keeping accuracy was explained through these models, both of which were significant at $p < .0005$. Moreover, both models were comprised entirely of cognitive predictors. For knowledge acquisition, half of the explained variance was attributed to what participants knew about the Ornish program at the time of program entry and the other half, the combined influence of explicit verbal memory and verbal working memory. Regarding diary-keeping improvements, the model shows that the majority of explained variance is attributed to verbal working memory. Of the adherence outcomes, the predictive models for diet and exercise were the strongest ($p < .0005$). Almost half of the variance in exercise adherence, and one-third of the variance in dietary adherence, are explained through their respective predictive models.

The answer to the third research question – Which of the non-neuropsychological variables are important to include in the predictive models? – is outcome dependent. The models showed that environmental demands (i.e., busyness) are important to consider for more time consuming aspects of the program, such as adherence to the exercise and stress management prescriptions which require a time investment of a minimum of 3 and 7 hours per week, respectively. Also, self-perceived physical vitality and mental health are, respectively, important predictors of exercise and stress management. Otherwise, the most important predictors for all models were neuropsychological and other cognitive (i.e., program knowledge) variables. Two models (Dietary Adherence and Food Diary Learning Slope) were comprised entirely of neuropsychological variables. The amount of variance explained in program-specific knowledge acquisition was wholly attributed to cognitive variables also, although half of this was attributed to neuropsychological variables and the other half, the amount of Ornish-specific knowledge the participant had at the time of program entry.

One of the most important findings of this research project answers the fourth and final research question – Which of the neuropsychological tests commonly used to identify cognitive impairments in cardiovascular disease are the best predictors of specific adherence and learning outcomes? Before reviewing the substantive findings, it is important to recall the methodology and selection criteria that were used to identify the "best" predictors for each model. The reader will remember that in the event that multiple variables from the same test qualified for inclusion and were highly correlated with one another, only the variable having the highest zero-order correlation with the outcome was retained. In part, this explains why different subtests of a single test (and especially, the Four-Word Short-Term Memory Test) are represented across the models. However, it is also the case that some subtests (and especially, those found on the Wisconsin Card Sorting Test (WCST) and the California Verbal Learning Test (CVLT)), are not highly correlated with one another because each measures very different neuropsychological constructs. By way of practical example, both situations are exemplified through the Exercise Adherence model. Two subtests from the WCST qualified as predictors but only one was included in the model because these were highly correlated with one another and redundant (i.e., WCST Perseverative Errors and WCST Perseverative Responses). By contrast, the CVLT List B subtest was the only working memory measure that qualified for inclusion; none of the Four-Word Short Term Memory subscales were strongly correlated with this outcome ($r$ = -.143 to .116). To more cohesively illuminate the neuropsychological constructs of greatest importance to adherence, it would be useful to consolidate test results using data reduction methods such as principal component analyses and this will be done in future studies. For the current study, however, it was counterintuitive to consolidate the data in this way. An important goal was to

determine which of the tests used in daily practice do the best job of capturing the neuropsychological constructs most important to adherence.

Clearly, the primary instrument used to capture verbal working memory, the Four-Word Short Term Memory Test, was the test most strongly represented across the models. Subscales of this test were represented in two of the four adherence models and both of the in-program learning models. Two different aspects of the California Verbal Learning Test (CVLT) were important. The explicit memory measure, CVLT Short Delay Free Recall, was important to the prediction of knowledge acquisition. For exercise adherence, a facet of verbal working memory involving one's sensitivity to proactive interference was important and represented through CVLT List B recall. In addition to these tests of verbal memory, subtests from the Wisconsin Card Sorting Test (WCST) that are sensitive to cognitive flexibility (WCST Perseverative Responses) and efficiency in novel problem solving (WCST Trials to Complete 1$^{st}$ Category) were, respectively, important to exercise and dietary adherence.

While tests of verbal memory and executive control were strongly represented across both the adherence and learning models, other tests included in the research protocol were conspicuously absent. These included tests of prospective memory (Time- and Event-Based Memory), general cognitive processing speed (Wechsler Digit Symbol), and a test of spatial analysis (Hooper Visual Orientation Test). No scores from these tests qualified for inclusion in any of the models. Another test of spatial analysis that includes a graphomotor component (Rey Complex Figure Drawing (RCFT)) was a significant predictor in two models (Group Support and Food Diary Learning Slope) although in both cases, there was an inverse relationship between this predictor and the outcome. While the significance of poor spatial recall (RCFT Delay Recall) in relation to Group Support is not yet known, the relevance of another subtest, the

RCFT Copy, to the efficiency of improvements in diary-keeping skills was more straightforward – those who had low scores on this measure of spatial-constructional abilities had more errors in the early weeks of the program but if verbal working memory was spared, diary-keeping improvements were more efficient. Taken together, the significance of tests of visual-spatial ability to predicting behavioral adherence and program-based learning was substantially less than tests of verbal memory and executive control. These findings demonstrate the importance of memory and executive control to learning and acting on new information in complex ways that require novel reasoning and strategic planning.

A potent testimony to the importance of verbal working memory to adherence-based learning is found through the model developed for Phase II stratification. The reader will remember that this model used pre-program data (both neurological and non-neuropsychological) to predict the level of program intensity each participant needed at the end of twelve weeks. Logistic regression was used to predict whether the participant was stratified to less intensive (Group A) or more intensive (Group B) programming. The regression analyses showed that including a measure of verbal working memory significantly improved classification accuracy. This was especially impressive because all other qualifying predictors in the model reflected pre-established stratification criteria; in the context of the Ornish program, these decisions are made using very specific parameters and decision-tree pathways for disease, psychological, and adherence variables. All of these data are available at the time of program entry except, of course, whether participants met minimum adherence criteria. Results show that pre-program scores on tests of verbal working memory served as potent surrogates for estimating future adherence. Using only the qualifying pre-program variables reflecting the pre-established pathways, the accuracy of predicting Phase II Stratification was less than 80%. By including a

test of verbal working memory in the model, the classification accuracy of the model was boosted to 99.5%, with only two participants misclassified.

## 5.2. Theoretical Relevance to Extant Research

In terms of advancing our understanding of the relationship between cognitive learning and adherence, Park and colleagues have long hypothesized that more effortful forms of cognitive processing and especially, verbal working memory, are key to medical adherence. However, not all of their studies have supported this hypothesis as strongly as the current study. One explanation may be the current use of slightly different methodology and sample characteristics. Two aspects of the current model are congruent with the work of Park and colleagues and two are different. Congruence is found through the basic hypothesis that more effortful forms of cognitive processing – and especially, working memory – are key to medical adherence and that a multidimensional model (including human and situational factors in addition to neuropsychological variables) may be needed for understanding some types of adherence. The differences relate to the current use of a comprehensive neuropsychological assessment battery comprised of tests commonly used in contemporary clinical practice and the use of a disease population having an accentuated risk for the specific neuropsychological and information-processing problems hypothetically linked to medical adherence. This does not imply that Park and colleagues have not examined adherence in populations having greater or lesser impairments in effortful processing – they certainly have. However, most of those studies focused on the relevance of effortful processing in relation to age-related differences across the lifespan. They have examined adherence-based learning in a variety of diseases but a majority of

those diseases do not carry the risks for neurological compromise associated with cardiovascular disease, and more specifically, individuals whose coronary risk factors are substantial enough to warrant an intensive lifestyle intervention such as the Ornish program. Moreover, a predominantly sixty-something sample having advanced cardiovascular risks may be at greatest risk for compromised effortful processing due to the presence of both advanced age and coronary risks.

The aspects of this study addressing program-specific knowledge acquisition are wholly consistent with the important work of Denise Park and her colleagues as well as other researchers. The reader will recall that approximately half of the variance in program-specific knowledge acquisition was predicted by Ornish-specific knowledge at the time of program entry and the other half, the combined effects of verbal working and explicit memory. These findings support recent work by these researchers (Hedden et al., 2005) that used structural equation modeling to show a direct path between verbal working memory and free recall and also, that this relationship is strongest in more elderly individuals. Results of the current study support those findings in two ways. First, current results exemplify that verbal working memory is an important adjunct to explicit free recall. Second, the low rate of knowledge acquisition in this sample – as reflected through a test requiring explicit verbal recall – is further testimony of the link between working memory, explicit recall, and learning. Taking the broader view, the current study is consistent with multiple other studies reported in the literature showing that knowledge acquisition in health-related interventions is poor (Glanz et al., 1990; Leslie and Schuster, 1991; Plous et al., 1995; Schuster & Waldron, 1991). In this study, the average mastery of information was 44.18% and the best, only 67%. Given the results of the current study as well as the work of Park and colleagues, it is possible that this phenomenon may be

explained by the synergistic effects of both age and disease factors on cognitive abilities that support both knowledge acquisition and the way this is measured – free recall on the Ornish Knowledge Test.

## 5.3. Practical Application of Current Research Findings

The pragmatic extension of the current research is to apply the neuropsychological supply – information processing demand model to direct patient care and education. For example, knowing that dietary and exercise adherence places great demands on verbal working memory and other aspects of executive control, then individuals with low supply of these information processing abilities are expected to struggle with those aspects of adherence. If these problems are identified early in the course of treatment, then additional supports (i.e., cognitive prostheses) could be included in the educational intervention to improve adherence prognoses. However, the current research showed that these adherence-based learning problems cannot be discerned through routine clinical contact provided by program staff. Consistent with other studies reported in the literature, Ornish program staff were not able to identify the neuropsychological factors most critical to adherence-based learning, despite the rather intense level of involvement they have with participants over an extended period of time. Most notably, both the nutritionist and the case manager were able to identify more superficial attributes of learning (procedural neatness and spatial organizational ability; fund of Ornish-specific knowledge) but not the neuropsychological skills that facilitate learning in these areas (i.e., verbal working memory, explicit memory). In no way does this reflect negatively upon the extremely dedicated, professional staff working in the program. Rather, this bespeaks the veiled phenomenology of

the problem. The cognitive impediments to adherence-based learning can only be identified through the administration of specific neuropsychological measures.

When envisioning the results of this research and the formulation of this discussion, one goal was to extol the dual, pragmatic utility of the NIP model – specifically, that the NIP not only provides the ability to accurately identify these problems but also, the foundation needed to develop theoretically-driven remedial strategies for accommodating cognitive shortcomings through the educational intervention. In much the same way as developmentally-based learning disorders are characterized through testing, followed by theoretically-driven recommendations for educational remediation guided by the results of that testing, it was hoped that the same could be applied to these cardiac-based learning disorders. Unfortunately, this goal was not fully realized. While the current research demonstrates that neuropsychological variables are of vital importance to adherence and in-program learning, the majority of regression equations did not explain enough variance to render these pragmatically useful in their current stage of model refinement. Even the strongest models explained only slightly more than half of the variance in adherence outcomes. The bright exception was the strength and accuracy of the Phase II Stratification model which could classify the general level of program intensity needed by participants at the end of twelve weeks with 99.5% accuracy.

