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A randomized clinical trial comparing liberalized diets and therapeutic diets in long-term-care residents

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A RANDOMIZED CLINICAL TRIAL COMPARING LIBERALIZED DIETS AND THERAPEUTIC DIETS IN LONG-TERM-CARE RESIDENTS

By

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The population of elderly people in the United States is predicted to increase in large numbers within the next few decades. Many of them will be admitted to long-term-care centers in the waning years of their lives. Health care professionals will need to be prepared for this influx of the elderly into these institutions and for their demands of improved quality of life in these centers. Unplanned weight loss has become one of the major predictors of mortality in long-term-care residents. The purpose of the study was to compare the use of liberalized diets with the traditional therapeutic diets long advocated in long-term-care facilities in the United States. The objectives were to conduct a randomized clinical trial with a treatment group (subjects who consumed liberalized diets) and a control group (subjects who continued with their usual therapeutic diets), and to compare outcomes between the two groups. The randomized clinical trial was conducted for 18 weeks from April to August 2009 at a long-term-care facility in rural North Mississippi. Twenty-two persons ranging in age from 54 to 100 years were approved by their physicians for participation in the trial. All of these persons

participated and completed the trial. Eleven of the participants received their prescribed therapeutic diet and 11 participants received a liberalized diet for the length of the trial study. At the end of the study, there were no significant differences ($p>0.05$) in mean body weights and laboratory values between the two groups. However, there was a trend of weight loss in the therapeutic diet group (mean weight loss of 2% (1.4 kg) during the 18-week trial), and although it was not significant ($p>0.05$), this supports the growing belief of those who advocate liberalized geriatric diets to improve quality of life and prevent unintentional weight loss. Participants in the liberalized diet group did not experience weight loss and gained 0.5 kg by the end of the study.

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CHAPTER I

INTRODUCTION

Tom Brokaw, a national news commentator, called his generation's parents the "Greatest Generation" who ever lived. However, it is the Baby Boomers, born 1946 through 1964, who have changed the face of this nation in every facet of their lives. These baby boomers are now becoming the senior citizens of this country and will continue to re-write history. This evolution of a new perspective on aging will be completed as they become the Oldest Generation of Americans. Indeed, by the year 2030, it is estimated that the 12% of the elderly (36.8 million persons over the age of 65 years) in the United States will double (Rowland & Bellizzi, 2008).

Statement of the Problem

According to Crogan and Pasvogel (2003), weight loss and malnutrition combine to create the devastating triad of poor quality of life, morbidity, and mortality. Unplanned weight loss has become one of the major predictors of mortality in long-term-care residents. Therapeutic diets, as a component of Medical Nutrition Therapy, have long been advocated in nursing homes. In a study by Buckler et al. (1994), most malnourished residents were on restrictive therapeutic diets. Yen (2005) stated that malnutrition is prevalent in long-term-care residents and advocated liberalized geriatric diets as an intervention to improve nutrition and quality of life. A liberalized diet, then,

may serve as the catalyst to help prevent malnutrition and the subsequent spiral of weight loss (Aldrich & Massey, 1999).

Purpose and Objectives of the Study

The purpose of the study was to compare the use of liberalized diets with the traditional therapeutic diets long advocated in long-term-care facilities in the United States. The objectives were to conduct a randomized clinical trial with a treatment, or intervention, group (those participants who will be consuming liberalized diets) and a control group (those participants who will continue with their usual therapeutic diets) and compare the outcomes between the two groups.

Benefits of the Study

A liberalized diet may improve appetite and prevent unintentional weight loss which could be advantageous to the participants. According to Speroff et al. (2005), positive dining experiences should serve to foster a greater degree of independence in elderly residents and aid in minimizing negative health outcomes. Those negative health outcomes included loss of mobility, dysphagia, and chronic diseases which have, in the past, necessitated therapeutic diets (Speroff et al., 2005). The present study closely monitored anthropometric measures and biochemical indicators, and it was predicted that some indicators would improve. Diet satisfaction should improve and this will help the long-term-care residents perceive an improvement in quality of life.

Significance of the Study

A randomized clinical trial will provide the best chance of affirming that the results from the study are caused by the treatment/intervention and not by other factors. Evidence-based nutrition guidelines have assessed the primary goals of Medical Nutrition Therapy for older adults with unintended weight loss as the following: increase energy, protein, and nutrient intakes; improve nutritional status; and improve quality of life. A liberalized diet may serve to meet these goals by improving appetite and preventing unintentional weight loss which will be advantageous to the participants.

CHAPTER II

REVIEW OF LITERATURE

Definitions, Demographics, Statistics, and Trends

In 2006 there were 37.3 million people in the United States 65 years and older. This group comprised roughly 12.4% of the people in this country (Galson, 2009). An American born at the beginning of the 20th century could expect to live 50 years. Now, at the beginning of the 21st century, life expectancy is 77 years of age. By the year 2125, life expectancy is anticipated to increase to an average of 85 years (Roberts & Rosenberg, 2006). According to Preston (2007), this increase in life expectancy has been brought about in part by an increase in national income, the best single indicator of living standards. Other factors that have contributed to this trend of increasing life expectancy include a diffusion of medical and health technologies, facilities, and personnel. By 2030, 71.5 million adults will be 65 years and older and 9.6 million of these adults will be 85 years of age and older (United States Census Bureau, 2000). Americans aged 85 years and older are the fastest growing group. It is estimated that in one-fifth of states, the number of older people will exceed the number of school-aged children (United States Census Bureau, 2000). With the influx of this group into the population, health care professionals should have superior knowledge of evidence-based research and clinical trials that contribute to the health and welfare of this burgeoning group of Americans.

As would be expected with this population, researchers and statisticians have given much attention to health trends as they relate to long-term care and medical care. Parker and Thorslund (2007) determined that studying health patterns in the elderly will lead to a better understanding of the primary factors associated with health and aging. These studies will enable researchers to make projections of future needs and resources. For the registered dietitian who works with this geriatric population and in long-term-care settings, this is an especially important issue. As the population ages, long- term care will expand to include a myriad of health services and settings. Care for the elderly will include not only long-term-care facilities, but also adult day services, adult foster homes, Alzheimer care units, assisted living facilities, continuing care retirement communities, residential care facilities, respite care services, and retirement homes/complexes/communities.

Long-Term Care and the Elderly

Approximately 1.3 to 1.5 million Americans over the age of 65 years are now residents in long-term-care facilities (Spillman & Black, 2005). This number may double and possibly even triple with the "graying of America" that is predicted in the next 20 years. The increasing age of these residents will give rise to increases in health problems, dementia-related cognition problems and diminished capacity to perform normal Activities of Daily Living (ADL). In addition, the average length of stay in a nursing home, now at 2.2 years, will also be expected to increase with improvements in health care and anticipated longevity of residents (Herman, 2005).

As this length of stay increases, it is imperative that a home like atmosphere be given to those residents, many of whom will remain in the institution until they die. Quality of life has now become a critical and vital component of the health care service provided to the elderly. Quality of life directly impacts interpersonal relationships with families, staff and peers. Respect and freedom of expression are also positive factors. Finally, there is the component of security which gives comfort, order, structure, and knowledge that the appropriate level of care will be provided. The six items that were determined to be most important to meet the desired levels of satisfaction were respect from employees, feeling at home, being able to feed oneself, varied menus, comfortable seating, and having appetizing meals (Lengyel et al., 2004). The importance of these findings to nutrition professionals are directed to the key aspects of the above study which relate solely or indirectly to nutritional interventions with long-term-care residents.

Socialization incurred from food and mealtime may contribute greatly to perception of quality of life for many elderly residents. As satisfaction with their meals increases, so does their perceived quality of life. At the other end of the spectrum, quality of life may be negated by the dining experience which may include unappetizing, unappealing and poorly presented meals, unfamiliar foods, and the failure of the staff to recognized the socio-cultural food preferences acquired over a period of many years. According to Johnson (2010), a concerted effort to provide meaningful social interactions, activities, and opportunities will be necessary to change the culture of long-term-care facilities so they are centered on the residents. When the elderly are admitted to long-term care, they are introduced to a new way of meal management and a new environment. As they experience loss of traditional and familiar modes of housekeeping

and mealtime experiences, they are sometimes faced with a loss of identity which affects their perceptions of quality of care and, ultimately, quality of life.

In addition, poorly trained staff or inadequate staffing may contribute to a lack of adequate time for meal enjoyment, since the elderly may experience difficulty in manipulating dishes and may require added time for the completion of those activities necessary for full meal enjoyment. Staff/caregiver-resident relationships remain a vital component in the achievement of positive quality of life perception in long-term-care residents. Carrier et al. (2009) concluded the resident/staff ratio was significantly related to quality of life for the residents. Although the assumption has always been that having a greater number of staff to assist residents should improve their quality of life, Carrier et al. (2009) reported that this may not be so. In their study, smaller institutions tended to have higher ratios of residents per staff member than larger institutions; however, residents in the smaller facilities appeared to develop stronger and more intimate relationships with staff and other residents. Carrier et al. (2009) speculated that perhaps residents living in the smaller facilities with higher resident/staff ratios felt more autonomous and this had a positive effect.

In the institutionalized elderly, where many choices and freedoms have been taken from them, quality of life is heralded as moving to the forefront of those areas that promote continued health and well being in this group. In a study by Simmons et al. (2009), most residents were able to answer valid questions regarding satisfaction with food service when no cognitive status criteria were used to exclude them from the interviews. Those residents who expressed more dissatisfaction had more symptoms of depression, and experienced lower food and fluid intake, leading to a less than desirable

quality of life. It is this balance of food preferences, meal presentation, staff participation and education, along with a general sense of autonomy and security that merge to transform and mold the complex theme of total nutritional care. It is the role of the registered dietitian and health care team to provide nutritional care and diet therapy that creates a balance of health maintenance and continued quality of life for the remaining quantity of years.

Clinical Trials

Clinical trials enable researchers to test a treatment for effectiveness or safety. A randomized clinical trial is commonly used in healthcare services. Zelen (1979) proposed the following method of planning for randomized clinical trials. There should be a random or chance mechanism to allocate subjects into two groups. The subjects in the first group would receive the standard treatment and those in the second group would receive the experimental treatment. In the final analysis the results of the group with the standard treatment would be compared to the results of the group with the experimental treatment. In a complete randomization trial, each subject will be randomly assigned to one of the two groups. One of the main drawbacks with this procedure would be the possibility of imbalances between groups.

According to Hirsch (2004), "Exploratory or pilot studies (usually observational or early-phase trials) enable decision-making of critical development milestones and better design of subsequent large-scale trials to rigorously test hypotheses." Although many clinical trials have large numbers of participants, trials with small sample sizes can have adequate statistical power to detect differences between treatments. Bray et al.

(2002) reported significant differences ($P < 0.05$) in a randomized clinical trial with 36 subjects (12 in each group, 3 groups) using the repeated-measures fixed design approach in the analysis, with treatments as fixed effects and time points as repeated factors. Their power analysis to detect a difference in weight (kg) between treatment groups with an α level of 0.05 and power of 80% or greater was determined to be a sample of 12 subjects in each treatment (Bray et al., 2002).

Health Issues

Clinical trials may enable researchers to understand more completely the aging process of the elderly and the myriad health issues and multiple disease processes which may negate their ability to obtain the necessary vitamins, minerals, and nutrients. Among these processes are unplanned weight loss, loss of appetite, eating dependency, loss of the major senses of taste and smell, poor oral health, the ever present risk of dehydration and pressure ulcer wounds, loss of mobility, depression, increasing stages of dementia and the resulting sun downing, and polypharmacy resulting from these multiple health problems.

Unplanned Weight Loss

In long-term care, the percentage of residents who experience unintentional weight loss may be as high as 65% (American Dietetic Association, 2005). This weight loss can spiral downward with a disastrous outcome of mortality for the malnourished resident. Beers and Berkow (1999) determined weight loss of 4% over one year is a significant amount of weight loss. Ryan et al. (1995) conducted a study that affirmed those subjects who lost at least 5% total body weight in one month were 4.6 times more

likely to die within a year. According to Morley (2007), nursing home residents who continue to lose weight have a 30% increase of mortality within a six-month period. Ben-Noun (2004) concluded the unplanned weight loss suffered by the elderly may be better understood by studying the causes of weight loss in the geriatric population throughout history. This knowledge can aid in understanding dietary mores and beliefs concerning the aging process.

The changes in energy regulation that occur during the normal aging process also contribute to the weight and fat losses experienced by this elderly population. There are many possibilities for these decreases in energy intake and expenditure including delayed rate of absorption of macronutrients secondary to reductions in taste and smell acuity, and numerous hormonal and metabolic mediators of energy regulation. In addition, changes in dietary intake and a reduction in the variety of foods consumed may further reduce energy intake. Interventions for prevention of this phenomenon include understanding by the health care team of the role diet plays in the maintenance of health through stability of late-life energy regulation. It is imperative to provide a variety of foods that are nutritious and palatable (Roberts & Rosenberg, 2006).

A study by Sturm et al. (2004) focused on the dual contribution of decreased premeal hunger and increased postmeal satiation as independent sources of impaired energy regulation. Their study also addressed the relevance of increased satiation and its association with the increased antral area after meal consumption. Satiation, thus, is defined as the sensation of fullness following a meal that leads to cessation of eating.

Mortality in the elderly is often associated with a decline in body mass and significant weight loss is considered a sentinel event in nursing home residents.

Significant weight loss is characterized as 5% in one month, 7.5% in three months, and 10% in six months (Mathus-Vliegen, 2004). Skates and Anthony (2009) discuss the use of The Mini-Nutritional Assessment Short Form (MNS-SF) with nursing home residents to ascertain the degree of nutritional risk and probability of weight loss in this population. This short form uses body mass index (BMI) and a list of pertinent questions which have points assigned to aid in determining significant weight loss, acute illness, mobility, dementia or depression, and appetite and intake changes. The BMI is an indicator of disease risk in both the underweight and the morbidly obese. It is one screening tool that would aid in determining the malnutrition state of residents in long-term care. According to Harris and Haboubi (2005), the World Health Organization categorizes underweight as a BMI of less than 18.5 kg/m^2, normal weight as 18.5–24.9 kg/m^2, obesity as 30.0–39.9 kg/m^2, and extreme obesity as a BMI of 40 kg/m^2 or greater.

As individuals age, there is a general tendency for gradual weight loss that makes adequate intake of nutrients even more crucial. Weight loss in this population may be a result of physical factors, psychosocial factors, and therapeutic diets which are not palatable to this population. The negative connotations associated with the therapeutic diet will be discussed throughout this review of literature. While the physical factors may be closely associated with the disease processes of aging, there are also psychosocial factors that must be considered. As residents enter long-term care, many experience a profound sense of loss as they leave a home environment where they have experienced a lifetime of memories. For many of them, this constitutes leaving a part of their identity behind and sets the stage for an extended period of readjustment to a new lifestyle. During this time, these residents may suffer from unintended weight loss as they become

acclimated to a new and different way of life. They may not be accustomed to the times that meals are served or the manner in which they are served. In addition, the menus may include foods which they are not accustomed to eating and may not include foods they eat on a daily basis. The ensuing emotions of anxiety, depression, and even anger will have a negative effect on food intake, thus leading to unplanned weight loss.

According to Morley (2003), the MEALS ON WHEELS mnemonic may be used to describe many of the pathological causes of weight loss in the elderly which may be reversible and include: *M*edications*; E*motional issues; *A*lcoholism*; L*ate life paranoia; *S*wallowing problems; *O*ral problems; *N*osocomial infections; *W*andering and other dementia-related behaviors; *H*yperthyroidism, hypercalcemia, hypoadrenalism, hyperglycemia; *E*ating problems, *L*ow salt, low cholesterol, and other therapeutic diets, and *St*ones (cholecystitis).

Loss of Appetite

Many underlying conditions can lead to anorexia, which is one of the premier factors in undernutrition in long-term-care settings. With a diminishing appetite, the body is deprived of nutrients necessary to sustain life. As the intake of total energy is reduced, there is a marked reduction in much needed protein, vitamins, minerals and other necessary nutrients. This leads to a noticeable increase in illness and infection which, in themselves, may lead to a higher metabolic rate. Thus, a cycle emerges where increased metabolic rates lead to increased requirements for energy and protein for individuals who already suffer from decreased intakes secondary to loss of appetite (American Dietetic Association, 2005).

Eating Dependency

Residents who are dependent on nursing staff for eating are at higher risk for malnutrition and dehydration. Speroff et al. (2005) determined self feeding is challenging for those residents who have multiple functional limitations. The health care team should collaborate to facilitate patient independence at meal time when possible. Residents may benefit from adaptive equipment such as specialized utensils and dinnerware or large handled and weighted cutlery. Desired foods which are easier to handle may be given to these residents to facilitate greater independence at mealtime. However, anyone who needs assistance at mealtime should be accorded the aid needed by the nursing staff in order to receive the optimal amount of food provided during the meal.

Loss of Major Senses

Altered sensations of thirst, hunger, and satiety are associated with the aging process (Morley, 2001). These observed deficits in taste and smell may lead to a reduction in the sensory enjoyment of foods, as cited by Drewnowski et al. (1996). The lack of satiety that is sensory-specific, a variety-seeking mechanism, may explain why the elderly restrict their food choices and seek a monotonous diet lacking in essential nutrients.

Poor Oral Health

With aging, the enamel thins on teeth. The teeth then become more sensitive to hot and cold food items. The elderly resident experiencing this problem will begin to limit foods and drinks which cause pain or discomfort. Another factor that may be

overlooked in long-term-care facilities is the poor dentition and ill-fitted dentures which may be a result of weight loss. This creates a cycle where poor eating may by facilitated by poor denture fit which in turn facilitates more problems with denture fit for the elderly experiencing this dilemma.

Higher nutritional deficiencies will be evident in those elderly who suffer from mouth discomfort, problems with chewing and swallowing, and poorly fitted dentures or compromised dentition. Gil-Montoya et al. (2006) cite the association of poor oral hygiene with high morbidity rates as a key reason for establishing individualized oral health policies and oral care protocols for each nursing home.