## 5.4. Future Directions

Future studies will focus on the further development and refinement of adherence prediction in the context of cardiovascular disease. Many avenues need continued exploration. One important question to be addressed is: Could the predictive models be improved through the

inclusion of other, more specific physiological variables (e.g., ejection fraction and aerobic capacity at the time of program entry), and/or, a combination of cognitive reserve variables (i.e., age, gender, education) included in all predictive models? In addition, it will be important to closely examine subsamples where disease and demographic variables may combine in synergistic ways to increase the risk for neuropsychological impairments and by extension, poor adherence outcomes (e.g., open-heart surgeries in more elderly individuals).

Already underway are data analyses of pre- and post-program neuropsychological improvements to examine the relationship of adherence to these improvements. The major question for these analyses is an extension of what is already known about physiological outcomes through the ongoing studies conducted by Dr. Ornish and colleagues – big changes (i.e., stringent adherence to the Ornish lifestyle) yield big improvements in cardiac risk reduction, including the reversal of cardiovascular disease. Will a similar dose-response relationship be observed for neuropsychological improvements? If strict adherence to the Ornish lifestyle yields substantial improvements in neuropsychological status, will these improvements include more effortful forms of cognitive processing that are most important to continued adherence with the Ornish lifestyle?

It is hoped that future studies will include samples from conventional cardiac rehabilitation programs. For several reasons, results of the current study may not generalize to those intervention programs. Selective attrition is a considerable obstacle impeding neuropsychological studies in all cardiac populations. Typically, the most neurologically impaired individuals withdraw from structured rehabilitation programs and for the Ornish program, these individuals may actually drop out before they begin. Simply gaining admission into the Ornish program requires that the individual clear numerous cognitive hurdles; all

prospective participants complete extensive questionnaires and must commit to a very intense level of program attendance along with the arduous homework associated with diary-keeping. To be explored is whether individuals found among the ranks of the conventional rehabilitation programs are more neuropsychologically impaired than Ornish program participants.

Finally, the current research shows that the neuropsychological supply and information processing conceptualization of adherence in cardiac populations is tenable. Continued efforts will be directed towards finding pragmatic ways to identify individuals who need enhanced learning supports to increase short-term adherence and long-term medical outcomes.

# APPENDIX A

## Letters of Support

PREVENTIVE MEDICINE RESEARCH INSTITUTE

900 Bridgeway, Suite 1
Sausalito, CA 94965
Tel. 415/332-2525
FAX 415/332-5730

April 18, 2003

Institutional Review Board
University of Pittsburgh
3500 Fifth Avenue, Suite 105
Pittsburgh, PA 15213

Members of the Institutional Review Board,

Ms. Kelly has gone through the proper channels at Lifestyle Advantage, Inc. and the Preventive Medicine Research Institute to seek approval for her research project, *Neuropsychological Prediction of Learning and Adherence in Cardiac Rehabilitation.* We are granting her permission to recruit participants from the hospital-based Dr. Dean Ornish Programs for Reversal of Heart Disease in the Pittsburgh area.

Sincerely,

Elaine B. Pettengill, RN, PhD
Associate Research Director
Preventive Medicine Research Institute
(415) 332-2525 ext.235
ebpett@aol.com

WESTMORELAND
REGIONAL HOSPITAL
PART OF THE WESTMORELAND HEALTH SYSTEM
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April 15, 2003

University of Pittsburgh Institutional Review Board
3500 Fifth Avenue, Suite 105
Pittsburgh, PA 15213

Project Title: *Neuropsychological Prediction of Learning and Adherence in Cardiac Rehabilitation* Principal Investigator: Mary Ann Kelly, MEd, Licensed Psychologist

Dear IRB Committee Members:

Ms. Kelly's research proposal involves the recruitment of individuals participating in a comprehensive lifestyle intervention offered at Westmoreland Regional Hospital. Westmoreland is one of many hospitals joining with Highmark/ Lifestyle Advantage, Inc. to offer this intervention, the *Dr. Dean Ornish Program for Reversing Heart Disease.*

Ms. Kelly has gone through the proper channels at Westmoreland Regional Hospital to seek approval for her research project. This has included presenting her research proposal to our IRB on April 2, 2003. The IRB committee members unanimously voted in favor of the research project.

I am the program director of the Ornish program at Westmoreland Regional Hospital. Based on the meetings we have had and the documents I have reviewed, I support Ms. Kelly's intent to include our program participants in her study.

Sincerely,

Cheryl D. McShea

Ms. Cheryl McShea, Program Director
Dr. Dean Ornish Program
For Reversing Heart Disease
(724) 832-4191

532 West Pittsburgh Street • Greensburg, PA 15601-2282 • (724) 832-4000 • www.westmoreland.org

Dr Dean Ornish PROGRAM for reversing heart disease

MVH Monongahela Valley Hospital

June 24, 2003

University of Pittsburgh Institutional Review Board
3500 Fifth Avenue, Suite 105
Pittsburgh, PA 15213

Project Title: *Neuropsychological Prediction of Learning and Adherence in Cardiac Rehabilitation* Principal Investigator: Mary Ann Kelly, MEd, Licensed Psychologist

Dear IRB Committee:

Ms. Kelly's research proposal involves the recruitment of individuals participating in a comprehensive lifestyle intervention offered at Mon-Valley Hospital. Mon-Valley is one of many hospitals joining with Highmark/Lifestyle Advantage, Inc. to offer this intervention, the *Dr. Dean Ornish Program for Reversing Heart Disease.*

Ms. Kelly has gone through the proper channels at Mon-Valley Hospital to seek approval for her research project. This has included having her research proposal and consent form approved by the Research Compliance Officer, Mr. Scott McCorkle and Vice President, Mrs. Donna Ramusivich.

We support Ms. Kelly's intent to include our Ornish program participants in her study.

Sincerely,

Mr. Randall Komacko
Dean Ornish Program Director

University of Pittsburgh

*School of Education*
*Department of Psychology in Education*

5C01 Wesley W. Posvar Hall
Pittsburgh, Pennsylvania 15260
412-624-7230
Fax: 412-624-7231

April 14, 2003

University of Pittsburgh Institutional Review Board
3500 Fifth Avenue, Suite 105
Pittsburgh, PA 15213

Project Title: *Neuropsychological Prediction of Learning and Adherence in Cardiac Rehabilitation* Principal Investigator: Mary Ann Kelly, MEd, Licensed Psychologist

Dear IRB Committee Members:

I am the chairman of Ms. Kelly's dissertation committee. All faculty committee members have reviewed and supervised this project and support the submission of this research protocol to the University of Pittsburgh Institutional Review Board.

Sincerely,

Roger Klein, PhD
Associate Professor

# APPENDIX B

## IRB Approval and Renewal Letters

# University of Pittsburgh

***Institutional Review Board***

3500 Fifth Avenue
Ground Level
Pittsburgh, PA 15213
(412) 578-3424
(412) 578-8553 (fax)


**MEMORANDUM:**

TO: Mary Ann Kelly, MEd

FROM: Philip Troen, M.D., Chair

DATE: May 5, 2003

SUBJECT: IRB #0304113: Neuropsychological Prediction of Learning and Adherence in Cardiac Rehabilitation

The above-referenced proposal has received expedited review and approval from the Institutional Review Board under 45 CFR 46.110 (5) (7).

Please note that the advertisement that was submitted for review has been approved as written.

Please include the following information in the upper right-hand corner of all pages of the consent form:

Approval Date: May 5, 2003
Renewal Date: May 4, 2004
University of Pittsburgh
Institutional Review Board
IRB #0304113

Adverse events which occur during the course of the research study must be reported to the IRB Office. Please call the IRB Adverse Event Coordinator at 578-8569 for the current policy and forms.

The protocol and consent forms, along with a brief progress report must be resubmitted at least **one month prior** to the expiration date noted above for annual renewal as required by Assurance No. M-1259, given to DHHS by the University of Pittsburgh.

**Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.**

CR:cc

# University of Pittsburgh

*Institutional Review Board*

3500 Fifth Avenue
Ground Level
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)


**MEMORANDUM:**

TO: Mary Ann Kelly, MEd

FROM: Robert Hardesty, M.D. Vice Chair *RHardesty*

DATE: April 23, 2004

SUBJECT: IRB #0304113: Neuropsychological Prediction of Learning and Adherence in Cardiac Rehabilitation

The renewal of the above-referenced proposal has received expedited review and approval by the Institutional Review Board. **This protocol is closed to accrual and all protocol interventions are complete.**

**Approval Date:** **April 23, 2004**

**Renewal Date:** **April 22, 2005**

Adverse events which occur during the course of the research study must be reported to the IRB Office. Please call the IRB Adverse Event Coordinator at 412-383-1145 for the current policy and forms.

The protocol and consent forms, along with a brief progress report must be resubmitted at least **one month prior** to the expiration date noted above for annual renewal as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh).

**Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.**

RH:cc

# University of Pittsburgh

***Institutional Review Board***

3500 Fifth Avenue
Ground Level
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)


**MEMORANDUM**

TO: Mary Ann Kelly, MEd

FROM: Richard Guido, M.D., Chairman

DATE: April 6, 2005

SUBJECT: IRB #0304113: Neuropsychological Prediction of Adherence and Learning in Cardiac Rehabilitation

---

Your renewal of the above-referenced proposal has received expedited review and approval by the Institutional Review Board under 45 CFR 46.110 (8). **This approval is for analysis of data only.**

**Approval Date:** **April 4, 2005**

**Renewal Date:** **April 3, 2006**

The protocol and consent forms, along with a brief progress report must be resubmitted at least **one month prior** to the expiration date noted above for annual renewal as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh).

**Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.**

RG:ky

ALLEGHENY GENERAL HOSPITAL

WEST PENN ALLEGHENY HEALTH SYSTEM

320 EAST NORTH AVENUE, PITTSBURGH, PA 15212-4772
412-359-3156

INSTITUTIONAL REVIEW BOARD #01
DHHS/OPRR ASSURANCE #M1050
(EXPIRES MARCH 23, 2004)

September 4, 2003

David Seigneur, MS
Department of Medicine

**RE: RC-3524 "Neuropsychological Prediction of Learning and Adherence in Cardiac Rehabilitation"**

Dear Mr. Seigneur:

The Institutional Review Board (IRB) of Allegheny General Hospital is in receipt of the above-referenced protocol.

The IRB has reviewed the information and determined that the above-referenced protocol and information flyer is **approved**. A stamped, approved Informed Consent is attached for your use. The IRB also acknowledges receipt of the completed *Request to Add/Remove Investigator(s) Form* to remove Roger Klein, PhD, Nancy Elman, PhD, Louis Pringel, PhD, and Christopher Ryan, PhD from the above referenced protocol. The IRB has reviewed the investigator changes and approves same.

This protocol has been reviewed via the "*expedited review*" process and approved on its scientific, safety, ethical and socio-economic merits, and approved in accordance with Institutional, Federal and State regulations by the IRB. It is the responsibility of the investigator to obtain any other necessary approvals prior to implementation of the research (AGH and/or ASRI).

Your approved protocol will be subject to review within one year from the date of initial review by the IRB.

Sincerely,

Matthew R. Quigley, MD
Chairman
Institutional Review Board

MRQ/ke
c.c. Vice President
Department Head

Attachment

ALLEGHENY
GENERAL HOSPITAL

WEST PENN ALLEGHENY HEALTH SYSTEM

320 EAST NORTH AVENUE, PITTSBURGH, PA 15212-4772
412-359-3156

INSTITUTIONAL REVIEW BOARD #01
DHHS/OPRR ASSURANCE #M1050
(EXPIRES MARCH 23, 2005)

August 16, 2004

David Seigneur MS
Department of

**RE: RC-3524 Neuropsychological Prediction of Adherence and Learning in Cardiac Rehabilitation**

Dear Mr.Seigneur:

The Institutional Review Board (IRB) of Allegheny General Hospital is in receipt of your continuing review forms for the above-referenced study.

The IRB has reviewed these forms and finds this study qualifies for expedited review, and, as such, approves this study for continuation.

Sincerely,

Matthew R. Quigley, M.D.
Chairman
Institutional Review Board

MRQ/lc

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100 Top Hospitals

April 7, 2003

Mary Ann Kelly, MEd
644 Seventh Street
Trafford, PA 15085

Dear Ms. Kelly:

Re: Neuropsychological Prediction of Learning and Adherence in Cardiac Rehabilitation

This letter will serve as official notice that the Westmoreland Health System Institutional Review Board, at its April 2, 2003 meeting, reviewed the above-mentioned study and informed consent form.

After review, the IRB unanimously approved the study and informed consent form.

Under FDA regulations, this approval will last only one year. If the study is expected to last beyond a year, you must request re-approval for the next year at least 6 weeks prior to the expiration date noted above.

The FDA requires you to notify the IRB of any new advertisements or recruiting materials, change of investigator or site location, serious adverse events, amendments or changes in the protocol, significant protocol deviations, patient death or termination of the study. Please note that you must submit all protocol amendments and/or advertisements to the IRB for review, and await a response from the IRB, prior to implementing the amendments and/or advertisements.

Sincerely,

Carol A Bucci

Carol Bucci, J.D.
Co-Chairman

CB:ao

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WESTMORELAND
REGIONAL HOSPITAL
PART OF THE WESTMORELAND HEALTH SYSTEM
100 Top Hospitals

August 26, 2003

Mary Ann Kelly, MEd
644 Seventh Street
Trafford, PA 15085

Dear Ms. Kelly:

Re: Neuropsychological Prediction of Learning and Adherence in Cardiac Rehabilitation
Revised Study, Informed Consent Form & Authorization for the Sharing of Health Information
Related to Possible Participation in a Research Study

This letter will serve as official notice that the Westmoreland Health System Institutional Review Board, at its July 23, 2003 meeting, reviewed the revisions to the above-mentioned study, informed consent form and authorization for PHI.

After review, the IRB unanimously approved the revisions.

Sincerely,

Carol A Bucci

Carol Bucci, J.D.
Co-Chairman

CB:ao

H:\DATA\MSFILES\IRB\KELLY703.DOC

532 West Pittsburgh Street • Greensburg, PA 15601-2282 • (724) 832-4000 • www.westmoreland.org

WESTMORELAND
HEALTH SYSTEM

May 20, 2004

Mary Ann Kelly, MEd
644 Seventh Street
Trafford, PA 15085

Dear Ms. Kelly:

Re: Neuropsychological Prediction of Learning and Adherence in Cardiac Rehabilitation
Revised Study, Informed Consent Form & Authorization for the Sharing of Health Information
Related to Possible Participation in a Research Study – Annual Review

This letter will serve as official notice that the Westmoreland Health System Institutional Review Board, at its April 20, 2004 meeting, reviewed the annual review report that you submitted.

After review, the IRB unanimously approved the annual review report and voted to keep the study open for an additional year.

Sincerely,

Carol G Bucci

Carol Bucci, J.D.
Chairman IRB

CB:ao

532 West Pittsburgh Street • Greensburg, PA 15601-2282 • (724) 832-5040 • www.westmoreland.org

# APPENDIX C

## Human Subject Consent Forms

ALLEGHENY GENERAL HOSPITAL
WEST PENN ALLEGHENY HEALTH SYSTEM
320 EAST NORTH AVENUE, PITTSBURGH, PA 15212-4772
412-359-3131

# AUTHORIZATION FOR THE SHARING OF HEALTH INFORMATION RELATED TO POSSIBLE PARTICIPATION IN A RESEARCH STUDY

Title of Research Study: Neuropsychological Prediction of Learning and Adherence in Cardiac Rehabilitation

PRINCIPAL INVESTIGATOR:
David Seigneur, MS
Program Director
Dr. Dean Ornish Program for Reversing Heart Disease
Allegheny General Hospital
320 East North Avenue
Pittsburgh, PA 15212
Telephone: 412-359-3276

CO-INVESTIGATOR:
Mary Ann Kelly, MEd
Licensed Psychologist/Doctoral Candidate
Psychology in Education
Applied Developmental Psychology
5-C Posvar Hall
University of Pittsburgh
Telephone: 412-979-0804

***What is the purpose of this authorization?***

In 1996 the government passed a law known as The Health Insurance Portability and Accountability Act (HIPAA), Public Law 104-191. This law, among other things will improve how your health care information is protected and kept confidential when it is shared with others. This includes both your medical records and insurance information as well as other personal health information. It also assures that everyone who shares this information will have to follow this law. This consent form describes to you how information about you may be used or shared if you are in a research study. It is important that you read this carefully.

A staff member of the *Dr. Dean Ornish Program for Reversing Heart Disease* has discussed with you that you may be eligible to take part in the above-named research study. You have indicated an interest in learning more about this research study from the researchers who are conducting the study. Thus, your authorization (permission) is being requested to:

- share the fact that you are interested in participating in this study with the involved researchers;
- allow the involved researchers to contact you so as to permit additional discussions of this study with you and/or to provide you with information on how you may take part in this study.

 Participant's Initials: _____

***What information about me will be shared with the researchers?***

- your name and telephone number

***To whom will the above information be given?***

We will share this information with Co-Investigator, Ms. Mary Ann Kelly via telephone, e-mail, or FAX. This information will be used to contact you to further discuss this research study with you.

***For how long is authorization valid?***

Once this information has been shared with the researchers, this authorization form will expire. We will not continue to share your future health information with these researchers, nor will we share your health information with any other researchers or individuals unless you sign a separate authorization form that permits us to do so.

***Is my permission to provide this information to the researchers voluntary?***

Your permission to provide this information to the researchers is completely voluntary. Whether or not you provide your permission will have no affect on your current or future medical care or your relationship with your doctor or health care provider. Whether or not you provide your permission will have no affect on your current or future relationship with Allegheny General Hospital, the West-Penn Allegheny Health System, the University of Pittsburgh, or the University of Pittsburgh Medical Center.

***May I withdraw, at a future date, my permission to provide this information to the researchers?***

You may withdraw, at any time, your permission to provide this information to the researchers. However, once this information has been shared with the researchers, the information will be in their possession. Hence, should you decide to withdraw your permission after your information has been given to the researchers you should send a written and dated notice of this decision to the principal investigator of this research study at the address listed above. Upon receipt of this request, the researchers will destroy your information that was provided to them. If you wish to withdraw your permission to provide this information to the researchers before it is given to them, you should contact, by telephone, your doctor or a member of your doctor's health care staff. With receipt of this request, your information will not be shared with the researchers.

Your decision to withdraw your permission to provide this information to the researchers will have no affect on your current or future medical care or your relationship with your doctor or health care provider. Your decision to withdraw your permission will have no affect on your current or future relationship with Allegheny General Hospital, the West-Penn Allegheny Health System, the University of Pittsburgh, or the University of Pittsburgh Medical Center.



Participant's Initials:_____

VOLUNTARY AUTHORIZATION

All of the above has been explained to me. By signing below I give my permission to share the information, specified above, with the researchers, identified above, for the purposes described.

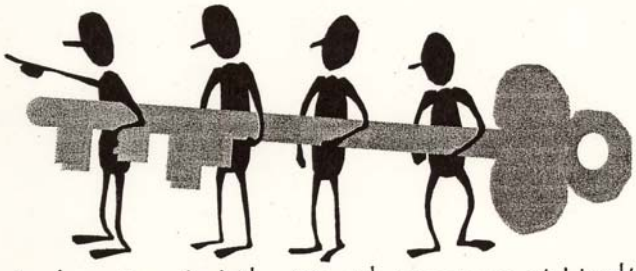
_____
Printed Name of Patient

_____ _____
Signature of Patient Date

_____ _____
Witness Date

APPROVED BY
THE INSTITUTIONAL REVIEW BOARD
OF
AGH/ASRI
9-4-03
DATE APPROVED

Dear Ornish Participant:



A fellow participant who attended the Ornish program at Health Place in Pittsburgh is conducting a research project with new participants. We are asking all new participants if they are interested in volunteering.

The research involves completing tests of memory and thinking and two brief questionnaires before you begin the program and at the end of twelve weeks. You will receive compensation of $20 for completion of the study.

Might you be interested in volunteering for this study?

_____ Yes, I would like to learn more about this research. I give my permission for the researcher, Ms. Mary Ann Kelly, to contact me

signature phone # date

_____ No, I'm not interested

Participation in this research study is entirely voluntary; if you're not interested, it will not affect your participation in the Ornish program in any way.

ALLEGHENY GENERAL HOSPITAL
WEST PENN ALLEGHENY HEALTH SYSTEM
320 EAST NORTH AVENUE, PITTSBURGH, PA 15212-4772
412-359-3131



Institutional Review Board
Allegheny General Hospital
Allegheny-Singer Research Institute
IRB Protocol #: RC-3524
Consent Form Approved: 9-4-03
Protocol Renewal Date: 9-3-04

CONSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY

TITLE: Neuropsychological Prediction of Learning and Adherence in Cardiac Rehabilitation

PRINCIPAL INVESTIGATOR: David Seigneur, MS
Program Director
Dr. Dean Ornish Program for Reversing Heart Disease
Allegheny General Hospital
320 East North Avenue
Pittsburgh, PA 15212
Telephone: 412-359-3276

CO-INVESTIGATOR: Mary Ann Kelly, MEd
Licensed Psychologist/Doctoral Candidate
Psychology in Education
Applied Developmental Psychology
5-C Posvar Hall
University of Pittsburgh
Telephone: 412-979-0804

SOURCE OF SUPPORT: Mary Ann Kelly, MEd, Co-Investigator

***Why is this research being done?***

Individuals having significant coronary risk factors, active heart disease, and those who have had heart surgery, sometimes have difficulties with memory, thinking, and emotions. Not everyone experiences these problems, but those who do may have greater difficulties managing their lifestyle in heart-healthy ways. We are trying to develop a practical way to identify these problems and their impact. Also, we're interested in how memory, thinking, and emotions change while you're in the program.

 Participant's Initials: _____

***Who is being asked to take part in this research study?***

You are being invited to participate in this study because you are planning to participate in the *Dr. Dean Ornish Program for Reversing Heart Disease* (hereafter, referred to as the program). You are one of thirty individuals being recruited from Allegheny General Hospital. You are eligible to participate in this study if this is your first time attending a site-sponsored Ornish program and you are English-speaking.