Dehydration

Dehydration is a fluid imbalance that can be caused by inadequate fluid intake or fluid loss, both of which can occur rapidly in the elderly. According to Holben et al. (1999), proper hydration is necessary not only to maintain skin integrity in the elderly, but also to decrease the propensity for pneumonia and urinary tract infections so often seen with aging. Mentes (2006) listed the risk factors which promote dehydration as: older age; race; medications; level of physical dependency; cognitive impairment; delirium; and concomitant conditions such as frailty, diabetes, cancer, cardiac impairments, and acute infections.

Pressure Wounds

There is limited evidence-based research available regarding the role of nutrition in the treatment of pressure ulcers (Dorner et al., 2008). However, there is a growing

consensus among researchers to address the importance of a comprehensive nutrition care plan for the treatment and prevention of pressure ulcers. Nutrition and accompanying adequate hydration are key indicators in the prevention and/or healing of skin breakdown and the resulting pressure wounds. Research by Desanti (2000) suggested that wounds increase body metabolism. If left untreated or allowed to progress to decreasing stages, this can lead to a significant weight loss, particularly in the area of lean body mass. There is enough scientific agreement on the correlation between nutritional status, body weight, and wound healing to warrant the early establishment of nutritional intervention in the wound healing process. Russell (2001) reported research that demonstrated how protein deficiency contributes to poor healing rates where collagen formation is reduced and wound dehiscence is increased. A diet high in protein, then, would benefit during the proliferate and remodeling phase of wound healing.

According to Mathus-Vliegen (2004), severe malnutrition, impaired oral intake, and the risk of pressure ulcer formation appear to be interrelated. It is difficult to prevent pressure ulcers solely by nutritional intervention, since there is such difficulty in meeting the daily requirements in the elderly. However, the consumption of a diet high in protein and energy may promote wound healing. Mathus-Vliegen (2004) stated, "Attention should be focused on early recognition of a depleted nutritional status and an adequate supervised intake of energy (35 kcal/kg) and protein (1.5 gm/kg), with provision of the recommended daily allowances of micronutrients and with correction of the nutrient deficiencies of old age." Any barriers to adequate nutritional intake should be addressed and corrected without delay to facilitate optimal wound healing.

Loss of Mobility

According to Thomas (2001), most of the elderly can be classified as sedentary since only 7.5% of persons 65 years and older participate in any type of aerobic activity. As these individuals experience functional limitation in the ADL, their level of life satisfaction decreases. The loss of the ability to pursue a formerly active lifestyle can have a profound effect on the perceived quality of life. As discussed earlier, a poor perception of quality of life is a key indicator of meal satisfaction.

Volpato et al. (2001) used data from the Cardiovascular Heart Study to propose a phenotype of frailty in which three of more of five components were present: unintentional weight loss, self-reported exhaustion, weakness, slow walking speed, and low physical activity. Further findings suggested that frail older adults were at an increased risk of subsequent falls, hospitalization, disability, and mortality. Furthermore, frail older women seem to be at increased risk of recurrent falls, fractures and mortality. According to Visser et al. (2003), the increased risk of falling is a result of the gradual loss of muscle strength and muscle mass which is characteristic of the aging process. They further determined that poor Vitamin D status and secondary hyperparathyroidism may also have a large impact on the loss of muscle strength and muscle mass. With this in mind, the preservation of remaining muscle strength in the elderly should be of major concern to practitioners.

During the aging process, strength is decreased as much as 20–40% in the proximal and distal muscles. This loss of skeletal muscle mass and strength that occurs during the seventh and eighth decade of life is known as sarcopenia (Doherty, 2006). Morley et al. (2002) also described sarcopenia as the loss of muscle mass and

diminishment of muscle function that occurs as a result of the aging process. According to Rizzoli et al. (2009) osteoporosis is also predominantly a condition of the elderly. It involves the balance between bone strength and the propensity for falling. According to Baker (2007), "The risk of osteoporosis is a result of genetic predisposition for mineralization and accelerated thinning of the bones along with a risk of negative calcium balance which increases with age. Other factors which increase negative calcium balances include absorption of less calcium in general, immobility, alcohol consumption, smoking, excess dietary protein, excess phosphates, and vitamin D deficiency." Nursing staff in long-term-care facilities must have appropriate prevention methods in place since hip fractures, which occur as a combination of falls and osteoporosis, can have devastating outcomes for the elderly.

Depression

The psychological state of depression, with its accompanying anxiety, loneliness, and grief, is often manifested in the lack of interest shown in meals or nutritional needs. Isolation and loneliness are often seen as social issues of grave concern in the elderly population. When the social environment is characterized by a pleasant, attractive eating facility and satisfactory interpersonal relationships, residents' intakes are increased and they report satisfaction with the meals. The health care team should consider the quality of the food, the quality of the environment, and the individual needs as they formulate a care plan for each resident (Marken, 2004). Any time the dining experience can be enhanced through social support and intervention there can be increased optimal health benefits, as well as psychosocial satisfaction. Weight loss, associated with depression

and accompanying health problems can be reversed with proper treatment of appropriate medication and thorough knowledge of residents' needs and concerns.

Increasing Stages of Dementia and Sun Downing

In a 1999–2000 study of nursing homes, 42% of the 1.5 million residents suffered from various stages of dementia (American Health Care Association, 2001). Documentation by Tamura et al. (2007) attested to the fact that many of these residents with various dementia related disorders, including Alzheimer's Disease, may be more prone to weight loss and resulting malnutrition as they experience increasing frailty and eating difficulties. In addition, increasing cognitive impairment may not be easily recognized by staff, thus creating a lag time between the initial start of weight loss and recognition of dementia related problems.

Many of these elderly eat more in the morning and this is often evidenced by an increase in the percentage of the breakfast meal that is consumed. This should be noted by the nursing staff and efforts made to increase the portion size of these particular residents who exhibit these characteristics. In addition, dietetics professionals should take additional measures to provide foods for later meals that are presented in an appetizing and palatable manner. This circadian shift is even more marked when there is evident cognitive impairment, as cited by Morley (2003). The term "sun downing" is often used in nursing homes to describe this unique change in the elderly that is exacerbated by Alzheimer's Disease or age-related dementia.

In a study conducted by Carrier et al. (2006) in long-term care facilities, 70% of the cognitively impaired participants were at risk of malnutrition. It was also determined

that physiological factors related to dementia could serve to advance the progression of malnutrition, one being the hypermetabolism often seen in this group. In those patients with agitation, caloric needs are increased. This research further cements the importance of acknowledging the environment in long-term care which could be modified to prevent or rectify existing problems determined to contribute to malnutrition among the cognitively impaired.

Simons et al. (2006) presented the following life style factors as confirmation of increased risk of dementia in the elderly: increasing age; lower educational status; high alcohol intake; and lack of physical activity. Specifically, they found gardening to offer positive protection against dementia as it can provide additional physical and mental benefits for the elderly.

Polypharmacy

Polypharmacy is the practice of prescribing multiple drugs for those persons, most notably the elderly, who suffer from a number of debilitating conditions. It is a predictor of unintentional weight loss. According to Doty et al. (2008) certain medications can cause ageusia, which is a loss of the sense of taste. This can significantly affect quality of life issues and dietary choices. In addition, antidepressants and other psychotropic drugs so often prescribed to this population can cause sedation and decreased attentiveness to the individual's surroundings, which can lead to decreased food intake during meals.

There are several major mechanisms involved in drug-nutrient interactions in elderly persons. According to Morley et al. (1988), those mechanisms relating to

nutrition include: appetite suppression; appetite stimulation; decreased nutrient absorption and damage to absorptive mucosal cells; decreased nutrient use; direct competition or antagonism; interference with or enhancement of biosynthesis of any enzyme, coenzyme, or transport protein; and hormonal effects of nutrients.

Discussion of Chronic Disease Processes

Chronic disease processes common to this group include anorexia of aging, cachexia syndrome, dysphagia, and malnutrition. Any of these problems can serve to initiate or exacerbate the malnutrition state.

Anorexia of Aging

As people age, they usually consume smaller amounts of food. This is directly correlated to decreased levels of physical activity, an increasing number of medical conditions, and earlier forms of satiety. In addition, multiple medications, smoking, and a decline in the senses of taste and smell combine to create a condition known as the anorexia of aging.

The development of the anorexia of aging, from a physiological perspective, is most often a result of altered gastric signals which send a signal of premature satiety. Tumor necrosis factor α, interleukin-1, interleukin-6, and ciliary neurotrophic factor are also determined to be particularly potent cytokines responsible for anorexia, muscle mass loss, and low albumin levels. The systemic effects of this cytokine production is evidenced in anemia, immune dysfunction, increased infections, decreased cognition, decreased function, and orthostatic hypotension as reported by MacIntosh (1999).

MacIntosh et al. (2001) reported the increased satiating effect of cholecystokinin (CCK) may be a factor in the anorexia of aging. This gastrointestinal peptide that decreases hunger is known to be increased in older persons. Cholecystokinin is released by the proximal small intestine when lipids and proteins are delivered from the antrum, that portion of the stomach where food collects prior to passage into the small intestine. Cholecystokinin reduces the rate of gastric emptying such that it is believed to be one of the contributing factors in the anorexia of aging.

At the same time, a decrease in ghrelin concentration may also be one of the factors associated with reduced appetite. Ghrelin, which is also produced in the empty stomach, is an orexigenic peripheral signal. It is a gastrointestinal hormone secreted by the epithelial cells lining the fundus of the stomach and acts as a stimulant for appetite and feeding. This loss of ghrelin production may, in itself, provide an explanation for the unbalanced energy homeostasis linked to the anorexia of aging. Frailty may also be related to this correlation between the grhelin mechanism and CCK response to appetite regulation. Frailty syndrome is characterized by negative energy balance, sarcopenia, diminished strength, and lack of tolerance for sustained exercise (Mateu et al., 2009).

Finally, an exaggerated postprandial insulin release may be the final contributing physiological factor in the anorexia of aging. It may be the alterations in this glucose homeostasis which contribute to the altered signals of hunger and satiety. In the study by Mateu et al. (2009), glucose concentrations in young adults were varied, but in the elderly it increased by almost 60% one hour after ingestion. The younger respondents also experienced an earlier and more intense recovery of hunger than did the elderly subjects.

Since insulin is a satiety hormone, the increased circulating concentrations may well be an additional component of the anorexia of aging.

Roberts and Rosenberg (2006) reported high postprandial glucose levels were also believed to contribute to the delayed return of hunger signals as a result of the satiety effect of the high insulin levels. Other mechanisms which regulate food intake, such as CCK and neuropeptide Y (NPY), may also alter central sensitivity. These high postprandial glucose and resulting insulin levels may also be explained by the reduced rate of gastric emptying which the elderly commonly experience. Delayed gastric emptying extends the time period over which nutrients appear in the circulation due to extended digestion. Thus, the delayed gastric emptying may play an important role in the decreased hunger in the elderly as a result of increased satiety.

Cachexia Syndrome

Evans et al. (2008) provided a definition whereby cachexia is defined as "a complex metabolic syndrome associated with underlying illness and characterized by loss of muscle with or without loss of fat." They noted that anorexia, inflammation, insulin resistance and increased muscle protein breakdown are associated with cachexia, with the most prominent feature being unintentional weight loss. The aging-disease dichotomy is often an inseparable conundrum. This is particularly true when anorexia and weight loss is accelerated in older persons when they develop one of more disease processes. Thus, cancer and end-stage heart disease can lead to "the cancer anorexia-cachexia syndrome" and the "cardiac cachexia syndrome," respectively. Cachexia is derived from the Greek words *kakos* meaning "bad" and *hexis* meaning "condition." It is a wasting syndrome,

then, that cannot be corrected alone by adequate nutrition since the problem lies with the hormonal and metabolic abnormalities as cited by (Mathus-Vliegen, (2004).

Dysphagia

According to Chiam (2008), 30–60% of long-term-care residents have dysphagia. Close supervision of eating habits is crucial in long-term-care facilities as residents may begin limiting their intakes of food due to impairments in swallowing. At the same time, they may also begin to avoid certain textures or foods with a particular consistency. Staff should be fully informed of residents' usual intakes, eating habits, and food preferences so early recognition of dysphagia can be addressed. Immediate acknowledgement of dysphagia may aid in eliminating the weight loss that often accompanies this problem. It is imperative that the highest priority be given to the preparation of meals for dysphagia patients. Care must be given to ensure meals are nutritious, appealing, and as attractive as possible in order to stimulate adequate or increased meal intake.

The Malnutrition State

Chen et al. (2001) used numerous criteria to define the malnutrition state. The criteria included: inadequate nutritional status; undernourishment as a result of insufficient dietary intake; poor appetite; muscle wasting; biochemical indicators, including but not limited to low serum albumin and unintentional weight loss. Sullivan (2009) determined protein-energy undernutrition is a common problem in the elderly which affects 40–85% of long-term-care residents with the variance in figures related to differences in populations evaluated and diagnostic criteria utilized.

Denny (2007) discussed the importance of addressing the malnutrition state, as it can have such adverse effects on every system of the body. These adverse consequences included: a reduction in the immune response that can lead to increased risk of infection; impaired wound healing; delayed recovery from illness; an increase in hospital admissions and hospital length of stay; and reduction in muscle strength, fatigue, and symptoms of depression.

Protein Energy Malnutrition (PEM) is one of the most serious problems for long-term-care professionals as PEM is associated with anemia, pressure ulcers, sarcopenia, increased risk of falls, bone loss and hip fractures, declining immune function, impaired immune response to vaccinations, infections, reduced cognitive impairment, functional decline, and poor quality of life according to Morley (2003). This catapults the elderly toward mortality and, at the least, higher utilization of health care resources in the form of more frequent hospitalization, total care needs, and more intense pharmacological and medical treatment. Protein energy malnutrition in long-term-care facilities is believed to range from 23–85% according to Chiam (2008). It is no wonder, with this high percentage, there is an increase in poor outcomes and, ultimately, increased mortality. Since malnutrition is so closely linked to mortality this should be a topic of close scrutiny by all health professionals who work with this population. According to Visvanthum (2003), failure to recognize PEM is unethical on the part of the healthcare professionals. When PEM in the elderly occurs, it creates a burden of significant cost to the individual, families, communities and the healthcare system itself. All healthcare institutions should strive to provide increased education to staff for evaluation and recognition of the malnutrition state in order to facilitate early treatment.

Nutrition and Vitamin Intake

Nutritional care may well be the catalyst in long-term care that serves to contribute the most to improving longevity, promoting improved health, and elevating quality of life. It is the actual nutrient requirements for this population that have stymied many professionals who have undertaken the task of assessing these needs and addressing subsequent care plans to meet these needs.

There is a common misconception by many in the health care field regarding the natural progression of age and disease in the elderly. Ledikwe et al. (2001) stated that although there is a reduction in energy requirements with increased age, there may actually be an increase in requirements for many vitamins and minerals. One of the key issues for the health care team and the registered dietitian is to provide diets that meet the lower energy needs and yet continue to meet nutrient requirements for these vitamins and minerals. Nutritional deficiencies, while they may be common in this age group, are not inevitable. At the same time, the treatment for these deficiencies and the resulting interventions can elicit positive effects and promotion of continuing or improving health consequences for the elderly.

The B vitamins include Vitamin B1 (thiamine), vitamin B2 (riboflavin), Vitamin B3 (niacin), Vitamin B5 (pantothenic acid), Vitamin B6 (pyroxidine), Vitamin B7 (biotin), Vitamin B9 (folic acid) and Vitamin B12 (cobalimin). Nowson (2007) determined that bioavailability of vitamin B6, vitamin B12, folate, iron, and calcium may all be reduced by the decrease of gastrointestinal function associated with aging. This decrease in gastrointestinal function reduces the secretion of gastric acid, intrinsic factor, and pepsin, thus contributing to deficiencies in these vitamins and minerals. Low levels

of Vitamin B12 and high serum folate have been associated with anemia and decreased cognitive function as determined by Morris et al. (2007) and Clarke et al. (2007). A follow-up study of the Framingham Osteoporosis Study was conducted by McLean et al. (2008) to determine the association of B-vitamin concentrations and bone loss and hip fractures. Findings indicated an association with lower Vitamin B6 and greater bone fragility as a result of a reduction in bone mass.

Autier and Gandini (2007) reported results of a meta-analysis of randomized controlled trials that suggested the intake of Vitamin D supplements may decrease total mortality. Heaney et al. (1982) reported the average elderly person is in negative calcium balance and, thus, losing bone mass. They surmised that inadequate calcium intake, along with decreased mechanical loading of the skeleton may serve as key contributors to this loss. Many of the elderly have very limited exposure to sunlight, which is a natural source of vitamin D. In addition, the body's ability to convert Vitamin D to the final active hormone is decreased with age. There is a 0.5–1% reduction in bone mass per year that begins around the age of 40 years. In women, there is additional increased loss in bone mass of 1–2% per year for as many as 10 years during menopause (Ahlborg et al., 2003). According to Marshall et al. (1996), it is this reduction in bone density which contributes to the high rate of hip and vertebral fracture seen in the elderly. There are more than 350,000 hip fractures reported each year, according to McCabe et al. (2004). As the population of people over the age of 65 years increases, this number is likely to be even higher.

The National Institutes of Health (NIH) consensus statement assesses hip fracture as the most serious of all age-related fractures when looking at the rate of incidence,

morbidity, mortality, and the enormous financial costs (Hellekson, 2002). Nowson (2007) determined the effects of this reduction in bone mass can be lessened in old age by consuming adequate intakes of calcium in the diet, maintaining reasonable levels of physical activity, particularly weight bearing activities. A study by Jackson et al. (2006) was conducted to determine the correlation between calcium and Vitamin D with hip fracture prevention in post-menopausal women. While there was significant improvement in bone density, it was noted the 12% reduction in the incidence of hip fractures was not significant. However, it is of note that the findings provide evidence of a positive correlation between calcium and Vitamin D and improved bone health.

Inadequate Vitamin D serum status is also associated with muscle weakness, especially in the proximal muscle groups. When given Vitamin D supplementation, Janssen et al. (2002) reported an improvement in muscle strength, walking distance, and functional ability in elderly people with a Vitamin D deficiency. The current Vitamin D recommendation is 400 to 600 IU/day in middle-aged and older adults. Bischoff-Ferrari (2009) believed the range of 700 to 800 IU/day vitamin D should be recommended in order to be effective in fracture prevention in the elderly.

Protein

Protein is the building block of all cells. It is the basis of the human body structure and required for all stages of healing. As stated by Dorner et al. (2008), "Protein is responsible for the synthesis of enzymes involved in pressure ulcer healing, cell multiplication, collagen and connective tissues synthesis."