***What procedures will be performed for research purposes?***

Your participation in this study requires scheduling two appointments with the Co-Investigator, Ms. Mary Ann Kelly, MEd. These appointments are scheduled on the days, times, and locations of your choosing. One appointment is scheduled before you begin the Ornish program and the other, at the end of twelve weeks. These appointments require between sixty and ninety minutes to complete the following:

1. Self-Completed Questionnaires: These include questions about how busy your life is and what you already know about the Ornish program and related topics.
2. Investigator-administered tests: These tests involve memory, visual-perception, and abstract thinking.

During the first twelve weeks of participating in the program, the Co-Investigator named above will periodically review your program records for two reasons:

1. To understand the nature of your heart disease.
2. To monitor your progress in the program.

***What are the possible risks, side effects, and discomforts of this research study?***

The only risk of this research study is any momentary frustration you may experience if you have difficulty answering some of the questions.

***What are possible benefits from taking part in this study?***

You will receive no direct benefit from taking part in this research study. Your participation will help us improve the clinical instruction methods used in lifestyle interventions in the future.

 Participant's Initials: _____

***What treatments or procedures are available if I decide not to take part in this research study?***

If you decide not to take part in this research study, this will not alter the treatments you receive in the program in any way. All aspects of treatment provided in the program remain the same whether you participate in this study or not.

***Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?***

Neither you, nor your insurance provider, will be charged for the costs of any of the procedures performed for the purpose of this research study.

***Will I be paid if I take part in this research study?***

You will receive compensation of $20 for completing this study. Payments of ten dollars are made at the end of each session. If you drop out of the program, you will receive ten dollars for completing the pre-test portion of the study. Funding for participant payments is the sole responsibility of Co-Investigator, Mary Ann Kelly, MEd.

***Who will pay if I am injured as a result of taking part in this study?***

I have been fully informed by _____ and understand fully, that in the event of any physical injury, or injuries, resulting from research procedures or protocols to which I have voluntarily and knowingly agreed to participate in, that no monetary compensation or free medical treatment will be made available to me by Allegheny General Hospital or Allegheny Singer Research Institute.

***Who will know about my participation in this research study?***

The hospital staff working directly with you in the Ornish program will know that you participated in this research study although they will not have access to your research results. Any information about you obtained from this research will be kept as confidential (private) as possible. The researcher has set up safeguards to keep private information about you confidential. All records related to your involvement in this research study will be stored in a locked file cabinet. Your identity on these records will be indicated by a case number rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research records. You will not be identified by name in any publication of the research results unless

you sign a separate consent form giving your permission (release). Although every effort will be made to keep research records about you private, complete confidentiality cannot be guaranteed. Such research records may be subject to subpoena or court order.

***Research Study Authorization of Protected Health Information and HIPAA Authorization***

In 1996 the government passed a law known as The Health Insurance Portability and Accountability Act (HIPAA), Public Law 104-191. This law, among other things will improve how your health care information is protected and kept confidential when it is shared with others. This includes your medical records and insurance information as well as other personal health information. It also assures that everyone who shares this information will have to follow this law. This consent form describes to you how information about you may be used or shared if you are in a research study. It is important that you read this carefully.

In order to participate in this research study, you must permit (allow) certain research records to be made about you in addition to the usual records the hospital and doctors create about your medical treatment. These research records will contain private medical and other information, which is protected by law. The researchers will only create the minimum amount of research records necessary to carry out the research. Your participation in this research study will not result in any identifiable information being placed into your hospital medical records.

Type(s) of research records that may be shared are:

- Medical Records relating to your general health and cardiac status
- Lab Results of blood work, EKG, and cardiac stress tests
- All records collected through your participation in the Ornish program

In addition to using these research records to carry out the research, the researchers will share portions of these research records to third parties involved in the research study. The third parties, who receive research information, may further share the information about you in accordance with their policies, practices and what the law requires. However, some third parties may not need to follow the HIPAA law. To the best of our knowledge, a complete and accurate description of who the third parties are and how they will use or share the information are as follows:

 Participant's Initials: _____

| THIRD PARTY | PURPOSE |
|---|---|
| Allegheny General Hospital<br>Allegheny-Singer Research Institute<br>University of Pittsburgh Research Conduct and Compliance Office | May share this signed consent form and records that identify you to meet regulatory requirements or for the purposes related in this research. |
| Mary Ann Kelly, MEd, Co-Investigator | Ms. Kelly is overseeing all aspects of this research and is responsible for collecting and analyzing data obtained about you through the research project and your medical records. |
| Administrative representatives from the Ornish Program including Dr. Dean Ornish, and staff affiliated with Highmark, Lifestyle Advantage, and the Preventive Medicine Research Institute. | May share this signed consent form and records that identify you for the purpose of monitoring the accuracy and completeness of research data and for performing scientific data analyses. |

The release of information described above will be the minimum necessary to abide by the law complete the research, and, perhaps, publish the research.

**Unlike your medical records, you will not have access to research records made about you.** Although every effort will be made to keep research records about you private, complete confidentiality cannot be guaranteed. Such research records may be subject to subpoena or court order. The researcher has set up safeguards to keep private information about you confidential.

There is no expiration for this Authorization unless you revoke (cancel) it. You may revoke this Authorization by writing to the Principal Investigator. If you revoke your Authorization, you will also be removed from the study. Revoking your Authorization only affects the use and sharing of your information after the written request is received. Any information obtained prior to receiving the written request, may be used to maintain integrity of the study (for example account for reporting of side effects, sending information to the FDA for studies it regulates).

Principal Investigator Name & Address: David Seigneur, MS, Program Director
Dr. Dean Ornish Program for Reversing Heart Disease
Allegheny General Hospital
320 East North Avenue
Pittsburgh, PA 15212
Telephone: 412-359-3276

 Participant's Initials: _____

If you choose to not sign this Authorization, you will not be permitted to participate in this research study. In order to participate in this study, you must agree to share your information with the groups above. Upon completion of the study or if you withdraw from the study at any time, the research records about you will be kept by the researcher (s) and all of the information provided above will continue to apply to your research records.

You give permission that your research records can be used and disclosed as described.

***Is my participation in this research study voluntary?***

Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. (Note, however, that if you do not provide your consent for the use and disclosure of your identifiable information for the purposes described above, you will not be allowed, in general, to participate in the research study.) Whether or not you provide your consent for participation in this research study will have no affect on your current or future medical care at Allegheny General Hospital, the West-Penn Allegheny Health System, the University of Pittsburgh, the University of Pittsburgh Medical Center, an affiliated health care provider, or your current or future relationship with a health care insurance provider. You are not under any obligation to participate in this research study.

***If I agree to take part in this research study, can I be removed from the study without my consent?***

It is unlikely that you will be removed from this research study by the researchers. The only condition that would cause your removal from is if your test results are incomplete or judged to be invalid.

***May I withdraw, at a future date, my consent for participation in this research study?***

You may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. (Note, however, that if you withdraw your consent for the use and disclosure of your identifiable medical record information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study.) Any identifiable research or medical information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

 Participant's Initials: _____

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator listed below.

Your decision to withdraw your consent for participation in this research study will have no affect on your current or future medical care at Allegheny General Hospital, the West-Penn Allegheny Health System, the University of Pittsburgh, the University of Pittsburgh Medical Center, an affiliated health care provider, or your current or future relationship with a health care insurance provider.

***Inquiries?***

If you have any questions about this research, or, need to report a research-related injury, please contact the Principal Investigator:

David Seigneur, MS, Program Director
Dr. Dean Ornish Program for Reversing Heart Disease
Allegheny General Hospital
320 East North Avenue
Pittsburgh, PA 15212
Telephone: 412-359-3276

**VOLUNTARY CONSENT**

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first two pages of this form. Any questions which I have about my rights as a research participant will be answered by the IRB Office of Allegheny General Hospital/Allegheny-Singer Research Institute (412-359-3156).

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

_____ _____
Participant's Signature Date

_____ _____
Witness Date

 Participant's Initials: _____

**CERTIFICATION of INFORMED CONSENT**

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise.

_____ _____

Signature of Investigator Date

 Participant's Initials: _____

Dr Dean Ornish PROGRAM for reversing heart disease

MVH Monongahela Valley Hospital

AUTHORIZATION FOR THE SHARING OF HEALTH INFORMATION RELATED TO POSSIBLI PARTICIPATION IN A RESEARCH STUDY

| | |
|---|---|
| Title of Research Study: | Neuropsychological Prediction of Learning and Adherence in Cardiac Rehabilitation |
| PRINCIPAL INVESTIGATOR: | Mary Ann Kelly, MEd<br>Licensed Psychologist/Doctoral Candidate<br>Psychology in Education<br>Applied Developmental Psychology<br>5-C Posvar Hall<br>University of Pittsburgh<br>Telephone: 412-979-0804 |
| CO-INVESTIGATORS: | Roger Klein, PhD<br>Dissertation Committee Chairman<br>Associate Professor<br>Psychology in Education<br>Developmental Psychology<br>5A28 Posvar Hall<br>University of Pittsburgh<br>Telephone: 412-648-7043 |
| | Nancy Elman, PhD<br>Associate Professor<br>Psychology in Education<br>Counseling Psychology<br>5F28 Posvar Hall<br>University of Pittsburgh<br>Telephone: 412-648-7093 |

 Participant's Initials: _____

Louis Pingel, PhD
Associate Professor/Associate Dean
Psychology in Education
Research Methodology
5T18 Posvar Hall
University of Pittsburgh
Telephone: 412-648-1775

Christopher M. Ryan, PhD
Professor of Psychiatry
University of Pittsburgh Medical Center
3501 Forbes Avenue, Suite 718
Telephone: 412-624-2963

***What is the purpose of this authorization?***

A staff member of the *Dr. Dean Ornish Program for Reversing Heart Disease* has discussed with you that you may be eligible to take part in the above-named research study. You have indicated an interest in learning more about this research study from the researchers who are involved in conducting the study. Thus, your authorization (permission) is being requested to:

- share the fact that you are interested in participating in this study with the involved researchers;
- share your health information related to your eligibility to take part in this study with the involved researchers; and
- allow the involved researchers to contact you so as to permit additional discussions of this study with you and/or to provide you with information on how you may take part in this study.

***What information about me will be shared with the researchers?***

If you give your permission, the following information about you will be shared by telephone, e-mail, or FAX with the Principal Investigator of the above-named research study:

- your name and telephone number

***To whom will the above information be given?***

We will share this information with the Principal Investigator listed above. This information will be used by the Principal Investigator to contact you to further discuss this research study with you.

These researchers recognize the importance of maintaining the confidentiality (privacy) of your health information, however it is not possible for us to guarantee its confidentiality after we have provided it to them.



Participant's Initials:_____

***For how long is authorization valid?***

Once this information has been shared with the researchers, this authorization form will expire. We will not continue to share your future health information with these researchers, nor will we share your health information with any other researchers unless you sign a separate authorization form that permits us to do so.

***Is my permission to provide this information to the researchers voluntary?***

Your permission to provide this information to the researchers is completely voluntary. Whether or not you provide your permission will have no affect on your current or future medical care or your relationship with your doctor or health care provider. Whether or not you provide your permission will have no affect on your current or future relationship with Mon-Valley Hospital, the University of Pittsburgh, or the University of Pittsburgh Medical Center.

***May I withdraw, at a future date, my permission to provide this information to the researchers?***

You may withdraw, at any time, your permission to provide this information to the researchers. However, once this information has been shared with the researchers, the information will be in their possession. Hence, should you decide to withdraw your permission after your information has been given to the researchers you should send a written and dated notice of this decision to the principal investigator of this research study at the address listed above. Upon receipt of this request, the researchers will destroy your information that was provided to them. If you wish to withdraw your permission to provide this information to the researchers before it is given to them, you should contact, by telephone, your doctor or a member of your doctor's health care staff. With receipt of this request, your information will not be shared with the researchers.

Your decision to withdraw your permission to provide this information to the researchers will have no affect on your current or future medical care or your relationship with your doctor or health care provider. Your decision to withdraw your permission will have no affect on your current or future relationship with Mon-Valley Hospital, the University of Pittsburgh, or the University of Pittsburgh Medical Center.

**********

VOLUNTARY AUTHORIZATION

All of the above has been explained to me. By signing below I give my permission to share the information, specified above, with the researchers, identified above, for the purposes described.

_____
Printed Name of Patient

_____ _____
Signature of Patient Date

The·Well·Being
center for mind/body health

AUTHORIZATION FOR THE SHARING OF HEALTH INFORMATION RELATED TO POSSIBLE PARTICIPATION IN A RESEARCH STUDY

Title of Research Study: Neuropsychological Prediction of Learning and Adherence in Cardiac Rehabilitation

PRINCIPAL INVESTIGATOR: Mary Ann Kelly, MEd
Licensed Psychologist/Doctoral Candidate
Psychology in Education
Applied Developmental Psychology
5-C Posvar Hall
University of Pittsburgh
Telephone: 412-979-0804

CO-INVESTIGATORS: Roger Klein, PhD
Dissertation Committee Chairman
Associate Professor
Psychology in Education
Developmental Psychology
5A28 Posvar Hall
University of Pittsburgh
Telephone: 412-648-7043

Nancy Elman, PhD
Associate Professor
Psychology in Education
Counseling Psychology
5F28 Posvar Hall
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 Participant's Initials: _____

Louis Pingel, PhD
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We will share this information with the Principal Investigator listed above. This information will be used by the Principal Investigator to contact you to further discuss this research study with you.

These researchers recognize the importance of maintaining the confidentiality (privacy) of your health information, however it is not possible for us to guarantee its confidentiality after we have provided it to them.



Participant's Initials:_____

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Once this information has been shared with the researchers, this authorization form will expire. We will not continue to share your future health information with these researchers, nor will we share your health information with any other researchers unless you sign a separate authorization form that permits us to do so.

***Is my permission to provide this information to the researchers voluntary?***

Your permission to provide this information to the researchers is completely voluntary. Whether or not you provide your permission will have no affect on your current or future medical care or your relationship with your doctor or health care provider. Whether or not you provide your permission will have no affect on your current or future relationship with Westmoreland Regional Hospital, the University of Pittsburgh, or the University of Pittsburgh Medical Center.

***May I withdraw, at a future date, my permission to provide this information to the researchers?***

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Your decision to withdraw your permission to provide this information to the researchers will have no affect on your current or future medical care or your relationship with your doctor or health care provider. Your decision to withdraw your permission will have no affect on your current or future relationship with Mon-Valley Hospital, the University of Pittsburgh, or the University of Pittsburgh Medical Center.

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_____
Printed Name of Patient

_____ _____
Signature of Patient Date

# University of Pittsburgh

*School of Education*
*Department of Psychology in Education*

5C01 Wesley W. Posvar Hall
Pittsburgh, Pennsylvania 15260
412-624-7230
Fax: 412-624-7231

Institutional Review Board
University of Pittsburgh
IRB Number: 0304113
Consent Form Approved: May 5, 2003
Protocol Renewal Date: May 4, 2004

CONSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY

TITLE: Neuropsychological Prediction of Learning and Adherence in Cardiac Rehabilitation

PRINCIPAL INVESTIGATOR:
Mary Ann Kelly, MEd
Licensed Psychologist/Doctoral Candidate
Psychology in Education
Applied Developmental Psychology
5-C Posvar Hall
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Research Methodology
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Telephone: 412-648-1775

Christopher M. Ryan, PhD
Professor of Psychiatry
University of Pittsburgh Medical Center
3501 Forbes Avenue, Suite 718
Telephone: 412-624-2963

SOURCE OF SUPPORT: Investigator-funded

***Why is this research being done?***

Individuals having significant coronary risk factors, active heart disease, and those who have had heart surgery, sometimes have difficulties with memory, thinking, and emotions. Not everyone experiences these problems, but those who do may have greater difficulties managing their lifestyle in heart-healthy ways. We are trying to develop a practical way to identify these problems and their impact. Also, we're interested in how memory, thinking, and emotions change while you're in the program.

***Who is being asked to take part in this research study?***

You are being asked to participate in this study because you are planning to participate in the *Dr. Dean Ornish Program for Reversing Heart Disease* (hereafter, referred to as the program). You are one of fifty individuals being recruited from hospital sites that have allied with Highmark/Lifestyle Advantage, Inc. to offer the Ornish program. You are eligible to participate in this study if this is your first time attending a site-sponsored Ornish program and you are English-speaking.

***What procedures will be performed for research purposes?***

Your participation in this study requires scheduling two appointments with the Principal Investigator. One appointment is scheduled before you begin the Ornish program and the other, at the end of twelve weeks. These appointments will require between sixty and ninety minutes. These appointments are scheduled on the days, times, and locations of your choosing. If you participate in this research study, you will complete two types of tests:

1. Self-Completed Questionnaires: These include questions about how busy your life is and what you already know about the Ornish program and related topics.
2. Investigator-administered tests: These tests involve memory, visual-perception, and abstract thinking.

During the first twelve weeks of participating in the program, the Principal Investigator will periodically review your program records for two reasons:

3. To understand the nature of your heart disease.
4. To monitor your progress in the program.

***What are the possible risks, side effects, and discomforts of this research study?***

The only risk of this research study is any momentary frustration you may experience if you have difficulty answering some of the questions.

***What are possible benefits from taking part in this study?***

You will receive no direct benefit from taking part in this research study. Your participation will help us improve the clinical instruction methods used in lifestyle interventions in the future.

***What treatments or procedures are available if I decide not to take part in this research study?***

If you decide not to take part in this research study, this will not alter the treatments you receive in the program in any way. All aspects of treatment provided in the program remain the same whether you participate in this study or not.

***Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?***

Neither you, nor your insurance provider, will be charged for the costs of any of the procedures performed for the purpose of this research study.

***Will I be paid if I take part in this research study?***

You will be paid a total of $20 for participating in this study. Payments of ten dollars are made at the end of each session. If you drop out of the program, you will receive ten dollars for completing the pre-test portion of the study.

 Participant's Initials: _____

***Who will pay if I am injured as a result of taking part in this study?***

University of Pittsburgh researchers and their associates who provide services at the UPMC Health System (UPMC HS) recognize the importance of your voluntary participation in their research studies. These individuals and their staff will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research. If you believe that you are injured as a result of the research procedures being performed, please contact the Principal Investigator or a co-investigator listed on the first two pages of this form immediately.

Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the UPMC HS. It is possible that the UPMC HS may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care unless otherwise specifically stated below. You will not receive any monetary payment for, or associated with, any injury that you suffer in relation to this research.

***Who will know about my participation in this research study?***

The hospital staff working directly with you in the Ornish program will know that you participated in this research study although they will not have access to your research results. Any information about you obtained from this research will be kept as confidential (private) as possible. All records related to your involvement in this research study will be stored in a locked file cabinet. Your identity on these records will be indicated by a case number rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research records. You will not be identified by name in any publication of the research results unless you sign a separate consent form giving your permission (release).

***Will this research study involve the use or disclosure of my identifiable medical information?***

This research study will involve the recording of current and future identifiable medical information including hospital and/or other (e.g., physician office) records. This is limited to information that is relevant to your heart disease and participation in the Ornish program (e.g., heart-related tests such as cholesterol/lipid levels, EKG, stress test, etc.). Your participation in this research study will not result in any identifiable information being placed into your hospital medical records.

 Participant's Initials: _____

***Who will have access to identifiable information related to my participation in this research study?***

In addition to the investigators listed on the first two pages of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study:

Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information (which may include your identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study.

In unusual cases, the investigators may be required to release identifiable information (which may include your identifiable medical information) related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

Authorized administrative representatives of the Ornish program, including Dr. Dean Ornish and staff affiliated with Highmark, Lifestyle Advantage, Inc., and the Preventive Medical Research Institute, may review and/or obtain identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of monitoring the accuracy and completeness of the research data and for performing required scientific analyses of the research data.

***For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?***

The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for a minimum of 5 years and for as long (indefinite) as it may take to complete this research study.

***May I have access to my medical information that results from my participation in this research study?***

No medical information will be generated from your participation in this research. You will not receive information about your individual performances on this test protocol. Once results are analyzed, you will be mailed a report that reviews the findings for the entire group of fifty participants.

***Is my participation in this research study voluntary?***

Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. (Note, however, that if you do not provide your consent for the use and disclosure of your identifiable information for the purposes described above, you will not be allowed, in general, to participate in the research study.) Whether or not you provide your consent for participation in this research study will have no affect on your current or future medical care at this hospital, the Ornish program, the UPMC Health System, an affiliated health care provider, or your current or future relationship with a health care insurance provider. You are not under any obligation to participate in this research study.

***May I withdraw, at a future date, my consent for participation in this research study?***

You may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. (Note, however, that if you withdraw your consent for the use and disclosure of your identifiable medical record information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study.) Any identifiable research or medical information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

Your decision to withdraw your consent for participation in this research study will have no affect on your current or future medical care at this hospital, the Ornish program, the UPMC Health System, an affiliated health care provider, or your current or future relationship with a health care insurance provider.

***If I agree to take part in this research study, can I be removed from the study without my consent?***

It is unlikely that you will be removed from this research study by the researchers. The only condition that would cause your removal from is if your test results are incomplete or judged to be invalid.

VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first two pages of this form.

Any questions which I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (412-578-8570).

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

_____ _____

Participant's Signature Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date

# APPENDIX D

## Non-Copyright-Protected Test Forms

| | | |
|---|---|---|
| debt | gist | topiary |
| debris | corps | caveat |
| aisle | hors d'oeuvre | superfluous |
| reign | sieve | leviathan |
| depot | hiatus | prelate |
| simile | gauche | quadruped |
| lingerie | zealot | sidereal |
| recipe | paradigm | abstemious |
| gouge | facade | beatify |
| heir | cellist | gaoled |
| subtle | indict | demesne |
| catacomb | detente | syncope |
| bouquet | impugn | ennui |
| gauge | capon | drachm |
| colonel | radix | cidevant |
| subpoena | aeon | epergne |
| placebo | epitome | vivace |
| procreate | equivocal | talipes |
| psalm | reify | synecdoche |
| banal | indices | |
| rarefy | assignate | |

Participant #: _____ Date _____

Ornish Knowledge Test – **Pre-Test**

This test tells us how much you already know about the Dr. Dean Ornish Program for Reversing Heart Disease and related topics. You are not expected to know all of the answers; these topics will be covered during the first twelve weeks of your program.
Just try your best!