There is not a decrease in protein needs during the aging process although there is a reduction in total body protein. According to Chernoff (2004), protein tissue, which accounts for 30% of whole-body protein, declines to 20% or less by 70 years of age. This would seem to lend credence to the belief of many researchers that the recommended dietary allowance (RDA) of 0.8 grams (gm) of protein per kilogram (kg) of body weight for adults should be increased to 1.0–1.2 gm protein per kg body weight. Protein needs may actually be much higher than this recommendation of 1.0–1.2 gm/kg body weight as a result of the disease processes and conditions such as skin breakdown and pressure wounds. Those residents experiencing malabsorption will need additional protein. In addition to disease processes, when the elderly are experiencing chewing/swallowing difficulties and/or gastrointestinal problems, many of them reduce or eliminate some of the meats and dairy products which are good sources of protein. This creates even more difficulties for the health care team searching for ways to incorporate more protein into the daily diet of the elderly residents.

According to Schalk et al. (2006), a decrease in serum albumin concentration in the elderly may be indicative of an increased risk of cardiovascular disease (CVD). Therefore, any changes in serum albumin may be used as early markers for CVD risk. Hostmark (2003) also determined the age-related increase in the occurrence of myocardial infarction may be accompanied by a decrease in serum albumin concentration in the elderly population.

Serum albumin value is also an indicator of zinc status. When serum albumin is decreased, the parallel in decreased zinc concentration is often noted. It is monitored dually with albumin concentration when assessing residents for PEM, psychosocial

issues, and other health conditions. Marcellini et al. (2006) suggested a zinc deficiency, with hypoalbumin values, is indicative of psychological impairment in the elderly. In addition, Meydani (2007) conducted research to determine the role of serum zinc and the incidence and duration of pneumonia in the elderly, the use of antibiotics during the illness, and finally, the incidence of pneumonia induced mortality. Findings were indicative of an association between normal serum zinc concentrations and a decrease in new onset pneumonia, decreased duration of pneumonia, decreased antibiotic treatment, and a decrease in mortality associated with pneumonia. Pilz et al. (2009) reported oxidative stress, immune dysfunction, and CVD are also associated with zinc deficiency.

Therapeutic and Liberalized Diets

In long-term-care settings, the dietitian works closely with the medical staff to provide palatable diets which aid in controlling the disease processes occurring in many of these residents. However, it should be noted the dietetics professional must carefully analyze each person's individual situation and overall prognosis to make the best possible choices concerning the nutrition care made available to each person.

According to Puckett (2005), "The concept of diet therapy has changed over the years as a result of legislation, social and economic factors, the promotion of health and disease prevention, technological changes in food production and preparation, knowledge of disease and nutrition, and customer demands to have their needs met. Past studies have suggested the use of therapeutic diets and decreased selection of foods in long term care may negate the goal of improved quality of life." With the rise in health care costs, coupled with the increase in longevity in this population, a decrease in the prevalence of

malnutrition will serve many purposes. Optimal nutrition leads to improved health, which in turn contributes to less dependency on health care professionals for ADL, less hospitalization or other acute setting experiences, and decreased use of health care resources.

Buckler et al. (1994) determined that most malnourished residents were those on restricted diets. Liberalized geriatric diets have been advocated for years as an intervention to improve nutrition and quality of life. The guidelines for optimal health remain the same as for the general population: choose a variety of foods; maintain a healthy weight, choose a diet low in fat, saturated fat, and cholesterol; eat plenty of vegetables, fruits, and grain products; use sugars and sodium in moderation, alcoholic beverages in small amounts. A balanced diet with a variety of foods that allows individual preferences appears to be best for the majority of older adults (Matthews, 1999).

The Modified My Pyramid for Older Adults (Figure 1) continues to emphasize nutrient dense food choices and importance of fluid balance. In addition, there is added guidance regarding forms of foods which may help meet the unique needs of older adults. According to Jean Mayer, who contributed to the Modified My Pyramid for Older Adults, "Older adults tend to need fewer calories as they age because they are not as physically active as they once were and their metabolic rates slow down. Nevertheless their bodies still require the same or higher levels of nutrients for optimal health outcomes" (United States Department of Agriculture, 2007). The importance of the provision of attractive, palatable food at mealtimes cannot be overemphasized.

There is an emergence of new attitudes in long-term-care facilities today regarding the provision of nutritional care for the elderly. The outdated conception of institutional care with its corresponding institutionalized meal plan has given way to the vision of the "Person-centered" or "Resident-centered" care model. The residents are involved in their care and subsequent care plan meetings in a way they have never been in the past. They are making decisions in the nutritional realm involving their feeding schedules, the types of menus they desire, and the general ambience of their dining atmosphere. They bring to the table a renewed participation in the meal time experience and more profound enjoyment of the meal process. This in turn, should be evidenced by the decrease in weight loss and undernutrition (Chiam, 2008). Their participation in these diet-related decisions, contingent on approval from the appropriate medical personnel, has empowered them and their health care team to become proactive in their quest to counteract the myriad negative effects of poor nutrition.

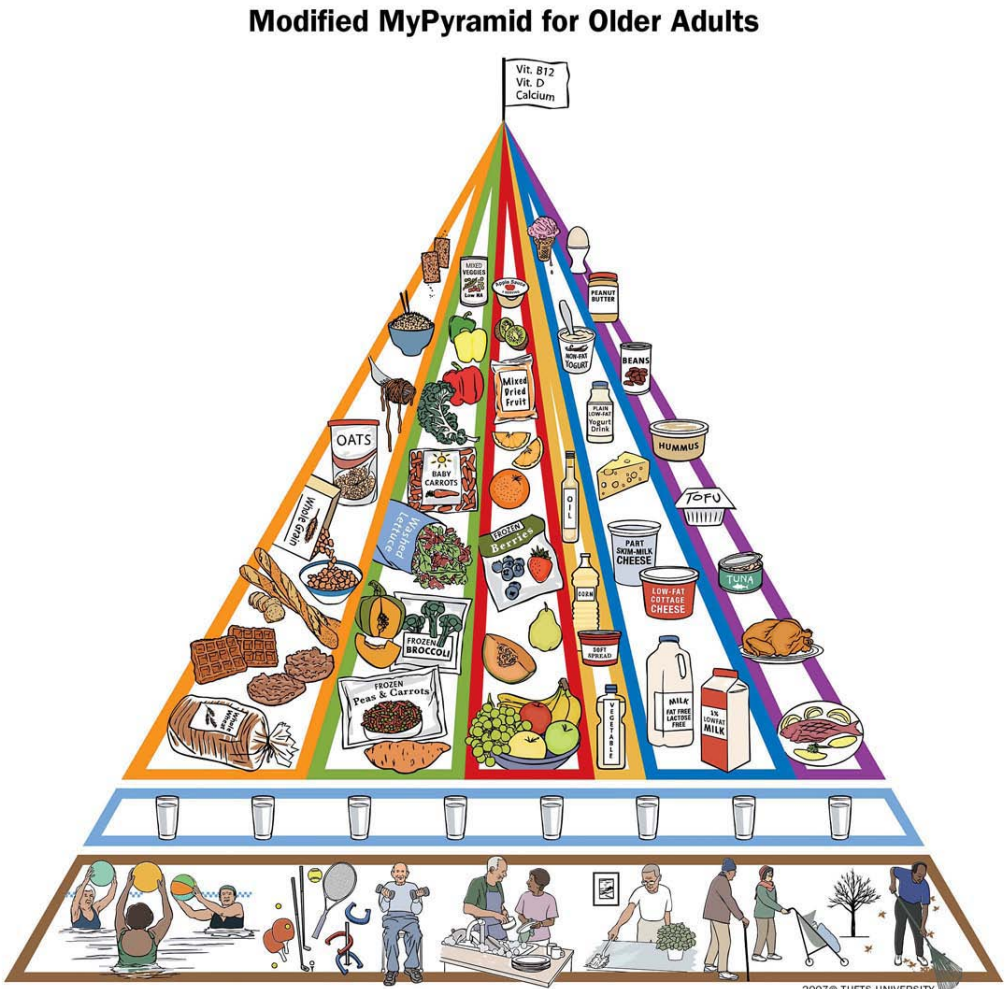

Figure 1 Modified MyPyramid for Older Adults.

Evans and Crogran (2005) conducted a study using the FoodEx-LTC to evaluate residents' food and food service satisfaction. It was their determination that the use of this form could aid in identifying those residents at risk for undernutrition as a result of poor food quality or lack of attention to food preferences. A liberalized diet was identified as a predictor of satisfaction with meals.

Liberalization of diets is but one of the interventions available for addressing the nutritional deficiencies found in this group. Chiam (2008) determined other interventions

to include: encouraging the use of flavor enhancers and frequent small meals; offering liquid nutritional supplements for use between meals; increasing protein intake; providing energy-rich food and finger foods for the cognitively impaired; providing preferred food and ensuring ethnic food preferences are made available; fortifying pureed meals; decentralized food portioning; verbal prompting for those residents with dementia; provision of adequate feeding assistance to allow time for chewing and swallowing; individualized nutritional care plans; improvement of the eating environment; and encouragement of continued family participation. However, a study by Smoliner et al. (2008) addressed the use of food fortification in frail nursing home residents. Their findings of significant functional decline, despite the introduction of energy and protein enriched meals and snacks, lend even more credence to the application of liberalized diets to enhance and bolster the failing appetites of these frail elderly.

In a study by Pedrolli and Costa (2007), it was determined that explicit nutrition policies should be established to address the global burden of malnutrition and undernutrition in hospitals and long-term-care centers. Hospitals and long-term-care centers should be provided with a recipe book, as cited in studies by Dorner et al. (2002), Nijs et al. (2006), and Koford and Birkermose (2004), which is based on these simple principles: a diet that is liberalized as much as possible for all patients/residents, with a standard diet which should be used by as many people as possible; a family style catering model in terms of presentation and planning; and menus that are easily understood by patients/residents and their families.

According to DePorter (2005), the importance lies in the health care profession's understanding of the dual role of food consumption and the dining experience. It is true

that it is the responsibility of the facility to provide nutrition and hydration to meet residents' needs in such a manner as to meet their emotional, physical, and functional needs. However, it is the perceived quality of life that will provide residents with the fortitude and desire to continue in the remaining years.

A liberalized diet is one that meets the nutritional needs of the resident, while providing food that is a source of enjoyment and palatability. Such a diet serves to increase the percentage of daily food intake and bolsters the elderly individual's resistance to the disease processes common in aging. The issue, then, becomes a focus on the quality of life for the resident in long-term care. It is the premise of many researchers and health care professionals that liberalized diets will serve a two-fold purpose: improve quality of life and result in better nutrition outcomes. The benefits are as follows: increased food intake; lower incidence of unintended weight loss; more consistent blood glucose concentrations; and the ever important positive perception of life quality. An added benefit for the long-term-care staff would be the freedom given to the dietary staff to simplify food preparation and promote creativity in dietary planning of meals.

Therapeutic diets are those that are designed to provide the nutritional needs of the individual, based on a particular medical condition or disease. Most of these diets are based on texture and/or nutritional modifications. Many times the texture of the diet is modified as a precaution by the medical staff or dietetics professional to minimize complications that might occur in those individuals who experience cerebrovascular accidents, Alzheimer's Disease, or advanced Organic Brain Syndrome. A diet with soft foods, minced foods, or pureed foods and/or thickened liquids would be an example of

texture modification in the diet. Additional nutritional modifications may call for reducing or adding calories or nutrients. Unfortunately, therapeutic diets are often unpalatable, difficult to follow, and lead to spiraling weight loss in long-term-care residents. According to Wright et al. (2005), the energy and protein requirements for elderly dysphagic residents are the same as those for residents on a normal or regular diet. When residents who enter a long-term-care facility are given therapeutic diets for the first time, they also often experience a deep sense of profound loss due to the absence of familiar foods they have eaten and enjoyed for a lifetime. This, in itself, can lead to psychosocial feelings of depression and despondency (Herman, 2005).

Older adults have many unique dietary needs which must be addressed in order to ensure they receive optimal nutrients each day. Many residents in long-term care have multiple health issues. In a study by Resnick et al. (2007), it was determined one in four nursing home residents over the age of 65 years (24.6%) had a diagnosis of Diabetes Mellitus. According to Hyman and Taffet (2009), hypertension is very common in many elderly residents, reaching a prevalence of 80% by age 85 years. Systolic hypertension is often in evidence in the elderly population since the large conduit arteries become stiff with age and treating systolic blood pressures initially higher than 160 mm/Hg is extremely beneficial in this population. Protogerou et al. (2007) determined the optimal diastolic blood pressure level for the healthy elderly individual was 70 mm/Hg.

It would not be uncommon to find a resident who has cardiac issues, hypertension, diabetes, and dysphagia resulting in chewing and/or swallowing problems. The typical therapeutic diet order for this resident would be as follows: Mechanical / Soft, Low Fat, No Concentrated Sweets and No Added Salt. A decrease in intake at

meals from this restrictive diet will ultimately culminate in an end result of increasing malnutrition, dehydration, and vitamin and mineral losses.

Much attention has been given in recent years to the concept of liberalized diets as an alternative to therapeutic diets. In a study conducted by Hanks et al. (1996) there was little difference in nutritional status in comparisons of elderly residents with diabetes who consumed a No Concentrated Sweets diet and those who consumed a restricted calorie-controlled diet. Further, Tariq et al. (2001) determined residents in long-term-care facilities with a diagnosis of diabetes could be successfully managed with a regular diet with no limitation on concentrated sweets. The position of the American Dietetic Association affirms the growing amount of evidence that supports the belief that allowing long-term-care residents to select liberalized diets will improve their quality of life and prevent weight loss while simultaneously maintaining acceptable biochemical and anthropometric measurements (American Dietetic Association, 2005).

CHAPTER III

METHODOLOGY

Purpose

The purpose of this study was to conduct a randomized clinical trial to compare the use of liberalized diets with the traditional therapeutic diets long advocated in long-term-care facilities.

Hypotheses

H_{O1}: There will be no significant differences in selected health indictors (body weight, BMI, ideal body weight percentage, blood pressure, blood glucose, hemoglobin A1c, albumin, hemoglobin, and hematocrit values) between long-term-care residents receiving the usual therapeutic diets (control group) and those receiving liberalized diets (treatment/intervention group).

H_1: Residents receiving liberalized diets (treatment/intervention group) will have better health indicators (body weight, BMI, ideal body weight percentage, blood pressure, blood glucose, hemoglobin A1c, albumin, hemoglobin, and hematocrit values) than residents receiving the usual therapeutic diets (control group).

H_{O2}: There will be no significant difference in diet satisfaction between the residents receiving liberalized diets and those receiving therapeutic diets

H_2: Residents receiving liberalized diets will have better diet satisfaction than residents receiving the usual therapeutic diets.

Participants

The participants for this study consisted of 22 long-term-care residents in a not-for-profit 36-bed skilled nursing facility. This facility is located in a rural area of North Mississippi. This facility opened in 1965 and is adjoined with a 38-bed acute care facility at North Mississippi Medical Center – Webster Health Services, 70 Medical Plaza, Eupora, Mississippi. This study was conducted for a period of 18 weeks, from April to August 2009.

Elderly residents were recruited to participate in the clinical trial after consultation with the residents, their families (when indicated), and with the residents' personal physicians. All participants in the study received prior approval from their personal physicians to be eligible to be included in the study. This research was explained to them in the presence of the Licensed Social Worker (LSW) / Activities Director, with adequate time given for questions and answers. At this time, the residents and their family members received assurance of the approval of the medical staff and that no risk would be involved with their participation in the study.

Food System and Diets

Upon admission to the facility, all participants are prescribed a diet which meets their nutritional needs. These diets take into consideration any existing conditions and diseases specific to the resident. A liberalized diet (or regular diet) is prescribed for those

residents who do not have any disease processes which require nutritional intervention. These residents have no restriction in the foods that are served to them. The dietary staff is given liberty to provide a variety of foods to meet the nutritional needs of the resident. Therapeutic diets are given to those residents who may require nutrition intervention as a result of a particular disease or condition. Some of the most common therapeutic diets prescribed include: the deletion of salt from the diets of those with hypertension; no concentrated sweets or limited carbohydrates given to a resident who is diagnosed with diabetes; and low fat diets for those with cardiac problems and diabetes.

Once a diet is prescribed, intake is recorded daily by nursing staff. Hospital protocol mandates nursing to alert the director of dietary or the clinical dietitian when intake by mouth is less than 50% for a period of one week. At that time, a nutrition consultation by the clinical dietitian will determine the need for further nutritional and/or medical interventions.

The facility uses a conventional food service system. Food is prepared on site from basic ingredients. All food is purchased from USDA approved sites and fresh vegetables and fruits in season are used throughout the year. There is little use of convenience foods. All food is prepared and maintained at appropriate temperatures until the meal is served to the residents. The food is prepared as close to serving time as possible. The meal is placed on the tray line, equipped with a steam table, no more than 30 minutes before the trays are plated. Plating involves placing standardized portions onto the plates which are placed on residents' trays; trays are inserted into food carts that are delivered to the long-term-care wing of the facility which is approximately 200 feet from the kitchen.

There is a winter menu and a summer menu used in the facility; the summer menu was in use during the duration of this study. The menu is a 28-day cycle menu that is reviewed and approved yearly by site inspectors for the state of Mississippi. Meals are served at the same times each day: breakfast is served at 6:30am, lunch is at 11:00am, and supper is served at 5:00pm. Each resident's meal intake is monitored and recorded by the nursing staff. Residents are encouraged to eat in the dining room.

Study Design

In this 18-week clinical trial, participants were randomized to either a control (therapeutic) diet, or intervention (liberalized) diet. A random number generator (SPSS, Inc., Chicago, IL) was used to assign subjects into the therapeutic or liberalized diet group. This study was a two-group, parallel-design randomized control trial with a small sample size. Participants were not informed of their group assignment; however, it was not a blind study since they ate together in the dining room.

Instrumentation and Procedures

The research topic was introduced to the medical staff at a Medical Staff Meeting attended by the hospital administrator, chief of staff, staff physicians, director of nursing, and director of pharmacy. Discussion of the research and weekly survey / data collection form (Appendix A) ensued, with concerns addressed to the satisfaction of the staff present at the meeting. During individual meetings with each physician to obtain clearance on their patients, the final survey was presented for discussion.

The first section of the data collection form (Appendix A) included the following demographic information: age, gender, and ethnic group. Health indicators for the study were determined, including height and weight, with alterations in biochemical assessments to be addressed on a weekly basis. Heights were measured to the nearest 0.25 inch by a wall-mounted ruler. Heights were determined by the demi-span method for participants who could not stand up straight. Demi-span is measured as the distance from the middle of the sternal notch to the tip of the middle finger in the coronal plane using a tape measure. Height is then calculated from a standard formula (Hickson & Frost, 2003). Body weights were recorded to the nearest 0.1 pound by participants standing on, or sitting in, a digital flip-seat scale (Detecto Bariatric Flip Seat Scale, Model No. CESS-91108-00, Claflin Medical Equipment Company, Warwick, Rhode Island). The residents' perceived satisfaction with their diet was self-rated using a five-point Likert scale from one (very unsatisfied) to five (very satisfied) (Appendix A).

Once physician approval had been established, those pre-approved residents were given the opportunity to participate in the study. Residents and legal guardians received a letter (Appendix B) explaining the study and its importance to quality of life. They were provided with a description of the study and the information that would be collected. Separate consent forms were developed for each of the institutions involved in the study to inform residents of the purpose of the study and their legal rights. A single consent form (Appendix C) was derived for Mississippi State University with all participants and/or family members to sign approval for participation in the study.

Two consent forms were developed for North Mississippi Medical Center – Webster Health Services in Eupora. Those residents who were ruled competent and lucid

by the medical staff signed Consent Form A (Appendix D). Other residents were given Consent Form B (Appendix D). Family members and/or legal guardians who signed Consent Form B were given an opportunity to meet with the principal investigator and their family member who had been selected for participation in the study. Again, detailed description of the study was provided with an overview of the process and estimated length of the study. Ample time was given for discussion and questions. These meetings were conducted during the regularly scheduled care plan meeting with health care staff or during a meeting specifically called for the purpose of the explanation of this study. There were no legal guardians who refused to allow their family member's participation in the study. It was agreed that all residents in the study would be randomly assigned to the control or the treatment group.

Regulations and Institutional Review Board Approval

Project approval was obtained prior to this study from the Institutional Review Board (IRB) through the Mississippi State University (MSU) Regulatory Compliance Office of MSU, Mississippi State, Mississippi, IRB # 08-092 (Appendix C). The IRB of North Mississippi Health Services (NMHS) of Tupelo, Mississippi, stamped approval on the Consent Forms (Appendix D). This study was approved by both MSU and NMHS in 2007. The trial (data collection) began in April 2009 with continuation of IRB approval.

This research required the approval of the joint boards for a number of reasons. The research was conducted at North Mississippi Medical Center – Webster Health Services in Eupora, which is an affiliate of the North Mississippi Health Services System. Hospital policy requires IRB approval for all research studies, and studies consisting of

elderly individuals who are considered a vulnerable population are scrutinized by the IRB. A vulnerable population is considered to be those who are relatively incapable of protecting their own interest (Levine, 1986). In addition, full-board IRB approval from Mississippi State University was required due to policy regarding studies involving vulnerable populations.

Data Collection

Per computerized randomized assignment, 50% of the subjects received a liberalized diet and the other subjects continued to receive their usual therapeutic diets approved by the Mississippi Dietetic Association and the American Dietetic Association. These therapeutic diets have been in place for numerous years at the facility.

Weekly weights were taken and biochemical assessments monitored per usual protocol were recorded on the Data Collection Form (Appendix A). This was conducted from Week 0 (the week prior to starting the study) through the end of the study (Week 18). The facility's clinical dietitian, who was also the study's investigator, conducted informal visits with the residents during data collection. The study did not, at any time, interfere with the normal care or daily routine of the residents.

Data Analysis

Baseline data of the two groups (therapeutic diet and liberalized diet) were compared using *t*-tests. This procedure was repeated at the end of the study (Week 18) to determine differences between participants on the therapeutic diet and those on the liberalized diet. The two groups were compared over the duration of the study (18

weeks) using ANOVA for repeated measures with the diets as fixed effects and time (weeks) as the repeated factors. This study was an "intention-to-treat" randomized clinical trial, and as such, all data were used for analysis (Hollis & Campbell, 1999). If outliers existed, they would not be omitted from analysis. Data from all participants that started the trial and all participants who completed the trial would be included in the statistical analyses.

Since change in body weight was the primary outcome of interest, ANOVA was conducted with body weight as the dependent variable and diet (therapeutic or liberalized diet) as the independent variable. The Kolmogorov-Smirnov Test was used to determine normality of variables (Mertler & Vannatta, 2005). An α level of 0.05 ($P < 0.05$) was considered significant. Data were analyzed using the Statistical Package for Social Sciences (SPSS) software, version 16.0 (SPSS, Inc., Chicago, IL). Variables are reported as means ± standard deviations (*SD*).

CHAPTER IV

RESULTS AND DISCUSSION

During an 18-week period, from April until August 2009, a randomized clinical trial was conducted with an elderly population in a long-term-care facility in rural North Mississippi. The trial was successful in that all of the participants who began the trial were able to complete the trial without difficulties. Information collected was used for data analysis regarding satisfaction with diet and to detect changes in weight, BMI, albumin concentrations, blood glucose values, and other clinical variables. All data were used for analysis. The Kolmogorov-Smirnov Test indicated normality for all variables. Additionally, the standard errors of kurtosis and skewness determined that all variables were within acceptable normal distribution limits (Mertler & Vannatta, 2005).

The ANOVA repeated measures analysis determined no differences ($P > 0.05$) in variables, including diet satisfaction, between the liberalized diet group and the therapeutic diet group over time (18 weeks). The *t*-tests also indicated no significant differences in outcomes between the two groups at the end of the trial. This indicates that the null hypothesis of the study cannot be rejected. The overall implication of this is restrictive therapeutic diets may not be necessary for many long-term-care residents, and allowing residents to have more freedom, such as liberalizing their diets, may be beneficial for perceived quality of life.

Demographic characteristics (Table 1) of gender, ethnicity, and age were analyzed to aid in the description of population variables. The following results were noted: the mean age of the therapeutic diet group was 78.9 ± 12.1 years and the mean age of the liberalized diet group was 80.8 ± 9.0 years. According to the National Nursing Homes Survey (2004), 31.4% of all nursing home residents are 75–84 years; 71.1% are females and 28.9% are males; and 85.5% are Caucasian and 12.5% are African Americans. There were ten females and one male in the therapeutic diet group and nine females and two males in the liberalized diet group. In the therapeutic diet group, ten of the participants were Caucasian and one participant was African American. In the liberalized diet group, nine of the participants were Caucasian and two participants were African American. The participants in this study were close to the national average as 86.4% were Caucasian and 13.6% were African American.

There was no difference ($P = 0.747$) in mean body weight between the therapeutic diet group and the liberalized diet group at baseline (Week 0) (Table 1) nor at the end of the study ($P = 0.541$) (Week 18) (Table 2). The therapeutic diet group had a mean body weight of 72.7 $\pm$ 16.0 kg and the liberalized diet group had a mean weight of 75.2 $\pm$ 19.3 kg at Week 0 (Table 1). At the end of the study, the therapeutic diet group had a mean body weight of 71.3 ± 14.1 kg and the liberalized diet group had a mean body weight of 75.7 ± 18.5 kg (Table 2).

The mean BMI of all participants ($n = 22$) of 28.1 $\pm$ 6.1 kg/m^2 was classified as overweight. Body mass indices ranged from 18.0 to 40.0 kg/m^2 with only one participant classified as underweight, eight had BMI's in the normal category (20.0–24.9 kg/m^2), four had BMI's indicating overweight (25.0–29.9 kg/m^2), seven were classified as obese

with a BMI greater than 30.0 kg/m^2, and one person had a BMI of 40.0 kg/m^2 which is morbid obesity (Harris & Haboubi, 2005). Examining the two groups, the BMI for the therapeutic diet group at baseline was 27.8 ± 5.1 kg/m^2 which was similar to the BMI for the liberalized diet group, 28.4 ± 7.2 kg/m^2 (P = 0.826) (Table 1). At the end of the study, the therapeutic diet group had a mean BMI 27.3 ± 4.5 kg/m^2 and the liberalized diet group had a similar BMI of 28.6 ± 7.1 kg/m^2 (P = 0.606) (Table 2). The percentage of ideal body weight (current weight / ideal body weight x 100) for the therapeutic diet group at baseline was 134.0 ± 27.1% and the percentage of ideal body weight for the liberalized diet group was 137.3 ± 39.1% (P = 0.819) (Table 1). At the end of the trial, percentages of ideal body weight for the therapeutic and liberalized diet groups were 131.1 ± 23.3% and 138.9 ± 38.9%, respectively, (P = 0.576) (Table 2).

Systolic blood pressure for the therapeutic diet group at baseline was 123.3 ± 9.5 mmHg and the systolic blood pressure for the liberalized diet group at baseline was 133.6 ± 14.9 mmHg (P = 0.065) (Table 1). At the end of the trial, the systolic blood pressure for the therapeutic diet group was 130.4 ± 5.0 mmHg and the systolic blood pressure for the liberalized diet group at Week 18 was 127.1 ± 18.4 mmHg (P = 0.575) (Table 2). Diastolic blood pressure for the therapeutic diet group at baseline was 71.1 ± 9.6 mmHg and the diastolic blood pressure for the liberalized diet group at baseline was 77.1 ± 7.1 mmHg (P = 0.110) (Table 1). At Week 18, the diastolic blood pressure for the therapeutic diet group was 72.9 ± 4.9 mmHg. This was slightly more than the 70 mmHg recommended by Protogerou et al. (2007). The diastolic blood pressure for the liberalized diet group was 68.6 ± 9.4 mmHg (P = 0.186) (Table 2). During this trial, twenty of the residents (90.8%) were receiving medication for elevated blood pressure, or

hypertension. This would be expected as Hyman and Taffet (2009) concluded 85% of the elderly experience hypertension by the age of 80 years.

Blood glucose concentration for the therapeutic diet group at baseline (Week 0) was 125.4 ± 47.1 mg/dl and the blood glucose concentration for the liberalized diet group at baseline was 144.0 ± 50.7 mg/dl ($P = 0.406$) (Table 1). At the end of the trial, the blood glucose concentration for the therapeutic diet group was 130.8 ± 31.3 mg/dl and the blood glucose concentration for the liberalized diet group at Week 18 was 173.6 ± 65.7 mg/dl ($P = 0.119$) (Table 2). Thirteen participants in this trial had a diagnosis of Diabetes Mellitus and were insulin dependent. According to Resnick et al. (2007), one out of every four (24.6%) long-term-care residents in the United States has a diagnosis of Diabetes Mellitus. Thus, the incidence of diabetes among participants in this study (59%) is greater than the national average for residents in a long-term-care facility. However, Mississippi has the highest prevalence of diabetes in the nation (Mokdad et al., 2003).

Blood glucose concentrations enable those in the medical profession to determine medication needs on a daily basis. However, it is the hemoglobin A1c concentration that will give a more definitive assessment, as it is a valuable measure of the overall effectiveness of blood glucose control over an average three-month period. The normal range is 4–5.9%. It may be 8.0% and above with someone who has poorly controlled diabetes. It is the recommendation of the Association for Clinical Endocrinologists that a range of 7.0% and below is desirable for those who have well controlled diabetes (Qaseem et al., 2007).

A stipulation by the medical staff, prior to beginning this research, was the agreement by the researcher that no additional invasive laboratory tests would be ordered for the residents, other than the ones previously scheduled. Laboratory values were not available for some of the participants in this clinical trial. Hemoglobin A1c level for the therapeutic diet group at baseline (Week 0) was 6.7 ± 1.3% (n = 6) and the hemoglobin A1c level for the liberalized diet group at baseline was 7.1 ± 1.0% (n = 4) (P = 0.615) (Table 1). At the end of the trial, the hemoglobin A1c level for the therapeutic diet group was 5.9 ± 0.7% (n = 4) and 6.4 ± 0.9% (n = 4) (P = 0.395) for the liberalized diet group at Week 18 (Table 2).

Albumin concentration is an indicator of protein status. Protein-energy malnutrition is of key concern to health care professionals as it implicates serious nutritional deficiencies in the elderly. In a study by Cederholm et al. (1995), low serum albumin concentration was a predictor for increased hospitalization for the elderly. Healthy ambulatory elderly persons have serum albumin concentrations 3.5 – 5.0 gm/dl. The albumin concentration reflects residents' nutritional status over the previous one- to two-month period due to its 21-day half life status. It is a marker for nursing staff and dietitians in determining those residents at risk for unintentional weight loss. Albumin concentration for the therapeutic diet group at baseline (Week 0) was 3.0 ± 0.4 gm/dl (n = 10) and albumin concentration for the liberalized diet group at baseline was 3.5 ± 0.4 gm/dl (n = 10) (Table 1). There was a significant difference (P = 0.01) in albumin concentrations at baseline between the groups but not at the end of the trial. At Week 18, the albumin concentration for the therapeutic diet group was 3.3 ± 0.4 gm/dl and the

albumin concentration for the liberalized diet group was 3.7 ± 0.5 gm/dl ($P = 0.154$) (Table 2).

Hemoglobin concentration is often assessed to determine anemia which can also be an indicator of possible PEM. Thus, it is often an indicator of potential unintentional weight loss. A normal hemoglobin concentration is greater than 11.5 gm/dl for females and greater than 13.0 gm/dl for males (Steensma & Ayalew, 2007). Mean hemoglobin concentrations were normal in this trial and the two groups had similar values. The therapeutic diet group at baseline (Week 0) had a mean value of 12.2 ± 1.7 mg/dl and the hemoglobin concentration for the liberalized diet group at baseline (Week 0) was 12.5 ± 1.9 mg/dl ($P = 0.713$) (Table 1). At the end of the trial, the hemoglobin concentration for the therapeutic diet group was 12.7 ± 1.2 mg/dl and hemoglobin concentration for the liberalized diet group at Week 18 was 12.6 ± 1.3 mg/dl ($P = 0.916$) (Table 2). An extensive analysis by Zakai et al. (2005) based on World Health Organization criteria for prevalence of anemia reported hemoglobin values less than 13.7 gm/dl for men, and 12.6 gm/dl or less for women, were indicators of greater prevalence of co-morbid conditions. Hemoglobin values for the present study indicate the possibility of co-morbid conditions in some of the participants. Additionally, some participants had low hemoglobin and hematocrit values as reported in Appendix E.

A normal hematocrit range for females is 37–47% and the normal range for males is 40–54%. Since the hematocrit concentration is a value of the percentage of red blood cells in the body, it is also an indicator of anemia and possible PEM (Lee & Nieman, 2010). Hematocrit concentration for the therapeutic diet group at baseline (Week 0) was 35.8 ± 4.5% and the hematocrit concentration for the liberalized diet group at baseline

(Week 0) was 35.8 ± 4.5% (P = 0.749) (Table 1). At the end of the trial, hematocrit concentrations for the therapeutic diet group and the liberalized diet group were 37.2 ± 4.3% and 37.4 ± 4.3%, respectively, (P = 0.912) (Table 2).

Table 1 Baseline Comparisons of Participants Randomly Assigned to the Control Group (Therapeutic Diet) or the Treatment Group (Liberalized Diet)

Variable	Therapeutic Diet	Liberalized Diet	*P* value
Sex	10 females 1 male	9 females 2 males	-
Race	10 Caucasian 1 African American	9 Caucasian 2 African Americans	-
Level of diet satisfaction[a]	3.6 ± 1.4[b]	3.6 ± 1.3	1.000
Age (years)	78.9 ± 12.1	80.8 ± 9.0	0.679
Height (cm)	161.6 ± 11.7	162.9 ± 9.9	0.786
Weight (kg)	72.7 ± 16.0	75.2 ± 19.3	0.747
Body mass index (kg/m^2)	27.8 ± 5.1	28.4 ± 7.2	0.826
Ideal body weight (%)	134.0 ± 27.1	137.3 ± 39.1	0.819
Systolic blood pressure (mmHg)	123.3 ± 9.5	133.6 ± 14.9	0.065
Diastolic blood pressure (mmHg)	71.1 ± 9.6	77.1 ± 7.1	0.110
Blood glucose (mg/dl)	125.4 ± 47.1	144.0 ± 50.7 (n = 9)[c]	0.406
Hemoglobin A1c (%)	6.7 ± 1.2 (n = 6)	7.1 ± 1.0 (n = 4)	0.615
Albumin (g/dl)	3.0 ± 0.4 (n = 10)	3.5 ± 0.4 (n = 10)	0.010*
Hemoglobin (mg/dl)	12.2 ± 1.7 (n = 10 women)	12.5 ± 1.9 (n = 8 women)	0.713
Hematocrit (%)	35.8 ± 4.5 (n = 10 women)	36.7 ± 6.2 (n = 8 women)	0.749

[a] Level of diet satisfaction determined by 1 = very unsatisfied, 2 = somewhat not satisfied, 3 = neither unsatisfied nor satisfied, 4 = somewhat satisfied, 5 = very satisfied
[b] Mean ± standard deviation
[c] Sample number (n) is indicated if all 11 participants were not included in the analysis
*Significant was determined at $P < 0.05$

Table 2 Means ± Standard Deviations Comparing Participants in the Therapeutic Diet Group versus the Liberalized Diet Group at the End of the Study (Week 18)

Variable	Therapeutic Diet	Liberalized Diet	*P* value
Level of diet satisfaction[a]	4.2 ± 0.8[b]	4.4 ± 0.7	.557
Weight (kg)	71.3 ± 14.1	75.7 ± 18.5	.541
Body mass index (kg/m^2)	27.3 ± 4.5	28.6 ± 7.1	.606
Ideal body weight (%)	131.1 ± 23.3	138.9 ± 38.9	.576
Systolic blood pressure (mmHg)	130.4 ± 5.0	127.1 ± 18.4	.575
Diastolic blood pressure (mmHg)	72.9 ± 4.9	68.6 ± 9.4	.186
Blood glucose (mg/dl)	130.8 ± 31.3 (n = 8)[c]	173.6 ± 65.7 (n = 8)	.119
Hemoglobin A1c (%)	5.9 ± 0.7 (n = 4)	6.4 ± 0.9 (n = 4)	.395
Albumin (g/dl)	3.3 ± 0.4 (n = 7)	3.7 ± 0.5 (n = 7)	.154
Hemoglobin (mg/dl)	12.7 ± 1.2 (n = 7 women)	12.6 ± 1.3 (n = 7 women)	.916
Hematocrit (%)	37.2 ± 4.3 (n = 7 women)	37.4 ± 4.3 (n = 7 women)	.912

[a] Level of diet satisfaction determined by 1 = very unsatisfied, 2 = somewhat not satisfied, 3 = neither unsatisfied nor satisfied, 4 = somewhat satisfied, 5 = very satisfied
[b] Mean ± standard deviation
[c] Sample number (n) is indicated if all 11 participants were not included in the analysis

At mid-point of the clinical trial (Week 9), the therapeutic diet group had a mean body weight of 72.4 ± 15.1 kg and the liberalized diet group had a mean body wt of 76.3 ± 19.2 kg (Table 3) which was not significantly different ($P > 0.05$). At Week 9, the therapeutic diet group had a mean BMI 27.7 ± 4.6 kg/m^2 and the liberalized diet group had a mean BMI of 28.9 ± 7.3 kg/m^2 ($P = 0.606$) (Table 3). At the end of the study, the therapeutic diet group had a mean BMI 27.3 ± 4.5 kg/m^2 and the liberalized diet group

had a mean BMI of 28.6 ± 7.1 kg/m^2 (Table 3). The percentage of ideal body weight (current weight / ideal body weight x 100) for the therapeutic diet group at Week 9 was 133.1 ± 23.8% and the percentage of ideal body weight for the liberalized diet group was 139.4 ± 39.2% (Table 3). The percentage of ideal body weight (current weight / ideal body weight x 100) for the therapeutic diet group at the end of the trial (Week 18) was 131.1 ± 23.3% and the percentage of ideal body weight for the liberalized diet group was 138.9 ± 38.9% (Table 3). When you observe the values in Table 3, the slight decrease in the therapeutic group over time is readily seen.