1. The Ornish program offers a way to modify lifestyle-related risk factors for heart disease. Can you name the four major components of Dr. Ornish's "integrated approach" to lifestyle modifications?

   _____ _____

   _____ _____

2. Daily fat intake is limited in the Ornish program. What percent of calories from fat is permitted?

   _____ %

3. State three reasons why caffeine is eliminated from the Ornish program.

   _____

   _____

   _____

4. Saturated fat intake is significantly limited in the Ornish program. How many milligrams of cholesterol are consumed each day in the Ornish program?

   _____mg.

5. To minimize heart disease risk, low density lipoprotein (LDL) levels should be less than _____

6. Limited consumption of sweets and refined grains is permitted in the program. Beyond weight management, why are sweets and refined grains limited?

_____

_____

7. Omega-3 Fatty Acid supplements are recommended for participants in the Ornish program.

   Which fatty acids are recommended?

_____

_____

   How does this recommendation differ for men and women?

_____

_____

8. Name three additional vitamin/mineral supplements thought to be important for heart health?

_____

_____

_____

9. Name five foods classified as “full fat soy products” in the Ornish nutrition guidelines.

_____

_____

_____

_____

_____

10. The Ornish program encourages strength training two or more days per week.
Why?

_____

_____

_____

_____

11. A primary goal of the group support component of the program is to promote interpersonal connectedness. This is important because the lack of social support and isolation increases the chances of what medical outcomes?

_____

_____

12. Name five diseases that occur less frequently in vegetarians?

_____ _____

_____ _____

_____

13. When lipid (cholesterol) levels are checked through blood tests, results are reported through several different lipid levels. Which of these lipid levels is the most important in terms of determining risk for progression of heart disease?

_____

14. Name two emotions that have been scientifically linked with heart disease.

_____

_____

15. The nutrition component of the Ornish program emphasizes eating foods containing phytochemicals. These foods are believed to fight diseases such as cancer and heart disease. Name five foods that are high in phytochemicals.

_____ _____

_____ _____

_____

16. Give five examples of whole grain food products.

Example: *whole wheat bread* _____

_____ _____

_____ _____

17. Body fat and muscle burn different amounts of calories each day.

Each pound of *fat* burns how many calories per day? _____ calories

Each pound of *muscle* burns how many calories per day? _____ calories

18. To obtain the aerobic, heart-conditioning benefit of exercise, it is important to keep your heart rate within a specific range.

What is the highest rate (maximum heart rate) you should not exceed while exercising? _____ beats per minute

What is the lowest rate (minimum heart rate) you should not drop below while exercising? _____ beats per minute

19. Why are fat free dairy products limited in the Ornish program?

_____

_____

20. Most fatal heart attacks occur in individuals having what percent blockage in a coronary artery?

_____%

Participant #: _____ Date _____

**Ornish Knowledge Test –** Post-Test

This test reviews topics covered during the first twelve weeks of the Dr. Dean Ornish Program for Reversing Heart Disease. You may not know all the answers.
Just try your best!

1. The Ornish program offers a way to modify lifestyle-related risk factors for heart disease. Can you name the four major components of Dr. Ornish's "integrated approach" to lifestyle modifications?

   _____ _____

   _____ _____

2. Daily fat intake is limited in the Ornish program. What percent of calories from fat is permitted?

   _____ %

3. State three reasons why caffeine is eliminated from the Ornish program.

   _____

   _____

   _____

4. Saturated fat intake is significantly limited in the Ornish program. How many milligrams of cholesterol are consumed each day in the Ornish program?

   _____mg.

5. To minimize heart disease risk, low density lipoprotein (LDL) levels should be less than _____

6. Limited consumption of sweets and refined grains is permitted in the program. Beyond weight management, why are sweets and refined grains limited?

_____

_____

7. Omega-3 Fatty Acid supplements are recommended for participants in the Ornish program.

   Which fatty acids are recommended?

_____

_____

   How does this recommendation differ for men and women?

_____

_____

8. Name three additional vitamin/mineral supplements thought to be important for heart health?

_____

_____

_____

9. Name five foods classified as “full fat soy products” in the Ornish nutrition guidelines.

_____

_____

_____

_____

_____

10. The Ornish program encourages strength training two or more days per week.
Why?

_____

_____

_____

_____

11. A primary goal of the group support component of the program is to promote interpersonal connectedness. This is important because the lack of social support and isolation increases the chances of what medical outcomes?

_____

_____

12. Name five diseases that occur less frequently in vegetarians?

_____ _____

_____ _____

_____

13. When lipid (cholesterol) levels are checked through blood tests, results are reported through several different lipid levels. Which of these lipid levels is the most important in terms of determining risk for progression of heart disease?

_____

14. Name two emotions that have been scientifically linked with heart disease.

_____

_____

15. The nutrition component of the Ornish program emphasizes eating foods containing phytochemicals. These foods are believed to fight diseases such as cancer and heart disease. Name five foods that are high in phytochemicals.

_____ _____

_____ _____

_____

16. Give five examples of whole grain food products.

Example: *whole wheat bread* _____

_____ _____

_____ _____

17. Body fat and muscle burn different amounts of calories each day.

Each pound of *fat* burns how many calories per day? _____ calories

Each pound of *muscle* burns how many calories per day? _____ calories

18. To obtain the aerobic, heart-conditioning benefit of exercise, it is important to keep your heart rate within a specific range.

What is the highest rate (maximum heart rate) you should not exceed while exercising? _____ beats per minute

What is the lowest rate (minimum heart rate) you should not drop below while exercising? _____ beats per minute

19. Why are fat free dairy products limited in the Ornish program?

_____

_____

20. Most fatal heart attacks occur in individuals having what percent blockage in a coronary artery?

_____%

Participant #_____ Date_____

**Pre-Test Post-Test (Circle One)**

## MARTIN & PARK ENVIRONMENTAL DEMANDS (MPED)

Please provide a rating of 1 through 5 for the following items

**1_____2_____3_____4_____5**
**Not busy at all Rarely busy Somewhat busy Very busy Extremely busy**

_____ 1. How busy are you during an average day?

**1_____2_____3_____4_____5**
**Never Rarely Sometimes Often Very Often**

_____ 2. How often do you have too many things to do each day to actually get them all done?

_____ 3. How often do you find yourself rushing from place to place trying to get to appointments or to get things done?

_____ 4. How often are you so busy that you miss scheduled breaks or rest periods?

_____ 5. How often are you so busy that you miss your regular meal times?

_____ 6. How often are you so busy that you forget what you are supposed to do?

Please provide a rating of 1 through 5 for the following items

**1_____2_____3_____4_____5**
**Never Rarely Sometimes Often Very Often**

_____ 7. How often are you so busy that you cannot follow your heart-healthy eating or exercise program as planned?

_____ 8. How often do you rush out of the house in the mornings to get to where you need to be?

_____ 9. How often do you have so many things to do that you go to bed later than your regular bedtime?

_____ 10. How often do your days follow a basic routine?

_____ 11. How often do you get out of bed in the morning and go to bed at night at about the same time?

_____ 12. How often do you eat all of your meals at the same time each day and night?

_____ 13. How often do you engage in activities at home at a specific time (i.e., read the paper after work, watch a particular television show, children, hobbies, etc.)?

**Participant #:** _____ **Staff** (Initials) _____ **Date:** _____

# Observed Learning: Nutrition Component

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| None | Minor | Moderate | Severe | Profound |

*Rate overall impact of sensory problems on learning*

1 2 3 4 5 Visual, hearing, and motor difficulties may have interfered with learning.

*Circle or underline any problems with the following:*

**Seeing** educational materials, slide presentations

**Hearing** lectures, instructions, and lectures

**Writing** in food diaries

***Describe any specific problems:*** _____

_____

_____

_____

***Circle or underline all examples that apply***

1 2 3 4 5 1. Confusion or difficulties paying attention. *(e.g. disoriented to day, date, place, and/or time; basic arousal level below average; distracted and/or skips from one topic to the next, falls asleep during sessions, etc.)*

1 2 3 4 5 2. Trouble remembering specific facts. *(e.g. serving amounts and limits in the Ornish pyramid; forgetting information from previous sessions; names of staff, other partcipants, etc.)*

1 2 3 4 5 3. Trouble understanding the importance of diet/nutrition to the management of his/her disease. *(e.g. doesn't seem to view the eating plan seriously enough; thinks he/she is adhering although is is not adhering completely; cavalier attitude, etc.).*

1 2 3 4 5 4. Difficulties with self-reflection, poor organization, or anticipation of future problems interferes with learning. *(e.g. inability to think ahead for things such as heart-healthy meal preparations at home and/or making sure healthy food choices are built into busy days/weeks; poor insight re: the use of food diaries to reflect upon and self-monitor progress; faulty future concerns (i.e. fails to ask questions re: how to maintain dietary adherence for special events, etc.)*

| Excellent | Above Average | Average | Below Average | Poor |
|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 |

5. As compared with other program participants, how do you rate this participant's learning of the nutritional component of the Ornish program?

**Participant #:**_____ **Staff (Initials)**_____ **Date:** _____

# Observed Learning: Exercise, Stress Management, and Group Therapy

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| None | Minor | Moderate | Severe | Profound |

***Rate overall impact of sensory problems on learning***

1 2 3 4 5 Visual, hearing, and motor difficulties may have interfered with learning.

***Circle or underline any problems with the following:***

**Seeing** educational materials, slide presentations

**Hearing** lectures, instructions, and lectures

**Writing** in food diaries

***Describe any specific problems:*** _____

_____

_____

_____

***Circle or underline all examples that apply***

1 2 3 4 5 1. Confusion or difficulties paying attention. *(e.g. disoriented to day, date, place, and/or time; basic arousal level below average; distracted and/or skips from one topic to the next; falls asleep during sessions, etc.)*

1 2 3 4 5 2. Trouble remembering specific facts. *(e.g. how to use specific exercise equipment;"safe" resting and exercise heart rates; information from previous sessions; names of staff, other participants, etc.)*

1 2 3 4 5 3. Trouble understanding the importance of lifestyle changes to the management of his/her disease. *(e.g. doesn't seem to take exercise, stress management, and group therapy seriously enough; thinks he/she is already adhering although is not adhering completely; cavalier attitude, etc.).*

1 2 3 4 5 4. Difficulties with self-reflection, poor organization, or anticipation of future problems interferes with learning. *(e.g. inability to think ahead for things such as making plans to exercise and practice stress management at home; fitting exercise and stress management into a busy week; poor insight re: the use of the Personal Awareness Logs to reflect upon and self-monitor progress; faulty future concerns (i.e. fails to ask questions re:stress management and exercise in special situations, such as travel, etc.)*

| Excellent | Above Average | Average | Below Average | Poor |
|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 |