The therapeutic diet group had a 1.9% weight loss and a 1.9% decrease in BMI at the end of Week 18 (Figures 2 and 3). This was not a significant weight loss ($P > 0.05$) nor was it a significant decrease in BMI. However, it should be noted this gradual weight loss was incurred during an 18-week trial (Figure 2). If this trend continues, it could be predicted to be greater than 4% at the end of a one year period. According to Beers (1999), a 4% weight loss in one year is significant in that it may represent a trend of spiraling unintentional weight loss that should be immediately addressed. In the past, researchers had assessed significant weight loss as 5% in one month, 7.5% in three months, and 10% in six months. According to Ryan et al. (1995), changes in weight over time are easy to track and may aid in identification of individuals in need of nutritional intervention. Research bears credence to the fact that continued unintentional weight loss is one of the key indicators of mortality in long-term care.

Table 3 Means ± Standard Deviations of Values for the Therapeutic Diet Group and the Liberalized Diet Group at Baseline, Week 9 and Week 18

Characteristic	Baseline	Week 9	Week 18
Level of diet satisfaction[a]			
Therapeutic diet	3.6 ± 1.4[b]	3.9 ± 0.9	4.2 ± 0.8
Liberalized diet	3.6 ± 1.3	4.3 ± 0.8	4.4 ± 0.7
Weight (kg)			
Therapeutic diet	72.7 ± 16.0	72.4 ± 15.1	71.3 ± 14.1
Liberalized diet	75.2 ± 19.3	76.3 ± 19.2	75.7 ± 18.5
Body mass index (kg/m^2)			
Therapeutic diet	27.8 ± 5.1	27.7 ± 4.6	27.3 ± 4.5
Liberalized diet	28.4 ± 7.2	28.9 ± 7.3	28.6 ± 7.1
Ideal body weight (%)			
Therapeutic diet	134.0 ± 27.1	133.1 ± 23.7	131.1 ± 23.3
Liberalized diet	137.3 ± 39.1	139.4 ± 39.2	138.9 ± 38.9
Systolic blood pressure (mmHg)			
Therapeutic diet	123.3 ± 9.5	130.7 ± 9.3	130.4 ± 5.0
Liberalized diet	133.6 ± 15.0	134.6 ± 18.7 (n = 10)[c]	127.1 ± 18.4
Diastolic blood pressure (mmHg)			
Therapeutic diet	71.1 ± 9.6	72.7 ± 8.5	72.9 ± 4.9
Liberalized diet	77.1 ± 7.1	67.0 ± 6.8 (n = 10)	68.6 ± 9.4
Blood glucose (mg/dl)			
Therapeutic diet	125.4 ± 47.1	145.1 + 48.2 (n = 7)	130.8 ± 31.3 (n = 8)
Liberalized diet	144.0 ± 50.7 (n = 9)	163.7 + 47.1 (n = 5)	173.6 ± 65.7 (n = 8)
Hemoglobin A1c (%)			
Therapeutic diet	6.7 + 1.3 (n = 6)	6.4 ± 0.9 (n = 2)	5.9 ± 0.7 (n = 4)
Liberalized diet	7.1 + 1.0 (n = 4)	6.7 ± 1.1 (n = 6)	6.4 ± 0.9 (n = 4)
Albumin (g/dl)			
Therapeutic diet	3.0 ± 0.4 (n = 10)	N/A[d]	3.3 ± 0.4 (n = 7)
Liberalized diet	3.5 ± 0.4 (n = 10)		3.7 ± 0.5 (n = 7)
Hemoglobin (mg/dl)			
Therapeutic diet	12.2 ± 1.7 (n = 10)[e]	N/A	12.7 ± 1.2 (n = 7)[e]
Liberalized diet	12.5 + 1.9 (n = 8)[e]		12.6 ± 1.3 (n = 7)[e]
Hematocrit (%)			
Therapeutic diet	35.8 ± 4.5 (n = 10)[e]	N/A	37.2 ± 4.3 (n = 7)[e]
Liberalized diet	36.7 ± 6.2 (n = 8)[e]		37.4 ± 4.3 (n = 7)[e]

[a] Level of diet satisfaction determined by 1 = very unsatisfied, 2 = somewhat not satisfied, 3 = neither unsatisfied nor satisfied, 4 = somewhat satisfied, 5 = very satisfied

[b] Mean ± standard deviation

[c] Sample number (n) is indicated if all 11 participants were not included in the analysis for this group

[d] N/A = not available

[e] Hemoglobin and hematocrit values included women only

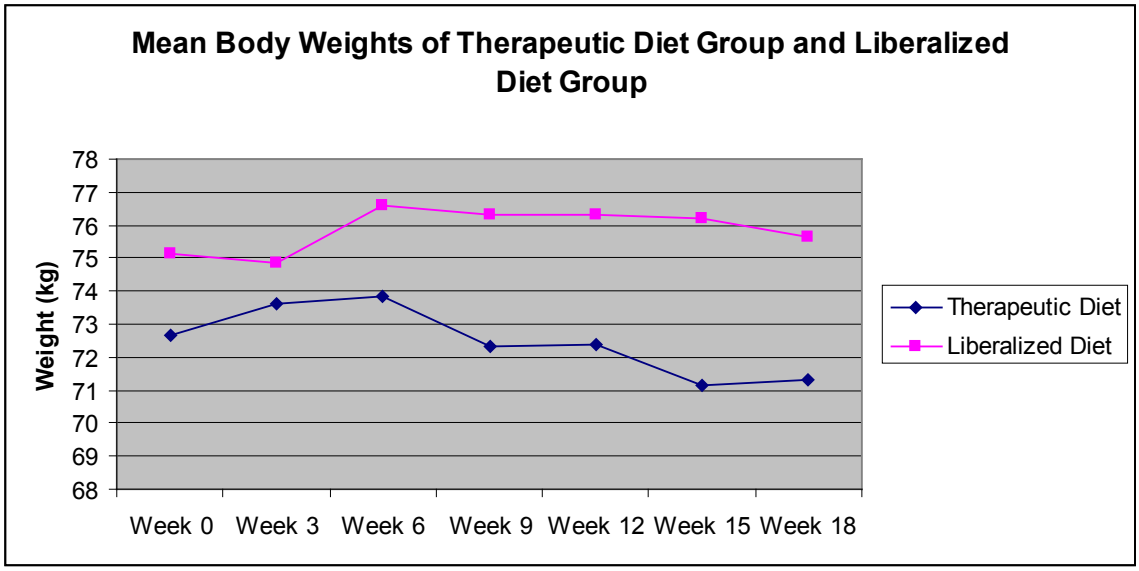

Figure 2 Mean Body Weights (kg) of Therapeutic Diet Group and Liberalized Diet Group from Week 0 (Baseline) to the End of the Study (Week 18).

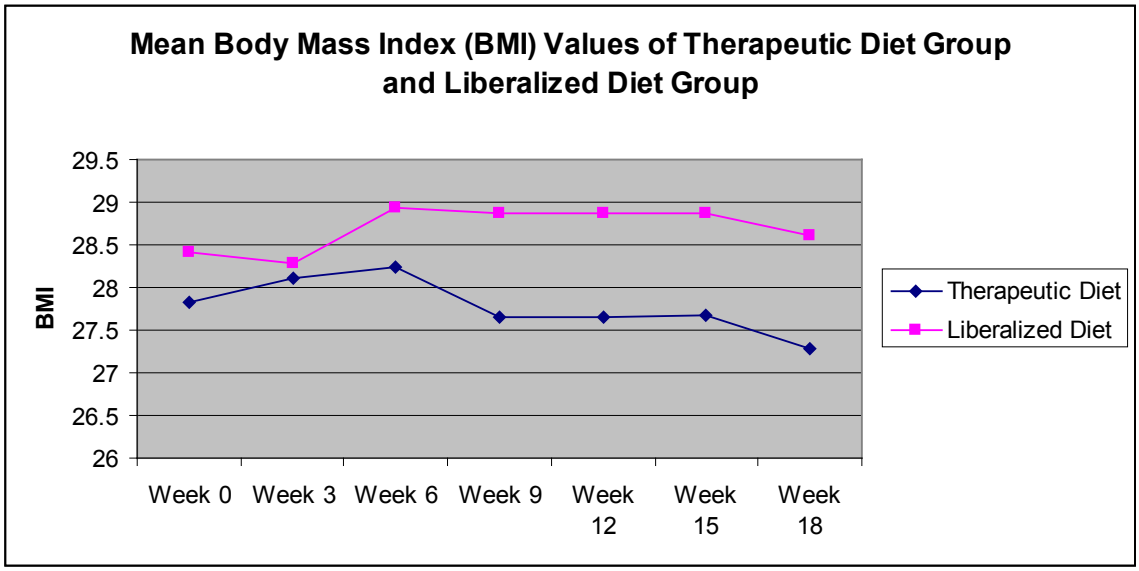

Figure 3 Mean Body Mass Index (BMI) Values (kg/m^2) of Therapeutic Diet Group and Liberalized Diet Group from Week 0 (Baseline) to the End of the Study (Week 18).

Blood glucose concentration for the therapeutic diet group at baseline (Week 0) was 125.4 ± 47.1 mg/dl and the blood glucose concentration for the liberalized diet group was 144.0 ± 50.7 mg/dl (Table 3). At Week 9, blood glucose concentration for the therapeutic diet group was 145.1 ± 48.2 mg/dl (n = 7) and the blood glucose concentration for the liberalized diet group was 163.7 ± 47.1 mg/dl (n = 5). At the end of the trial, the blood glucose concentration for the therapeutic diet group was 130.8 ± 31.3 mg/dl and the blood glucose concentration for the liberalized diet group at Week 18 was 173.6 ± 65.7 mg/dl (Table 3).

Figure 4 illustrates the mean blood glucose values in 3-week increments over the 18-week trial period. Seven of the participants in the therapeutic diet group were receiving daily insulin medication and six of the participants in the liberalized diet group were receiving insulin on a daily basis. It was the premise of the researcher and the medical staff that adjustments in daily insulin could be made to account for increases in glucose concentrations as a result of a more liberalized diet. Tariq et al. (2001) conducted a similar study with 28 residents ranging in age from 59 to 93 years. The control group and the treatment group showed no difference in mean blood glucose concentrations at baseline and at three months after the diet change. However, increases in medication were required throughout the study although the overall increase in insulin dose was small. To reiterate, it was the belief throughout the trial that a more liberalized diet would, in effect, serve to aid in halting poor nutritional outcome and increase perceived quality of life.

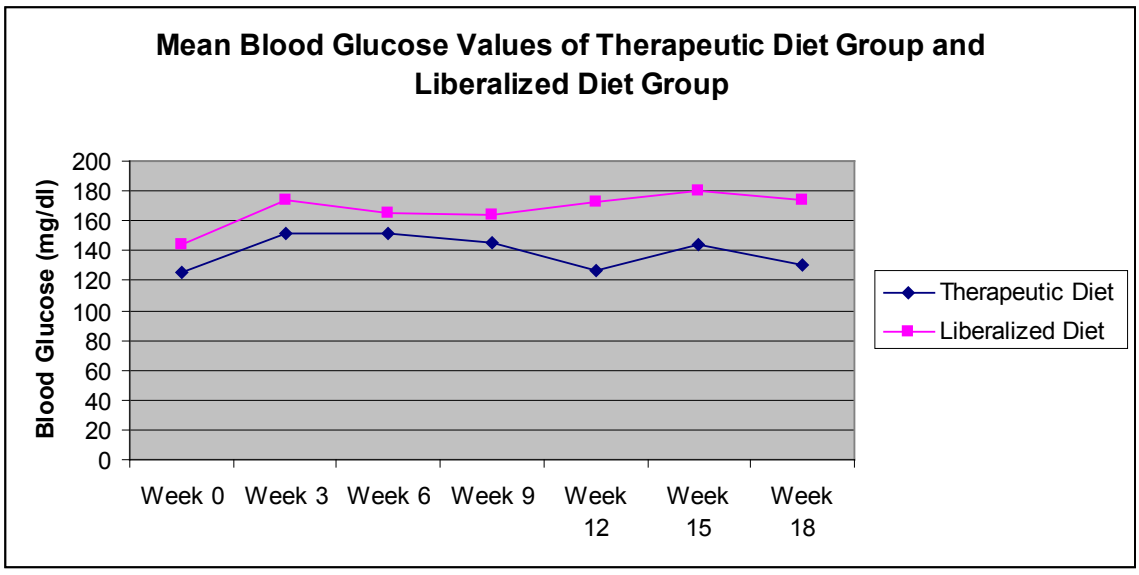

Figure 4 Mean Blood Glucose Values (mg/dl) of Therapeutic Diet Group and Liberalized Diet Group from Week 0 (Baseline) to the End of the Study (Week 18).

Diet satisfaction was determined by conducting informal interviews with the residents or their families. Using a likert scale from one to five, the question was asked: "How satisfied are you with your diet and with the food being served?" The subject (or their family member) could rank their answer in the following way: 1 = very unsatisfied; 2 = somewhat not satisfied; 3 = neither unsatisfied nor satisfied; 4 = somewhat satisfied; 5 = very satisfied.

Diet satisfaction for the therapeutic diet group at baseline (Week 0) was 3.6 ± 1.4 *SD* and diet satisfaction for the liberalized diet group at baseline (Week 0) was 3.6 ± 1.3 *SD* (Table 3). Diet satisfaction for the therapeutic diet group at Week 9 was 3.9 ± 0.9 *SD* and diet satisfaction for the liberalized diet group at Week 9 was 4.3 ± 0.8 *SD*. At this point, the diet satisfaction of the liberalized diet group was showing an increase in satisfaction by the subjects, although it was not significant ($P > 0.05$). At the end of the

trial, the diet satisfaction for the therapeutic diet group was 4.2 ± 0.8 *SD* and the diet satisfaction for the liberalized diet group at Week 18 was 4.4 ± 0.7 *SD* (Table 3). Although both groups showed an increase, the liberalized diet group rated their diet satisfaction slightly higher, although it was not significant ($P > 0.05$).

Figure 5 illustrates the small increase in diet satisfaction in the liberalized diet group. According to Evans and Crogran (2005), a liberalized diet was identified as a predictor of satisfaction with meals. It is to be noted that the researcher met with all participants often. It would not have been moral or ethical to ignore requests for additional or different food items for either group. In fact, the researcher made every effort to meet the needs of all the participants on a daily basis. When requests were made for food preferences and food dislikes, these needs were immediately addressed by the dietary staff. In doing so, this may have biased the degree of diet satisfaction with the therapeutic diet group, but at the same time the needs of a vulnerable population were met.

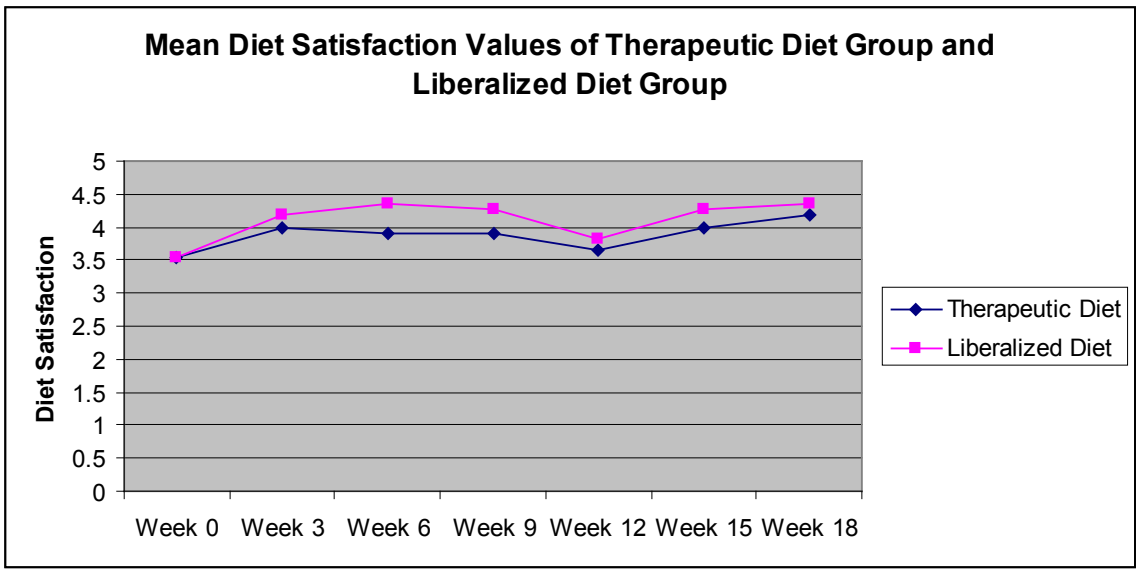

Figure 5 Mean Diet Satisfaction Values (1 = very unsatisfied, 2 = somewhat not satisfied, 3 = neither unsatisfied nor satisfied, 4 = somewhat satisfied, 5 = very satisfied) of Therapeutic Diet Group and Liberalized Diet Group from Week 0 (Baseline) to the End of the Study (Week 18).

CHAPTER V

CONCLUSION

The elderly population in the United States is increasing and is predicted to increase in large numbers within the next few decades. Long-term-care facilities may be called on to meet the needs of this population. Providing liberalized diets may improve appetite and prevent unintentional weight loss which could be advantageous to this population. According to Speroff et al. (2005), a positive dining experience should serve to foster a greater degree of independence in the elderly resident and aid in minimizing negative health outcomes. With this premise, a randomized clinical trial was conducted with 22 residents in a long-term-care facility in rural North Mississippi.

A randomization procedure was used to assign the participants into two groups: a control group and an intervention group. The control group included subjects who continued with their usual therapeutic diets, and the intervention group included those subjects who received a liberalized diet. There were nineteen females and three males. Nineteen of the participants were Caucasian and three were African American. They ranged in age from 54 years to 100 years and all participants completed the study.
At the end of 18 weeks, outcomes were compared between the two groups.
Unintentional weight loss is one of the key indicators of mortality. At the end of the trial, there was no significant difference ($P > 0.05$) in mean body weights between the two

groups. However, there was a trend of weight loss in the therapeutic diet group (mean weight loss of 2% (1.4 kg) during the 18-week trial), and although it was not significant, it supports the growing belief of those who advocate liberalized geriatric diets to improve quality of life and help prevent unintentional weight loss. Participants in the liberalized diet group did not experience weight loss and gained 0.5 kg by the end of the study. The health indicators for this study were not adversely affected by the liberalized diet.

Dietitians working in long-term-care facilities wishing to implement liberalized diets should present evidence-based research to the medical staff, especially as it is related to improving quality of life. Liberalized diets may halt unintentional weight loss that is commonly seen in institutionalized elderly. Implementing liberalized diets can easily be done by relaxing the strict therapeutic guidelines that are so often prescribed for residents when they enter long-term-care facilities.

This study supports the position of the American Dietetic Association (2005) that allowing residents to select liberalized diets may improve their quality of life and prevent weight loss. However, one small clinical trial is not adequate for generalization to the entire long-term-care population. Larger trials should be conducted to obtain more statistically relevant conclusions with the elderly population. Results obtained in this trial indicate a need for greater adherence to quality of life issues, such as more liberalized diets, in the growing long-term-care population.

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APPENDIX A

DATA COLLECTION FORM

Liberalized Diets Data Collection Form Connie Black, MS, RD, LD

Subject number_____

Today's Date_____

Subject's Age (yrs) _____

Subject's Gender: Male ___ Female___

Subject's Race: African-American/Black___ Caucasian/White___ Other___

Weight_____

Record the following information from the resident's medical chart if it is available, and note the date of the blood pressure reading or lab values if different than today's date.

Blood pressure_____

Blood sugar_____

Albumin_____

Pre-albumin_____

Hemoglobin_____

Hematocrit_____

Height_____

(Calculate the BMI later) BMI (calculated as kg/m^2) = _____

Subjects will be asked: "On a scale of 1 to 5 with 1 being very unsatisfied and 5 being very satisfied, how satisfied are you with your diet and the food that you are being served?" *If subjects want a clarification, it can be explained further by using the ratings below.*

Check one: ____1 = very unsatisfied

____2 = somewhat not satisfied

____3 = neither unsatisfied nor satisfied

____4 = somewhat satisfied

____5 = very satisfied

APPENDIX B

LETTER INTRODUCING THE STUDY TO THE RESIDENTS/RESIDENTS FAMILIES

Dear Long-Term Care Resident and/or Legal Guardian:

I am conducting research on liberalized diets in long-term care. I believe that improved quality of life from a health perspective and increased overall well-being will be realized when residents are allowed to receive more variety in their diets. This study has been approved by Mississippi State University, where I am a graduate student, and North Mississippi Health Services.

Some participants will receive liberalized, or regular, diets and others will receive their usual therapeutic diets. I will be collecting data that includes weights, lab values from your medical charts, and results of questionnaires which will enable me to determine if liberalized diets are beneficial.

There are two consent forms, one from North Mississippi Health Services-Eupora and one from Mississippi State University. The two forms are necessary to satisfy research protocol for both institutions. The signed consent forms will be kept on file in my office secured in a locked drawer. Thank you in advance for your participation in this study.

Sincerely,

Connie Ray Black

Connie Ray Black, MS, RD, LD
Assistant Director, Food and Nutrition Services

APPENDIX C

CONSENT FORM AND INSTITUTIONAL REVIEW BOARD APPROVAL FROM

MISSISSIPPI STATE UNIVERSITY

CONSENT FORM

Title of Study: Implementation of liberalized diets in a long-term-care facility

Definition of Liberalized Diets: Many residents in long-term care are given diets that have been altered in some way. Some of these diets have no concentrated sugar, low sodium, a certain number of carbohydrates, no added salt, etc. When these residents are given the regular diet, which has not been altered in any way, we say their diet has been liberalized. They are receiving regular meals with no alterations.

Purpose of this research project: To compare the use of liberalized diets with the traditional diets used in long-term-care (LTC) residents.

Names of researchers: Connie Ray Black, M.S., R.D., L.D., Clinical Dietitian and Assistant Director of Food and Nutrition, North Mississippi Health Services – Eupora, and also a graduate student at Mississippi State University; and Diane K. Tidwell, Ph.D., R.D., L.D., Associate Professor, Department of Food Science, Nutrition, and Health Promotion, Mississippi State University.

How will the research project be conducted? We will be asking LTC residents that have been pre-approved by their physician if they would like to participate in this project. There will be two groups of LTC residents; Group 1 will receive a liberalized, or regular, diet and Group 2 will continue with their usual diet. Both of these groups will be selected at random but not all residents will receive the liberalized diets. Group 2 will continue with the diets that are prescribed for them. Once a week, we will obtain and record body weights from both groups. If any lab values are available in medical charts, the values will be noted on the Liberalized Diets Data Collection Form (see attached). Once a week, Ms. Connie Black or Dr. Diane Tidwell will ask the participants in both groups if they are satisfied with their diet and the food they are being served (see attached). The study will last approximately 12 weeks. At the end of the study, we would like to see if there are any differences in weight gain or weight loss or if weights remain the same. We will also compare lab values such as blood sugar between the two groups. We are really interested in gaining information about the use of liberalized diets in LTC residents.

Are there any risks or discomforts to me because of my participation? Minimal risk may be involved with diet change; however, only LTC residents approved by their physician may participate in the project since all diets are ordered by the doctor. Your diet will continue to be monitored as usual. Obtaining body weights and lab values will continue as usual, this study will not require any additional interference in your normal care.

Does participation in this research project provide any benefits to others or myself? If selected to be on the liberalized diet, you may enjoy a wider selection of foods to choose from. You will be helping LTC dietitians learn more about liberalizing diets of LTC residents, and if liberalized diets help to improve the quality of life in a LTC facility. The results of this project will add to the knowledge about the use of liberalized diets in long-term care.

How will my information be kept confidential? We are not collecting any personal information on the data collection forms. Ms. Connie Black will have a list of participants and which person is on which diet, and she will keep this information and the data forms locked in a file drawer in her office, the Clinical Dietitian's Office, Department of Food and Nutrition, North Mississippi Health Services – Eupora, 600 Veterans Blvd, Eupora, Mississippi. Each participant will have a random three-digit subject number. At the end of the study, the data collection forms will be given to Dr. Diane Tidwell for data analysis on her computer in her office at Mississippi State University. The data collection forms will only be viewed by the researchers listed above, and will be destroyed at the end of the project when the written report is completed. See attachment for data collection form. All information and numbers will be reported as group averages, individual numbers such as weights and lab values of subjects will not be used.

Who do I contact with questions about this project? If you should have any questions about this project, please feel free to contact any of the researchers: Ms. Connie Black, 500 Veterans Memorial Blvd, Eupora, MS 39744, 662-258-9248 or 258-6221, cblack@dtcweb.net; and/or Dr. Diane Tidwell, Department of Food Science, Nutrition and Health Promotion, PO Box 9805, Mississippi State, MS 39762, 662-325-0293 or 325-3200, dtidwell@fsnhp.msstate.edu. If you have questions regarding your rights as a subject in human subjects' research, please contact the Mississippi State University Office of Regulatory Compliance at 662-325-5220 or via email at irb@research.msstate.edu or PO Box 6223, Mississippi State, MS 39762.

What if I do not want to participate, or if I begin the study and do not want to continue with the study? Please understand that your participation is voluntary, your refusal to participate will involve no penalties whatsoever. Your family members or those who have power of attorney for you will also be advised of your participation in this study and included in the initial presentation of the diet guidelines. If you begin the study, you may discontinue your participation at any time without any penalties, grudges, ill feelings, or repercussions. Participating in this project is completely voluntary.

If you would like to know the results of our study, please contact one of the researchers two weeks after the end of the study and a copy of the results will be sent to you. You will be given a copy of this form.

_____ _____

Participant's Signature Date

_____ _____

Investigator's Signature Date

Mississippi State UNIVERSITY

April 18, 2007

Connie Ray Black
P. O. Box 85
Ackerman, MS 39735

RE: Your application regarding study number 07-043: Implementation of liberalized diets in a long-term-care facility

Dear Ms. Black:

Your request for approval of the new study listed above was reviewed at the 3/28/2007, meeting of the Mississippi State University Institutional Review Board.

This is to confirm that your application was approved. You are granted permission to conduct your study as described in your application effective immediately. The study is subject to continuing review on or before 3/15/2008, unless closed before that date.

Please note that any changes to the study as approved must be promptly reported and approved. Some changes may be approved by expedited review; others require full board review. Contact Christine Williams (cwilliams@research.msstate.edu or by phone at 662-325-5220) if you have any questions or require further information.

Sincerely,

Christine Williams
IRB Compliance Administrator

cc: Diane Tidwell

Office for Regulatory Compliance
P. O. Box 6223 • 8A Morgan Street • Mailstop 9563 • Mississippi State, MS 39762 • (662) 325-3294 • FAX (662) 325-8776

APPENDIX D

NORTH MISSISSIPPI MEDICAL CENTER CONSENT FORMS

NORTH MISSISSIPPI HEALTH SERVICES

Institutional Review Board

INFORMED CONSENT (*A-Patient*)

Study Title: Implementation of liberalized diets in a long-term-care facility

Principal Investigator: Connie Ray Black, M.S., R.D., L.D.
Clinical Dietitian, NMMC-Eupora
70 Medical Plaza
Eupora, MS 39744
662-258-6221

Sub-Investigators: Diane K. Tidwell, Ph.D., R.D., L.D.
Associate Professor
Department of Food Science, Nutrition, and Health
Mississippi State University
Box 9805
Mississippi State, MS 39762-9805

Research Site: North Mississippi Medical Center -Eupora
Long Term Care Facility

What is the purpose of this research study?
The purpose of this study is to compare the use of liberalized diets in long-term-care (LTC) residents. "Liberalized" diets simply allow residents who would be on restricted diets (for example, low salt or low sugar) to be able to have a non-restricted "Regular" diet.

What is my involvement in this study?
You are being asked to participate in this study because you are a LTC resident who is on a restricted diet. You have been **pre-approved by your physician** to participate in this study. If you agree to participate in this study, you will be randomly (like flipping a coin) placed into one of two study groups.

Group 1: Will receive a non-restricted (regular).
Group 2: Will continue with their usual restricted diet.

Once a week Connie Black will obtain and record your body weight and any lab values available in your medical record. Once a week Connie Black will meet with you to determine your degree of satisfaction with the diet and food being served. The study will involve 12 subjects and last for 12 weeks. At the end of the 12 weeks all data will be analyzed for differences in lab values, weight, and perceived satisfaction of dissatisfaction with the diets. No follow-up study is planned.

"APPROVED"
AUG 27 2007
BY NMHS IRB

Subject Initials: ____

What are the risks of my involvement in this study?
Your participation in this study will involve minimal risk. You will continue to receive your usual care: your diet and weight will continue to be monitored. Your usual lab work will be done. **Your physician is aware of this study and has approved of your participation**. This study will not require any additional interferences in your normal care.

What are the benefits of my involvement in this study?
We cannot guarantee any benefit to you for participating in this study. Your involvement, however, will increase our knowledge of the effect of liberalized diets on nutrition and quality of life LTC residents. This knowledge may help other LTC residents.

Will my records be kept private?
All data will be kept confidential. You will be assigned a subject code and your name will not be associated with your information. Your clinical study record will include personal health information from your medical record and your satisfaction responses. Those who will have access to the data include Connie Black, clinical dietitian at the facility and principle investigator and Diane Tidwell, registered dietitian, associate professor at MSU, and co-investigator. All documents will be held by Connie Black in a locked drawer in the Clinical Dietitian's Office at NMMC-Eupora for up to five years and will then be destroyed. The NMHS IRB may review these records and the NMMC employee(s) involved with this study will also have access.

What if I have a question or problem?
You may freely ask questions about this informed consent form or the study, now or at any time during the study. If you have any have any questions about this study, please contact Connie Black at 662-258-6221. If you have any questions concerning this study or consent form beyond those answered by the investigator, including questions about the research, your rights as a research subject or research- related injuries, please feel free to contact Karen Koch, PharmD, Manager of the North Mississippi Health Services, Institutional Review Board at 662-377-3778. **A copy of this consent form will be given to you.**

Can I leave the study after it has begun?
Please understand that your participation is voluntary, your refusal to participate will involve no penalty or loss of benefits to which you are entitled. You may stop your participation at any time without affecting your ongoing medical care. Additionally, you should feel free to leave blank any questions you feel uncomfortable answering.

Important:
You are making a decision whether or not to participate in this study. Your signature indicates that you have:

- read and understood the information provided above,
- asked the dietician any questions you may have had,
- had all your concerns addressed by your dietician,
- and have decided to participate.

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Subject Initials: ____

Subject Statement:
I have read, or have had read to me, and understand this consent form and my questions have been answered. The purpose of the research, the study procedures that I will undergo, and the possible risks and discomforts as well as the benefits I may experience have been explained to me. Therefore, I voluntarily agree to consent to participate in this research study.

_____ _____
Name of Subject (please print) Date

_____ _____
Signature of Subject Date

By participating in this study, I understand and authorize Connie Black (PI), Diane Tidwell (SI), and the NMHS IRB, to have access to my medical records protected health information for the purposes of clinical research and to utilize the protected health information in accordance with federal and state law.

_____ _____
Name of Subject (please print) Date

_____ _____
Signature of Subject Date

_____ _____
Signature of Person Witnessing Consent Date

Investigator's Statement:
I have given this research subject information of the study, which in my opinion is accurate and sufficient for the subject to understand fully the nature, risks and benefits of the study, and the rights of a research subject. There has been no coercion or undue influence.

_____ _____
Investigator's Signature Date

"APPROVED"
AUG 27 2007
BY NMHS IRB

NORTH MISSISSIPPI HEALTH SERVICES

Institutional Review Board

INFORMED CONSENT (*B-Legally Authorized Representative*)

Study Title: Implementation of liberalized diets in a long-term-care facility

Principal Investigator: Connie Ray Black, M.S., R.D., L.D.
Clinical Dietitian, NMMC-Eupora
70 Medical Plaza
Eupora, MS 39744
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Sub-Investigators: Diane K. Tidwell, Ph.D., R.D., L.D.
Associate Professor
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You are being asked to participate in this study because you are a LTC resident who is on a restricted diet. You have been **pre-approved by your physician** to participate in this study. If you agree to participate in this study, you will be randomly (like flipping a coin) placed into one of two study groups.

Group 1: Will receive a non-restricted (regular).
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Once a week Connie Black will obtain and record your body weight and any lab values available in your medical record. Once a week Connie Black will meet with you to determine your degree of satisfaction with the diet and food being served. The study will involve 12 subjects and last for 12 weeks. At the end of the 12 weeks all data will be analyzed for differences in lab values, weight, and perceived satisfaction of dissatisfaction with the diets. No follow-up study is planned.

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BY NMHS IRB

Subject Initials: ____

What are the risks of my involvement in this study?
Your participation in this study will involve minimal risk. You will continue to receive your usual care: your diet and weight will continue to be monitored. Your usual lab work will be done. **Your physician is aware of this study and has approved of your participation**. This study will not require any additional interferences in your normal care.

What are the benefits of my involvement in this study?
We cannot guarantee any benefit to you for participating in this study. Your involvement, however, will increase our knowledge of the effect of liberalized diets on nutrition and quality of life LTC residents. This knowledge may help other LTC residents.

Will my records be kept private?
All data will be kept confidential. You will be assigned a subject code and your name will not be associated with your information. Your clinical study record will include personal health information from your medical record and your satisfaction responses. Those who will have access to the data include Connie Black, clinical dietitian at the facility and principle investigator and Diane Tidwell, registered dietitian, associate professor at MSU, and co-investigator. All documents will be held by Connie Black in a locked drawer in the Clinical Dietitian's Office at NMMC-Eupora for up to five years and will then be destroyed. The NMHS IRB may review these records and the NMMC employee(s) involved with this study will also have access.

What if I have a question or problem?
You may freely ask questions about this informed consent form or the study, now or at any time during the study. If you have any have any questions about this study, please contact Connie Black at 662-258-6221. If you have any questions concerning this study or consent form beyond those answered by the investigator, including questions about the research, your rights as a research subject or research- related injuries, please feel free to contact Karen Koch, PharmD, Manager of the North Mississippi Health Services, Institutional Review Board at 662-377-3778. **A copy of this consent form will be given to you.**

Can I leave the study after it has begun?
Please understand that your participation is voluntary, your refusal to participate will involve no penalty or loss of benefits to which you are entitled. You may stop your participation at any time without affecting your ongoing medical care. Additionally, you should feel free to leave blank any questions you feel uncomfortable answering.