5. As compared with other program participants, how do you rate this participant's learning in the Ornish program?

# APPENDIX E

## Ornish Food Diaries and Personal Awareness Logs (PAL)

Name:_____ Week Beginning:_____

# Reversal Diet Food Diary

| Monday<br>Food & Amount: | Tuesday<br>Food & Amount: | Wednesday<br>Food & Amount: | Thursday<br>Food & Amount: |
|---|---|---|---|
| Grains | Grains | Grains | Grains |
| Nonfat Dairy | Nonfat Dairy | Nonfat Dairy | Nonfat Dairy |
| Vegetables | Vegetables | Vegetables | Vegetables |
| Fruits | Fruits | Fruits | Fruits |
| Protein | Protein | Protein | Protein |
| Sweets | Sweets | Sweets | Sweets |
| Alcohol | Alcohol | Alcohol | Alcohol |

## Reversal Diet Food Diary

**Friday**
**Food & Amount:**
Grains

Nonfat Dairy

Vegetables

Fruits

Protein

Sweets

Alcohol

**Saturday**
**Food & Amount:**
Grains

Nonfat Dairy

Vegetables

Fruits

Protein

Sweets

Alcohol

**Sunday**
**Food & Amount:**
Grains

Nonfat Dairy

Vegetables

Fruits

Protein

Sweets

Alcohol

# Dietary Log

## *Food groups*

*Please indicate the number of servings consumed from each group for each day*

*(PROTEIN SOURCES)*

| (Points) Food Group Servings | (1) Whole Grains 6 or more | (1) Veggie 3 or more | (1) Fresh Fruit 2 to 4 | (1) Soy* Prod (full fat) 1 | (1) Peas, beans, Egg whites 1 to 3 | (1) nonfat dairy 0 - 2 | (1) Sweets 0 to 2 | (1) lowfat foods ≤3gm fat 0 to 3 | (1) Suppl √ for all | (½) NO Caffeine | (½) limited Alcohol | Food Grp Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Mon | | | | | | | | | | | | |
| Tues | | | | | | | | | | | | |
| Wed | | | | | | | | | | | | |
| Thur | | | | | | | | | | | | |
| Fri | | | | | | | | | | | | |
| Sat | | | | | | | | | | | | |
| Sun | | | | | | | | | | | | |
| *Total Weekly Points* | | | | | | | | | | | | |

*Dietary Guidelines:*
*Please indicate if you were able to follow the diet guidelines with a "Y" (Yes) or "N" (No)*

| (5) NO ADDED FAT & OIL | (5) NO MEAT FISH POUL-TRY | D.Guideline Total |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

**1 Food Group Serving Size =**

- ½ cup for fruits, cooked grains, vegetables, cooked beans, peas, cooked cereals, pasta, rice
- cold cereals: ¼ cup Grape Nuts, ½ cup shredded wheat, ¾ cup flakes
- 1 cup for soy milk, soup
- 1 slice of bread or 1 tortilla
- 1 oz soy cheese
- 2 tsp jams, jelly, sugar, syrup
- ¼ block firm tofu
- ½ cup soft tofu
- Alcohol—1.5 oz liquor, 4 oz wine, 12 oz beer
- Low fat: ≤3grm fat- no hydrogenated, no saturated fat in ingredients

Recommended # of Daily Servings:

- Whole grains: 6 or more
- Fresh vegetables: 3 or more
- Fresh fruit: 2 to 4
- Soy Product: 1 or more (tofu, soy milk, soy beans, etc.)
- Peas, Beans: 1-3
- No added fats or oils
- No animal products-note exceptions
- No caffeine
- Sweets – 2 servings or less
- Foods w/added fat- 0-3
- Sodium—moderate salt unless medically prohibited
- Water – minimum of 8 cups/day

**Recommended Daily Variety of Fruits and Vegetables**
**(Choose a *Variety* of Colors!)**

Dark green/Cruciferous
- broccoli, Brussels sprouts, cabbage, cauliflower, kale (1 or more)

Vitamin C Source
- citrus, kiwi, strawberries, red peppers, broccoli (1 or more)

Beta-carotene source
- sweet potatoes, carrots, apricots, mango, papaya

Folate
- green leafies, fortified cereals and orange juice, yeast breads and wheat germ

- **Supplements (Vit Suppl):**
- Multivitamin with B12, no iron – 1 daily
- Vitamin E: 400 IU daily
- Vitamin C: 1 – 3 grams daily
- 3 gm fish oil for men
- 2 gm fish oil & 2 gm flaxseed oil for women

Name: MARY ANN KELLY WEEK 3 Week Beginning: February 4, 2002

# Reversal Diet Food Diary

— = servings
( ) = not wholegrain
low fat processed foods ≤ 3g fat
~~ = full fat soy

## Monday

Food & Amount:

Grains
2 2 sl Whole Wheat/Grain "Dakota" (Montana Mills) no oil or eggs
0.12 Y8c br. rice, wh. wheat pasta (in soup)
2 1 sm large whole wheat pizza crust
2 2 pcs. whole grain cornbread (Hodgkin's Mill) 4.12
(1) 3c air-popped popcorn
(1) 1 nonfat tortilla (not whole wheat)

Nonfat Dairy
1 2TB fat free sour cream
.25 Y4c skim milk 1.25 (in cornbread)

Vegetables
2 1c (cooked) mixed veggies (soup)
2 2c salad romaine, radicchio, radish, celery, cucumber, zucchini, tomatoes, green onions
1 Y2c spinach (cooked)
1 Y2c red, yellow, green peppers onions, tomatoes, mushrooms (on pizza) (cooked) 6.12
.5 Y2c salsa

Fruits
1 1 Y4c fresh strawberries
1 2 fresh tangerines 2

Protein
1 Y2c low fat tofu/ranch dressing
2 1/4 c black beans
3/4c chic peas, lentils

Sweets
Y2c edamame (in soup)
Y2 oz Veggie Shreds (mozzarella)

Alcohol

3c Cafix
1c Postum

## Tuesday

Food & Amount:

Grains
2 1c Kashi
1 Y2c puffed millet
1 Y2c puffed wheat
2 1 whole wheat sandwich roll
2 1c whole wheat/quinoa pasta
.5 Y4 whole wheat pita

8.5

Nonfat Dairy
1 1c nonfat skim milk 1
.5 (Y2c nonfat ice cream) counted below also under sweets

Vegetables
1 ~~Vegetables~~ lettuce, tomatoe, onion, pickle (on sandwich)
3 3c salad (romaine, radicchio, radish, celery, cucumber, carrots, gr. onions, broccoli, mushrooms (with no fat/no cal dressing)
1 Y2c fat free marinara 6

Fruits
1 1sm banana
1 Y2c tangerine juice 2

Protein
1 1 svg tofu-ham lunch meat
1 1sl tofu pepper-jack cheese veggie slice
(taste of tempeh, veggie pepperoni 2oz smoothie)

Sweets
1 Y2c nonfat ice cream

Alcohol

4c Cafix

## Wednesday

Food & Amount:

Grains
2 1 whole wheat Bagel (Thomas)
2 1 whole wheat pita
.5 Y4c whole wheat bulgur
2 2sl whole rye bread
1 1sl whole wheat bread
.12 Y8c whole wheat pasta (in soup)
2 2 pcs. homemade (whole grain) cornbread
(3) 3sl pizza shell (no-fat) white, not whole wheat flat bread 1.5

Nonfat Dairy 37
.25 Y4c skim milk (in soup)
.12 Y8c skim milk (in cornbread) 1.2 33

Vegetables
1 1c homemade tabouli (lemon juice, mint, parsley, onions, tomatoes, cuffes)
1 Y2c veggie broth
1 Y2c cooked onions, tomatoes
3 3c salad (romaine, radicchio, radish, celery, onion carrot, mushroom, tomatoes, zucchini, broccoli) with no fat no calorie dressing
1 Y4c fat free marinara, Y4c cooked gr. peppers

Fruits
1 1 sm. banana
1 1 tangelo 2

Protein
.5 Protein Y2 svg (8pcs) veggie pepperoni
1 Y2c chic peas
1 Y2c lentils
1 1/2 oz Veggie Shreds, Mozarella
Sweets Edamame
2 2TBS honey spread, orange

Alcohol

3c Cafix

## Thursday

Food & Amount:

Grains
2 1c Kashi
1 Y2c puffed millet
1 Y2c puffed wheat
2 1c whole wheat pasta
1 1pc whole grain cornbread 9
2 4 RY-VITA Whole grain RYE CRACKERS (fat free)
(1) 3c air-popped popcorn

Nonfat Dairy
1 1c nonfat skim milk 1

Vegetables
3 3c salad (romaine, radicchio, carrot celery, onions, tomatoes, broccoli, mushrooms, portabello zucchini)
1 Y2c mushrooms
.5 Y2c green pepper, celery, onion (raw)
2 1c corn, cooked 1.5

Fruits
1 1sm banana 2
1 1c melon, pineapple

Protein
~~1 tempeh~~ (1c no fat mayo) → mock chicken salad
1 Y2c lima beans (in garlic/lima bean soup)
Y2c seitan (in mushroom stroganoff)
1 low fat tofu/ranch/basil dressing
Sweets vanilla ice cream
1 Y2c fat free, no sugar added
1 1TB fat free caramel topping

Alcohol

4c Cafix

— = servings.
( ) = not whole grain
food ≤ 3g fat
* = full fat soy

# Reversal Diet Food Diary

## Friday

**Food & Amount:**

Grains
1 1 svg (16 tidbits) fat-free sourdough pretzel tidbits
2 1 whole wheat pita
2 4 RYVITA crackers (whole grain rye)
.5 ¼c whole wheat bulgur (in tabouli)
12 ⅛c whole wheat pasta (in soup)
2 1c whole wheat pasta
2 1c Kashi
1 ~~⅛c~~ puffed millet
1 ½c puffed wheat

Nonfat Dairy
1 8oz skim milk

Vegetables (2 mints, 2 lemon) (in tabouli)
1 1c raw parsley, onions, tomatoes, cukes
3 3c raw salad (same ingreds. as previous)
2 1c cooked cabbage, zucchini, onions, tomatoes (in soup)
1 ½c cooked portabello mushroom

Fruits
1 1 orange
1 1 sm. banana

Protein
~~½c tempeh~~ mock chicken salad (2 nofat mayo)
* ¼c edamame
.5 ¼c seitan (in mushroom stroganoff)
1 Sweets ½c lima beans (in soup)
½c chic peas
½c fat free, no sugar added vanilla ice cream
1 Alcohol

## Saturday

**Food & Amount:**

Grains
2 2 sl "Dakota" whole wheat - no added fat or eggs
1 ½ whole wheat pita
2 1c whole wheat spaghetti
2 2pcs whole grain cornbread

(1) 2 sm. red potatoes
(2) 1 sourdough roll (fat free - Panera)

Nonfat Dairy
1 8oz skim milk 1½
0.5 1 TB fat free sour cream

Vegetables
2 2c yellow, green peppers, mushrooms onions (raw)
2 2c salad (Romaine, tomatoes, onions) 1½
1 ½c Marinara (Dellalo - Fat Free)
.5 1c Mesa Bean & Veg. Soup (Panera) (.5 g fat / 5 sug. - corn oil towards end of nutrit. info)
← Protein veggies

Fruits
1.5 1½ orange
1 1 sm banana 1½

Protein
2 ½c Egg beaters
.5 ¼c beans (in veg. bean soup)
.5 ¼c low fat tofu dressing
1 ~~Sweets~~ Veggie Shreds, mozzarello
1 TB Honey
1 ½c fat free vanilla ice cream
Alcohol no sugar added