Important:
You are making a decision whether or not to participate in this study. Your signature indicates that you have:

- read and understood the information provided above,
- asked the dietician any questions you may have had,
- had all your concerns addressed by your dietician,
- and have decided to participate.

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BY NMHS IRB

Subject Initials: ____

Subject Statement:
I have read, or have had read to me, and understand this consent form and my questions have been answered. The purpose of the research, the study procedures that I will undergo, and the possible risks and discomforts as well as the benefits I may experience have been explained to me. Therefore, I voluntarily agree to consent to participate in this research study.

_____ _____
Name of Subject (please print) Date

_____ _____
Signature of Subject Date

Legal Representative Consent:
The person being considered for this study is unable to provide consent for himsefl/herself. The purpose of the research, the study procedures, the possible risks and discomforts as well as the benefits have been explained to me and to the subject. I hae beren asked to evaluate thisinformation and to consent to participation in the study on behalf of the subject. I know of no reason nor to follow the person's assent to participate in this research study.

_____ _____
Legally Authorized respresentative (please print) Date / Time

_____
Legally Authorized respresentative (signature)

Relationship to the Subject: please check the descriptioin which fits the consenting person the best:

- ☐ Legally appointed guardian
- ☐ Subject advocate named in "Durable Power of Attorney for Health Care"
- ☐ Spouse
- ☐ Adult son or daughter
- ☐ Parent
- ☐ Adult brother or sister
- ☐ Explicitly authorized person

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BY NMHS IRB

Subject Initials: ____

By participating in this study, I understand and authorize Connie Black (PI), Diane Tidwell (SI), and the NMHS IRB, to have access to the subject's medical records proteched health information for the purposes of clincial research and to utilize the protected health information in accordance with federal and state law.

Legally Authorized respresentative (please print) Date / Time

Legally Authorized respresentative (signature)

Signature of Person Witnessing Consent Date

Investigator's Statement:
I have given this research subject information of the study, which in my opinion is accurate and sufficient for the subject to understand fully the nature, risks and benefits of the study, and the rights of a research subject. There has been no coercion or undue influence.

Investigator's Signature Date

"APPROVED"
AUG 27 2007
BY NMHS IRB

APPENDIX E

SUBJECTS' DATA FOR THE RANDOMIZED CLINICAL TRIAL

Table 4 Data for the Randomized Clinical Trial

Subject	Diet	Age	Sex	Height (cm) Week 0	Weight (kg) Week 0	Body Mass Index (kg/m^2) Week 0	Ideal Body Weight (%) Week 0	Systolic Blood Pressure (mm Hg) Week 0	Diastolic Blood Pressure (mm Hg) Week 0
289*	Therapeutic	73	Female	170.18	63.6364	21.9731	104.0000	128	72
265	Therapeutic	81	Female	180.34	109.0909	33.5427	154.8387	112	60
634	Therapeutic	69	Female	149.86	79.1818	35.2577	178.6666	114	68
255	Therapeutic	84	Female	152.40	56.5909	24.3653	124.5000	130	68
139	Therapeutic	69	Female	160.02	92.6818	36.1954	177.3043	142	68
214	Therapeutic	54	Female	137.16	56.7273	30.1532	146.8235	110	82
891	Therapeutic	86	Female	167.64	69.2727	24.6496	117.2308	122	60
635	Therapeutic	82	Female	165.10	74.5455	27.3481	131.2000	120	80
182	Therapeutic	84	Male	167.64	64.5455	22.9675	100.0000	130	90
180	Therapeutic	86	Female	167.64	71.1364	25.3127	120.3846	120	72
952	Therapeutic	100	Female	160.02	62.0455	24.2308	118.6957	128	62
522	Liberalized	85	Female	163.83	95.9091	35.7336	172.2449	130	70
770	Liberalized	67	Male	170.18	69.0909	23.8565	102.7027	132	72
661	Liberalized	77	Female	182.88	104.0909	31.1230	143.1250	136	90
918	Liberalized	83	Female	162.56	77.9273	29.4744	142.8667	128	82
338	Liberalized	93	Female	157.48	56.1364	22.6356	111.8182	124	74
424	Liberalized	71	Female	160.02	98.1818	38.3432	187.8261	130	88
245	Liberalized	81	Male	175.26	55.2727	17.9948	75.9375	110	70
501	Liberalized	89	Female	152.40	93.0000	40.0413	204.6000	124	76
680	Liberalized	85	Female	152.40	60.6818	26.1267	133.5000	160	70
292	Liberalized	68	Female	162.56	55.6818	21.0708	102.0833	136	78
195	Liberalized	90	Female	152.40	60.6818	26.1267	133.5000	160	78

*These were not the random 3-digit subject codes used in the study. New numbers were generated for this Appendix. Race was removed from this Appendix to further delink identifiers.

Table 4 (continued)

Subject	Blood Glucose (mg/dl) Week 0	Albumin (g/dl) Week 0	Hemoglobin (mg/dl) Week 0	Hematocrit (%) Week 0	Diet Satisfaction Week 0	Weight (kg) Week 1	Body Mass Index (kg/m^2) Week 1	Ideal Body Weight (%) Week 1	Systolic Blood Pressure (mmHg) Week 1	Diastolic Blood Pressure (mmHg) Week 1
289	75.00		11.70	34.30	3	63.6364	21.9731	104.0000	120	60
265	128.00	2.50	9.40	28.60	2	109.0909	33.5427	154.8387	150	70
634	130.00	3.00	12.60	37.60	5	79.1818	35.2577	178.6666	110	80
255	171.00	2.60	11.70	33.90	4	56.5909	24.3653	124.5000	140	60
139	106.00	3.60	13.90	40.80	5	92.6818	36.1954	177.3043	130	56
214	128.00	3.20	15.70	44.90	4	53.4091	28.3895	138.2353	130	80
891	75.00	3.30	12.00	35.10	4	69.2727	24.6496	117.2308	140	80
635	176.00	3.20	12.70	36.60	2	74.5455	27.3481	131.2000	120	80
182	100.00	3.50	13.40	39.20	4	76.8386	27.3507	119.0845	121	70
180	218.00	2.80	11.40	34.10	1	71.1364	25.3127	120.3846	100	60
952	72.00	2.70	10.70	32.40	5	62.0455	24.2308	119.0000	128	62
522	228.00	3.20	12.80	38.90	4	95.9091	35.7336	172.2449	136	80
770		3.30	13.10	36.10	2	69.0909	23.8565	102.7027	120	70
661	80.00	3.30	13.90	39.70	5	104.0909	31.1230	143.1250	120	80
918	188.00	3.40	9.80	28.10	4	77.9273	29.4744	142.8667	120	90
338	161.00	3.70	15.00	45.70	5	56.1364	22.6356	111.8182	120	60
424	159.00	4.10	12.20	35.80	2	98.1818	38.3432	187.8261	120	70
245	109.00	3.70	15.50	44.10	5	55.2727	17.9948	75.9375	120	90
501	173.00	3.40	11.70	34.20	2	93.0000	40.0413	204.6000	140	80
680	78.00	3.00	10.20	28.80	2	60.6818	26.1267	133.5000	150	60
292	120.00	4.00	14.40	42.00	4	54.4091	20.7784	100.6667	140	40
195					4	60.6818	26.1267	133.5000	160	78

Table 4 (continued)

Subject	Blood Glucose (mg/dl) Week 1	Albumin (g/dl) Week 1	Hemoglobin (mg/dl) Week 1	Hematocrit (%) Week 1	Diet Satisfication Week 1	Weight (kg) Week 2	Body Mass Index (%) Week 2	Ideal Body Weight (%) Week 2	Systolic Blood Pressure (mmHg) Week 2	Diastolic Blood Pressure (mmHg) Week 2
289	112.00		11.70	34.30	4	63.6364	21.9731	104.0000	120.00	60.00
265	114.00	2.50	9.40	28.60	2	109.0909	33.5427	154.8387	140.00	78.00
634	122.00	3.20			4	79.1818	35.2577	178.6666	128.00	76.00
255	141.50	2.60	11.70	33.90	4	56.5909	24.3653	124.5000	118.00	68.00
139			13.90	40.80	4	92.6818	36.1954	177.3043	140.00	70.00
214	187.00				4	53.4091	28.3895	138.2353	130.00	80.00
891					4	69.2727	24.6496	117.2308	140.00	80.00
635	154.00	3.20	14.10	39.80	4	74.5455	27.3481	131.2000	118.00	80.00
182			13.00	38.10	4	76.8386	27.3507	119.0845	134.00	78.00
180	92.00	2.80	11.40	34.10	4	71.1364	25.3127	120.3846	100.00	60.00
952					4	62.0455	24.2308	118.6957	122.00	68.00
522	225.00				4	95.9091	35.7336	172.2449	100.00	60.00
770		3.30	13.10	36.10	2	69.0909	23.8565	102.7027	124.00	70.00
661			13.90	39.70	5	104.0909	31.1230	143.1250	120.00	80.00
918	117.00	3.40	10.70	30.60	4	77.9273	29.4744	142.8667	138.00	74.00
338	138.00				4	56.1364	22.6356	111.8182	132.00	70.00
424					2	98.1818	38.3432	187.8261	140.00	78.00
245	117.50	3.20	14.90	43.40	5	55.2727	17.9948	75.9375	120.00	80.00
501	158.00	3.50	11.70	34.20	4	93.0000	40.0413	204.6000	140.00	80.00
680					3	60.6818	26.1267	133.5000	130.00	70.00
292	138.00				5	53.6364	20.2068	98.3333	120.00	70.00
195	135.00				4	60.6818	26.1267	133.5000	140.00	60.00

Table 4 (continued)

Subject	Blood Glucose (mg/dl) Week 2	Diet Satisfaction Week 2	Weight (kg) Week 3	Body Mass Index (kg/m^2) Week 3	Ideal Body Weight (%) Week 3	Systolic Blood Pressure (mmHg) Week 3	Diastolic Blood Pressure (mmHg) Week 3	Blood Glucose (mg/dl) Week 3	Diet Satisfaction Week 3	Weight (kg) Week 4
289	78.00	4	63.6364	21.9731	104.0000	130.00	74.00	97.00	4	63.6364
265		3	109.0909	33.5427	154.8387	110.00	70.00		3	109.0909
634	149.50	5	79.1818	35.2577	178.6666	110.00	64.00	160.50	5	79.1477
255	118.00	4	56.5909	24.3653	124.5000	130.00	88.00	153.00	4	56.5909
139	106.00	4	92.6818	36.1954	177.3043	140.00	70.00		3	92.6818
214	171.00	4	53.4091	28.3895	138.2353	120.00	80.00	194.00	5	53.4091
891		4	69.2727	24.6496	117.2308	120.00	60.00		5	70.0909
635		2	75.7273	27.7817	133.2800	140.00	60.00		3	75.7273
182		4	76.8386	27.3507	119.0845	130.00	70.00		4	76.0909
180	157.00	3	71.1364	25.3127	120.3846	122.00	68.00	155.00	4	71.1364
952	72.00	3	62.0455	24.2308	118.6957	120.00	80.00		4	62.0455
522	224.00	4	95.9091	35.7336	172.2449	180.00	80.00	215.00	4	95.9091
770		2	69.0909	23.8565	102.7027	124.00	68.00		2	69.0909
661		5	104.0909	31.1230	143.1250	120.00	80.00		5	104.0909
918	122.00	5	77.9273	29.4744	142.8667	144.00	68.00	134.50	5	77.9273
338	156.00	4	56.1364	22.6356	111.8182	120.00	62.00	152.50	4	56.1364
424		3	98.1818	38.3432	187.8261	138.00	60.00	281.00	3	98.1818
245	135.33	5	55.2727	17.9948	75.9375	120.00	80.00	131.43	5	55.2727
501		4	93.0000	40.0413	204.6000	140.00	80.00		4	93.0000
680	82.00	3	60.6818	26.1267	133.5000	130.00	70.00		4	60.6818
292	180.00	5	52.2727	19.7808	95.8333	132.00	66.00	166.00	5	52.2727
195	111.00	5	60.6818	26.1267	133.5000	110.00	70.00	136.00	5	60.6818

Table 4 (continued)

Subject	Body Mass Index (kg/m^2) Week 4	Ideal Body Weight (%) Week 4	Systolic Blood Pressure (mmHg) Week 4	Diastolic Blood Pressure (mmHg) Week 4	Blood Glucose (mg/dl) Week 4	Diet Satisfaction Week 4	Weight (kg) Week 5	Body Mass Index (kg/m^2) Week 5	Ideal Body Weight (%) Week 5
289	21.9731	104.0000			116.00	4	62.0455	21.4238	101.0000
265	33.5427	154.8387	140.00	80.00		4	109.0909	33.5427	154.8387
634	35.2426	178.4872	120.00	68.00	150.50	5	79.1477	35.2426	178.4872
255	24.3653	124.5000	140.00	60.00	145.00	4	57.0000	24.5415	125.4000
139	36.1954	177.3043	138.00	70.00		4	94.7273	36.9942	181.2174
214	28.3895	138.2353	130.00	72.00	180.00	5	56.2727	29.9116	145.6471
891	24.9407	118.6154	132.00	70.00		5	70.0909	24.9407	118.6154
635	27.7817	133.2800	120.00	60.00	219.00	3	75.6364	27.7483	133.1200
182	27.0757	117.8873	140.00	70.00		4	76.0909	27.0757	117.8873
180	25.3127	120.3846	136.00	78.00	169.00	4	70.1818	24.9731	118.7692
952	24.2308	118.6957	110.00	70.00		4	62.2727	24.3196	119.1304
522	35.7336	172.2449			236.00	4	97.5455	36.3433	175.1837
770	23.8565	102.7027	110.00	80.00		2	75.6364	26.1166	112.4324
661	31.1230	143.1250	130.00	50.00		5	103.4545	30.9327	142.2500
918	29.4744	142.8667	110.00	70.00	129.00	5	80.1364	30.3099	146.9167
338	22.6356	111.8182	160.00	70.00	153.00	4	58.6364	23.6437	23.6437
424	38.3432	187.8261	120.00	70.00		3	97.4545	37.9792	186.4348
245	17.9948	75.9375	120.00	80.00	148.67	5	57.9545	18.8679	79.6875
501	40.0413	204.6000	112.00	58.00		4	92.4545	39.8065	203.4000
680	26.1267	133.5000	140.00	64.00		4	61.9545	26.6747	136.3000
292	19.7808	95.8333	140.00	50.00	154.50	5	55.9091	21.1568	102.5000
195	26.1267	133.5000	124.00	72.00		4	61.5909	26.5181	133.5000

Table 4 (continued)

Subject	Ideal Body Weight (%) Week 5	Systolic Blood Pressure (mmHg) Week 5	Diastolic Blood Pressure (mmHg) Week 5	Blood Glucose (mg/dl) Week 5	Diet Satisfaction Week 5	Weight (kg) Week 6	Body Mass Index (kg/m^2) Week 6	Ideal Body Weight (%) Week 6	Systolic Blood Pressure (mmHg) Week 6	Blood Glucose (mg/dl) Week 6
289	101.0000	130.00	60.00	136.00	4	62.0455	21.4238	101.0000	122.00	70.00
265	154.8387	150.00	72.00		3	109.0909	33.5427	154.8387	136.00	
634	178.4872	124.00	70.00	152.00	5	79.1477	35.2426	178.4872	140.00	141.00
255	125.4000	108.00	64.00	274.00	4	57.0000	24.5415	125.4000	148.00	
139	181.2174	140.00	80.00		4	94.7273	36.9942	181.2174	140.00	
214	145.6471	120.00	60.00	154.00	5	56.2727	29.9116	145.6471	140.00	259.00
891	118.6154	128.00	68.00		4	70.0909	24.9407	118.6154	150.00	
635	133.1200	112.00	60.00	201.00	3	75.6364	27.7483	133.1200	140.00	199.83
182	117.8873	150.00	72.00		4	76.0909	27.0757	117.8873	120.00	
180	118.7692	108.00	64.00	167.00	5	70.1818	24.9731	118.7692	134.00	90.00
952	119.1304	160.00	80.00		4	62.2727	24.3196	119.1304	136.00	
522	175.1837	132.00	72.00	226.92	4	97.5455	36.3433	175.1837		234.15
770	112.4324	150.00	70.00		3	75.6364	26.1166	112.4324	152.00	
661	142.2500	150.00	62.00		5	103.4545	30.9327	142.2500	118.00	
918	146.9167	140.00	60.00	112.00	5	80.1364	30.3099	146.9167	132.00	136.50
338	23.6437	142.00	70.00	204.00	4	58.6364	23.6437	23.6437	120.00	
424	186.4348	140.00	72.00		3	97.4545	37.9792	186.4348	148.00	
245	79.6875	140.00	80.00	148.29	5	57.9545	18.8679	79.6875	110.00	137.42
501	203.4000	112.00	58.00		4	92.4545	39.8065	203.4000	140.00	180.00
680	136.3000	128.00	76.00		4	61.9545	26.6747	136.3000	130.00	
292	102.5000	122.00	76.00	121.50	5	55.9091	21.1568	102.5000	138.00	136.00
195	133.5000	150.00	80.00	132.00	4	61.5909	26.5181	133.5000	126.00	

Table 4 (continued)