3c Cafix

## Sunday

**Food & Amount:**

Grains (whole wheat & whole grain cornmeal)
3 3 pcs whole grain cornbread (homemade)
1.5 1 very large whole wheat tortilla (Paramount)
.12 ⅛c whole wheat pasta (in soup)
1 4 svgs Whole Brown Rice Snap Crackers (counted the same as rice cakes)
2 1 whole wheat pita

7.62

Nonfat Dairy
1 2 TB fat free sour cream

* ¼c chopped spinach, cooked
.25 Vegetables ¼c salsa, raw
2 1c veggie broth
3 3c salad (spinach, radicchio, romaine, radish, mushroom, celery, yellow/green peppers, carrots, broccoli, cucumber, green onions)
.75 ¾c mixed veggies cooked, in soup

Fruits
1 1 sm banana 2
1 1 orange

1 ~~Protein~~ ½c low fat tofu/ranch/basil dressing
1 * ¼c edamame (in soup)
* ¼c Veggie Shreds, cheddar 1
¼c black beans
~~Sweets~~ 3/4c lima beans
~~Tofu~~ bologna, 3 slices
½c fat free Sorbet (Haagen Dazs Peach)
1 sugar, brown (on pita) 2
Alcohol

5c Cafix

# Dietary Log

## Food groups

*Please indicate the number of servings consumed from each group for each day*

(PROTEIN SOURCES)

| (Points) Food Group Servings | (1) Whole Grains 6 or more | (1) Veggie 3 or more | (1) Fresh Fruit 2 to 4 | (1) Soy* Prod (full fat) 1 | (1) Peas, beans, Egg whites 1 to 3 | (1) nonfat dairy 0 - 2 | (1) Sweets 0 to 2 | (1) lowfat foods ≤3gm fat 0 to 3 | (1) Suppl √ for all | (¼) NO Caffeine | (¼) limited Alcohol | Food Grp Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Mon | 6.12 | 6.5 | 2 | 1 | 3 | 1.25 | 0 | 0.5 | ✓ | N | N | |
| Tues | 8.5 | 5 | 2 | 1 | 2 | 11.5 | 1 | 1 | ✓ | N | N | |
| Wed | 9.62 | 7 | 2 | 1 | 2.5 | 0.37 | 2 | 0.5 | ✓ | N | N | |
| Thur | 9 | 6.5 | 2 | 1 | 3 | 1 | 2 | 1 | ✓ | N | N | |
| Fri | 10.62 | 7 | 2 | 1 | 2.5 | 1 | 1 | 1 | ✓ | N | N | |
| Sat | 7 | 4.5 | 2.5 | 1 | 3 | 1.5 | 2 | 2 | ✓ | N | N | |
| Sun | 7.62 | 6.5 | 2 | 1 | 3 4 | 1 | 2 | 0.5 | ✓ | N | N | |
| Total Weekly Points | 7 | 7 | 1 | 1 | 4 | 1 | 1 | 1 | 1 | 3.5 | 3.5 | 69/70 |

*Dietary Guidelines:*
*Please indicate if you were able to follow the diet guidelines with a "Y" (Yes) or "N" (No)*

| (5) NO ADDED FAT & OIL | (5) NO MEAT FISH POUL-TRY | D.Guideline Total |
|---|---|---|
| N | N | |
| N | N | |
| N | N | |
| N | N | |
| N | N | |
| N | N | |
| N | N | |
| 35 | 35 | 70/70 |

**1 Food Group Serving Size =**

- ½ cup for fruits, cooked grains, vegetables, cooked beans, peas, cooked cereals, pasta, rice
- cold cereals: ¼ cup Grape Nuts, ½ cup shredded wheat, ¾ cup flakes
- 1 cup for soy milk, soup
- 1 slice of bread or 1 tortilla
- 1 oz soy cheese
- 2 tsp jams, jelly, sugar, syrup
- ⅓ block firm tofu
- ½ cup soft tofu
- Alcohol—1.5 oz liquor, 4 oz wine, 12 oz beer
- Low fat: ≤3grm fat- no hydrogenated, no saturated fat in ingredients

Recommended # of Daily Servings:

- Whole grains: 6 or more
- Fresh vegetables: 3 or more
- Fresh fruit: 2 to 4
- Soy Product: 1 or more (tofu, soy milk, soy beans, etc.)
- Peas, Beans: 1-3
- No added fats or oils
- No animal products-note exceptions
- No caffeine
- Sweets – 2 servings or less
- Foods w/added fat- 0-3
- Sodium—moderate salt unless medically prohibited
- Water – minimum of 8 cups/day

Recommended Daily Variety of Fruits and Vegetables
(Choose a *Variety* of Colors!)

Dark green/Cruciferous
- broccoli, Brussels sprouts, cabbage, cauliflower, kale (1 or more)

Vitamin C Source
- citrus, kiwi, strawberries, red peppers, broccoli (1 or more)

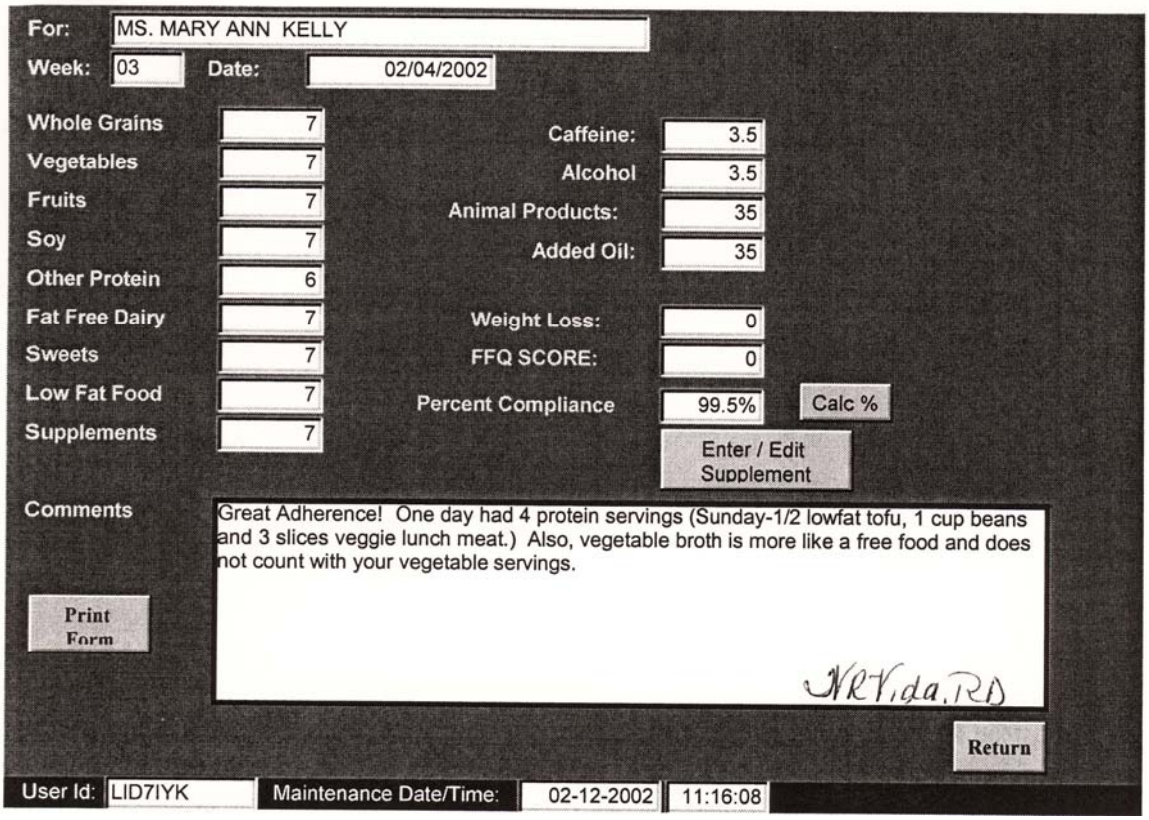
Beta-carotene source
- sweet potatoes, carrots, apricots, mango, papaya

Folate
- green leafies, fortified cereals and orange juice, yeast breads and wheat germ

Supplements (Vit Suppl):

- Multivitamin with B12, no iron – 1 daily
- Vitamin E: 400 IU daily
- Vitamin C: 1 – 3 grams daily
- 3 gm fish oil for men
- 2 gm fish oil & 2 gm flaxseed oil for women

*Your comments:*


For: MS. MARY ANN KELLY
Week: 03
Date: 02/04/2002
Whole Grains 7
Vegetables 7
Fruits 7
Soy 7
Other Protein 6
Fat Free Dairy 7
Sweets 7
Low Fat Food 7
Supplements 7
Caffeine: 3.5
Alcohol 3.5
Animal Products: 35
Added Oil: 35
Weight Loss: 0
FFQ SCORE: 0
Percent Compliance 99.5%
Calc %
Enter / Edit Supplement
Comments
Great Adherence! One day had 4 protein servings (Sunday-1/2 lowfat tofu, 1 cup beans and 3 slices veggie lunch meat.) Also, vegetable broth is more like a free food and does not count with your vegetable servings.
NRVida,RD
Print Form
Return
User Id: LID7IYK
Maintenance Date/Time: 02-12-2002 11:16:08

## Personal Awareness Log (PAL)

**Name:**_____ **Week Starting:** _____

**Stress Management**: 1. List total minutes. 2. Check the modalities practiced. (Class is 60 minutes, however list any additional stress management time on the day of class).

| | Minutes | Breath | Poses | Meditation | Relaxation | Imagery |
|---|---|---|---|---|---|---|
| Mon. | | | | | | |
| Tues. | | | | | | |
| Wed. | | | | | | |
| Thurs. | | | | | | |
| Fri. | | | | | | |
| Sat. | | | | | | |
| Sun. | | | | | | |

**Total Minutes:** _____ (Should be at least 420 minutes per week)

**Example of using a stress management technique in your daily life:**

_____

_____

_____

## Exercise Sessions

| Day of the Week | Type of Aerobic Exercise | Aerobic Exercise Duration | Type of Resistance Training | Aerobic Exercise Heart Rate | Rating of Perceived Exertion (RPE) |
|---|---|---|---|---|---|
| **Mon.** | | | | | |
| **Tues.** | | | | | |
| **Wed.** | | | | | |
| **Thurs.** | | | | | |
| **Fri.** | | | | | |
| **Sat.** | | | | | |
| **Sun.** | | | | | |

**Total Minutes:** _____ (Should be at least 180 minutes per week)

## Group Support

**Please rate your participation in group immediately after group.**

**1 = None of the time** **2 = A little of the time** **3 = Some of the time**
**4 = A good bit of the time** **5 = Most of the time** **6 = All of the time**

| Weekly Support Group Goals | Rating 1st day | Rating 2nd day |
|---|---|---|
| **Awareness of Feelings** | | |
| **Self Disclosure & Sharing of Feelings** | | |
| **Expression of Empathy** | | |
| **Listening of Empathy** | | |
| **Connecting Socially with Group Members** | | |
| **Taking Responsibility for Group Process** | | |

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