Subject	Diet Satisfaction Week 6	Weight (kg) Week 7	Body Mass Index (kg/m^2) Week 7	Ideal Body Weight (%) Week 7	Systolic Blood Pressure (mmHg) Week 7	Diastolic Blood Pressure (mmHg) Week 7	Blood Glucose (mg/dl) Week 7	Diet Satisfaction Week 7	Weight (kg) Week 8	Body Mass Index (kg/m^2) Week 8	Ideal Body Weight (%) Week 8
289	3	62.5000	21.5807	102.0000	122.00	60.00		3	62.2727	21.5023	101.0000
265	3	109.0909	33.5427	154.8387	132.00	76.00		3	109.0909	33.5427	154.8387
634	5	79.1477	35.2426	178.4872	100.00	60.00	132.50	5	79.1477	35.2426	178.4872
255	4	57.0000	24.5415	125.4000	126.00	70.00	239.00	4	57.0000	24.5415	125.4000
139	3	94.7273	36.9942	181.2174	140.00	80.00		4	94.7273	36.9942	181.2174
214	5	56.2727	29.9116	145.6471	140.00	60.00	191.00	5	56.2727	29.9116	145.6471
891	5	70.0909	24.9407	118.6154	124.00	82.00		5	70.0909	24.9407	118.6154
635	4	75.6364	27.7483	133.1200	140.00	76.00	190.50	2	75.6364	27.7483	133.1200
182	4	76.0909	27.0757	117.8873	132.00	70.00		4	76.0909	27.0757	117.8873
180	3	70.1818	24.9731	118.7692	122.00	82.00	150.00	4	70.1818	24.9731	118.7692
952	4	62.2727	24.3196	119.1304	110.00	60.00		4	62.2727	24.3196	119.1304
522	4	97.5455	36.3433	175.1837	138.00	74.00	149.75	4	97.5455	36.3433	175.1837
770	3	75.6364	26.1166	112.4324	130.00	82.00		3	75.6364	26.1166	112.4324
661	5	103.4545	30.9327	142.2500	136.00	82.00		5	103.4545	30.9327	142.2500
918	5	80.1364	30.3099	146.9167	132.00	76.00	152.50	5	80.1364	30.3099	146.9167
338	5	58.6364	23.6437	23.6437	130.00	70.00	269.00	4	58.6364	23.6437	23.6437
424	4	97.4545	37.9792	186.4348	130.00	80.00		4	97.4545	37.9792	186.4348
245	5	57.9545	18.8679	79.6875	90.00	70.00	138.92	5	57.9545	18.8679	79.6875
501	4	92.4545	39.8065	203.4000	112.00	76.00		4	92.4545	39.8065	203.4000
680	4	61.9545	26.6747	136.3000	146.00	70.00		4	61.9545	26.6747	136.3000
292	5	55.9091	21.1568	102.5000	128.00	68.00	145.00	5	55.9091	21.1568	102.5000
195	4	61.5909	26.5181	135.5000	122.00	70.00	149.00	4	61.5909	26.5181	135.5000

Table 4 (continued)

Subject	Systolic Blood Pressure (mmHg) Week 8	Diastolic Blood Pressure (mmHg) Week 8	Blood Glucose (mg/dl) Week 8	Diet Satisfaction Week 8	Weight (kg) Week 9	Body Mass Index (kg/m^2) Week 9	Ideal Body Weight (%) Week 9	Systolic Blood Pressure (mmHg) Week 9	Diastolic Blood Pressure (mmHg) Week 9	Blood Glucose (mg/dl) Week 9
289				4	60.9091	21.0314	100.0000	144.00	78.00	
265	140.00	90.00		1	103.6364	31.8558	147.0968	132.00	72.00	163.67
634	122.00	78.00		4	72.4091	32.2420	163.3846	120.00	80.00	123.00
255	126.00	72.00	161.00	4	55.9091	24.0718	123.0000	122.00	70.00	60.00
139	140.00	80.00		3	93.8630	36.6569	179.5652	140.00	80.00	
214	120.00	80.00	216.00	5	56.4545	30.0083	146.1176	120.00	80.00	187.00
891	122.00	60.00		5	70.2000	24.9795	118.7692	130.00	62.00	
635	130.00	90.00	166.33	2	76.7273	28.1485	135.0400	130.00	60.00	207.00
182	140.00	50.00		4	76.0455	27.0596	117.8169	140.00	60.00	147.00
180	120.00	66.00	169.00	3	68.3636	24.3261	115.6923	140.00	78.00	128.00
952	128.00	70.00		4	61.3636	23.9141	117.3913	120.00	80.00	
522			248.20	4	98.1818	36.5804	176.3265			213.00
770	120.00	60.00		3	69.6364	24.0449	103.5135	120.00	60.00	
661	120.00	70.00		5	103.4545	30.9327	142.2500	130.00	60.00	
918	132.00	76.00	157.50	5	81.4545	30.8085	149.3333	110.00	80.00	132.50
338	140.00	70.00	263.00	4	57.7273	23.2771	115.4545	170.00	70.00	216.00
424	120.00	60.00		4	99.8182	38.9823	190.9565	110.00	60.00	
245	118.00	70.00	103.00	5	57.7273	18.7939	79.3750	130.00	70.00	117.50
501	140.00	72.00		4	92.7273	39.9239	204.0000	140.00	72.00	
680	140.00	60.00		4	62.9091	27.0856	138.4000	146.00	70.00	
292	140.00	50.00	168.50	5	54.4091	20.5892	99.7500	140.00	60.00	139.33
195	160.00	80.00	114.00	5	61.5909	26.5181	133.5000	150.00	68.00	

Table 4 (continued)

Subject	Diet Satisfaction Week 9	Weight (kg) Week 10	Body Mass Index (kg/m^2) Week 10	Ideal Body Weight (%) Week 10	Systolic Blood Pressure (mmHg) Week 10	Diastolic Blood Pressure (mmHg) Week 10	Blood Glucose (mg/dl) Week 10	Diet Satisfaction Week 10	Weight (kg) Week 11
289	4	60.9091	21.0314	100.0000	120.00	62.00		4	60.9091
265	3	103.6364	31.8558	147.0968	132.00	72.00	131.25	3	103.6364
634	4	72.4091	32.2420	163.3846	120.00	68.00	128.00	5	72.4091
255	4	55.9091	24.0718	123.0000	108.00	64.00	88.00	4	55.9091
139	5	93.8630	36.6569	179.5652	140.00	80.00		4	93.8630
214	5	56.4545	30.0083	146.1176	120.00	80.00	199.00	5	56.4545
891	5	70.2000	24.9795	118.7692	124.00	70.00		5	70.2000
635	2	76.7273	28.1485	135.0400	150.00	60.00	150.00	2	76.7273
182	4	76.0455	27.0596	117.8169	140.00	80.00		4	76.0455
180	3	68.3636	24.3261	115.6923	128.00	78.00	158.00	3	68.3636
952	4	61.3636	23.9141	117.3913	132.00	70.00		4	61.3636
522	4	98.1818	36.5804	176.3265	160.00	78.00	268.00	3	98.1818
770	3	69.6364	24.0449	103.5135	140.00	80.00		3	69.6364
661	5	103.4545	30.9327	142.2500	140.00	80.00		5	103.4545
918	5	81.4545	30.8085	149.3333	110.00	80.00		5	81.4545
338	3	57.7273	23.2771	115.4545	138.00	70.00	224.50	3	57.7273
424	4	99.8182	38.9823	190.9565	140.00	72.00		2	99.8182
245	5	57.7273	18.7939	79.3750	100.00	64.00	112.50	5	57.7273
501	4	92.7273	39.9239	204.0000	130.00	70.00		5	92.7273
680	4	62.9091	27.0856	138.4000	160.00	70.00		4	62.9091
292	5	54.4091	20.5892	99.7500	140.00	72.00	146.56	5	54.4091
195	5	61.5909	26.5181	133.5000	148.00	78.00		5	61.5909

Table 4 (continued)

Subject	Body Mass Index (kg/m^2) Week 11	Ideal Body Weight (%) Week 11	Systolic Blood Pressure (mmHg) Week 11	Diastolic Blood Pressure (mmHg) Week 11	Blood Glucose (mg/dl) Week 11	Diet Satisfaction Week 11	Weight (kg) Week 12	Body Mass Index (kg/m^2) Week 12	Ideal Body Weight (%) Week 12	Systolic Blood Pressure (mmHg) Week 12	Diastolic Blood Pressure (mmHg) Week 12
289	21.0314	100.0000	150.00	72.00		3	60.9091	21.0314	100.0000	124.00	63.00
265	31.8558	147.0968	134.00	78.00	99.50	3	103.6364	31.8558	147.0968	138.00	80.00
634	32.2420	163.3846	118.00	70.00	145.50	4	72.4091	32.2420	163.3846	110.00	68.00
255	24.0718	123.0000	110.00	70.00	113.00	4	55.9091	24.0718	123.0000	130.00	60.00
139	36.6569	179.5652	140.00	80.00		4	93.8630	36.6569	179.5652	140.00	70.00
214	30.0083	146.1176	130.00	80.00	155.00	5	56.4545	30.0083	146.1176	130.00	72.00
891	24.9795	118.7692	118.00	68.00		5	70.2000	24.9795	118.7692	142.00	82.00
635	28.1485	135.0400	130.00	70.00	193.00	2	76.7273	28.1485	135.0400	130.00	78.00
182	27.0596	117.8169	128.00	72.00		4	76.0455	27.0596	117.8169	130.00	78.00
180	24.3261	115.6923	134.00	70.00	130.00	3	68.3636	24.3261	115.6923	160.00	74.00
952	23.9141	117.3913	128.00	60.00		4	61.8182	24.1421	118.2609	160.00	90.00
522	36.5804	176.3265			194.00	4	98.1818	36.5804	176.3265		
770	24.0449	103.5135	140.00	80.00		3	69.6364	24.0449	103.5135	134.00	60.00
661	30.9327	142.2500	140.00	80.00		5	103.4545	30.9327	142.2500	128.00	74.00
918	30.8085	149.3333	140.00	68.00	130.50	5	81.4545	30.8085	149.3333	120.00	70.00
338	23.2771	115.4545	164.00	70.00	315.50	3	57.7273	23.2771	115.4545	150.00	76.00
424	38.9823	190.9565	130.00	84.00		2	99.8182	38.9823	190.9565	140.00	70.00
245	79.3750	18.7939	132.00	78.00	145.40	5	57.7273	18.7939	79.3750	130.00	68.00
501	39.9239	204.0000	140.00	80.00		5	92.7273	39.9239	204.0000	140.00	80.00
680	27.0856	138.4000	160.00	70.00		4	62.9091	27.0856	138.4000	160.00	90.00
292	20.5892	99.7500	128.00	72.00	150.20	5	54.4091	20.5892	99.7500	130.00	78.00
195	26.5181	135.5000	150.00	60.00		4	61.5909	26.5181	135.5000	132.00	70.00

Table 4 (continued)

Subject	Blood Glucose (mg/dl) Week 12	Diet Satisfaction Week 12	Body Weight (kg) Week 13	Body Mass Index (kg/m^2) Week 13	Ideal Body Weight (%) Week 13	Systolic Blood Pressure (mmHg) Week 13	Diastolic Blood Pressure (mmHg) Week 13	Blood Glucose (mg/dl) Week 13	Diet Satisfaction Week 13	Weight (kg) Week 14
289		4	57.9545	20.0112	94.0000	144.00	70.00	115.00	3	57.9545
265	121.67	3	95.4545	29.3408	135.4839	130.00	70.00	136.00	3	95.4545
634	116.00	4	71.8636	31.9991	162.1538	112.00	60.00	162.00	4	71.8636
255	102.00	4	55.2273	23.7782	121.5000	125.00	79.00	122.00	4	55.2273
139		4	93.6364	36.5681	179.1304	140.00	70.00		4	93.6364
214	109.00	5	55.4545	29.4767	143.5294	130.00	80.00	154.00	5	55.4545
891		5	73.1364	26.0244	123.7692	100.00	60.00		5	73.1364
635	145.00	2	74.5455	27.3481	131.2000	120.00	90.00	124.00	2	74.5455
182		4	77.6364	27.6256	120.2817	140.00	60.00		4	77.6364
180	163.00	2	66.0909	23.5174	111.8462	140.00	74.00	136.00	2	66.0909
952		3	61.8182	24.1421	118.2609	128.00	70.00		4	61.8182
522	230.00	3	99.4545	37.5584	178.6122	132.00	72.00	221.33	3	99.4545
770		3	69.3636	23.9507	103.1081	130.00	70.00		3	69.3636
661		5	104.0909	31.1137	143.1250	120.00	70.00		5	104.0909
918	119.50	5	80.2727	30.3615	147.1667	120.00	70.00	146.00	5	80.2727
338	210.50	3	57.7273	23.2771	115.4545	142.00	80.00	233.50	4	56.5909
424		2	100.2727	39.1599	191.8261	120.00	70.00		3	100.2727
245	143.50	5	57.2727	18.6459	78.7500	96.00	65.00	126.00	5	57.2727
501		3	92.5455	39.8456	203.6000	148.00	80.00		4	92.7273
680		4	63.6818	27.4183	140.1000	130.00	70.00		4	63.6818
292	161.00	5	53.0909	20.0904	97.3333	140.00	70.00	142.38	5	53.0909
195		4	61.4545	26.4594	135.2000	150.00	70.00	128.00	4	61.4545

Table 4 (continued)

Subject	Body Mass Index (kg/m^2) Week 14	Ideal Body Weight (%) Week 14	Systolic Blood Pressure (mmHg) Week 14	Diastolic Blood Pressure (mmHg) Week 14	Blood Glucose (mg/dl) Week 14	Diet Satisfaction Week 14	Weight (kg) Week 15	Body Mass Index (kg/m^2) Week 15	Ideal Body Weight (%) Week 15	Systolic Blood Pressure (mmHg) Week 15
289	20.0112	94.0000	150.00	66.00	81.00	4	57.9545	20.0112	94.0000	146.00
265	29.3408	135.4839	106.00	153.50		3	95.4545	29.3408	135.4839	120.00
634	31.9991	162.1538	122.00	70.00	195.00	4	71.8636	31.9991	162.1538	112.00
255	23.7782	121.5000	110.00	80.00	65.33	4	55.2273	23.7782	121.5000	130.00
139	36.5681	179.1304	132.00	72.00		5	93.6364	36.5681	179.1304	138.00
214	29.4767	143.5294	120.00	60.00	203.00	5	55.4545	29.4767	143.5294	130.00
891	26.0244	123.7692	122.00	70.00		5	73.1364	26.0244	123.7692	120.00
635	27.3481	131.2000	130.00	80.00	162.79	3	74.5455	27.3481	131.2000	112.00
182	27.6256	120.2817	150.00	70.00		4	77.6364	27.6256	120.2817	120.00
180	23.5174	111.8462	120.00	70.00	238.75	4	66.0909	23.5174	111.8462	130.00
952	24.1421	118.2609	122.00	68.00		4	61.8182	24.1421	118.2609	132.00
522	37.5584	178.6122	120.00	70.00	221.50	4	99.4545	37.5584	178.6122	160.00
770	23.9507	103.1081	110.00	80.00		3	69.3636	23.9507	103.1081	130.00
661	31.1137	143.1250	150.00	80.00		5	104.0909	31.1137	143.1250	128.00
918	30.3615	147.1667	136.00	80.00	151.00	5	80.2727	30.3615	147.1667	128.00
338	22.8189	113.1818	120.00	60.00	173.00	3	56.5909	22.8189	113.1818	120.00
424	39.1599	191.8261	140.00	90.00		3	100.2727	39.1599	191.8261	140.00
245	18.6459	78.7500	120.00	70.00	135.50	5	57.2727	18.6459	78.7500	136.00
501	39.9239	204.0000	110.00	60.00		4	92.7273	39.9239	204.0000	160.00
680	27.4183	140.1000	100.00	70.00		3	63.6818	27.4183	140.1000	140.00
292	20.0904	97.3333	128.00	78.00	158.21	5	53.0909	20.0904	97.3333	128.00
195	26.4594	135.2000	144.00	70.00	145.00	4	61.4545	26.4594	135.2000	140.00

Table 4 (continued)

Subject	Diastolic Blood Pressure (mmHg) Week 15	Blood Glucose (mg/dl) Week 15	Diet Satisfaction Week 15	Weight (kg) Week 16	Body Mass Index (kg/m^2) Week 16	Ideal Body Weight (%) Week 16	Systolic Blood Pressure (mmHg) Week 16	Diastolic Blood Pressure (mmHg) Week 16	Blood Glucose (mg/dl) Week 16	Diet Satisfaction Week 16
289	62.00	101.50	4	52.7273	19.9328	94.0000			96.00	4
265	72.00	146.00	3	95.4545	29.3408	135.4839	140.00	60.00		3
634	70.00	151.50	4	71.8636	31.9991	162.1538	124.00	68.00	200.00	4
255	40.00	118.00	4	55.2273	23.7782	121.5000	104.00	62.00	82.00	5
139	70.00		4	93.6364	36.5681	179.1304	142.00	70.00		4
214	72.00	186.00	5	55.4545	29.4767	143.5294	140.00	70.00	229.00	5
891	80.00		5	73.1364	26.0244	123.7692	132.00	70.00		5
635	60.00	162.10	2	74.5455	27.3481	131.2000	128.00	68.00	136.07	4
182	68.00		4	77.6364	27.6256	120.2817	150.00	60.00		4
180	60.00		4	66.0909	23.5174	111.8462	130.00	54.00	189.00	4
952	62.00		5	61.8182	24.1421	118.2609	140.00	76.00		4
522	70.00	183.36	4	99.4545	37.5584	178.6122	130.00	78.00	247.45	3
770	80.00	100.00	3	69.3636	23.9507	103.1081	136.00	74.00		3
661	72.00		5	104.0909	31.1137	143.1250	110.00	70.00		5
918	78.00	134.00	5	80.2727	30.3615	147.1667	134.00	68.00	94.00	5
338	60.00	241.00	3	56.5909	22.8189	113.1818	138.00	72.00	193.00	3
424	82.00	375.00	4	100.2727	39.1599	191.8261	148.00	60.00	270.33	2
245	52.00		5	57.2727	18.6459	78.7500	100.00	68.00	138.92	5
501	50.00		4	92.7273	39.9239	204.0000	142.00	74.00		4
680	90.00	85.00	5	63.6818	27.4183	140.1000	148.00	72.00		4
292	76.00	138.70	5	53.0909	20.0904	97.3333	120.00	80.00	135.33	5
195	78.00		4	61.4545	26.4594	135.2000	150.00	70.00		4

Table 4 (continued)

Subject	Weight (kg) Week 17	Body Mass Index (kg/m^2) Week 17	Ideal Body Weight (%) Week 17	Systolic Blood Pressure (mmHg) Week 17	Diastolic Blood Pressure (mmHg) Week 17	Blood Glucose (mg/dl) Week 17	Diet Satisfaction Week 17	Weight (kg) Week 18	Body Mass Index (kg/m^2) Week 18	Ideal Body Weight (%) Week 18
289	57.7273	19.9328	94.0000	142.00	60.00	152.00	5	59.7727	20.6390	97.0000
265	95.4545	29.3408	135.4839	120.00	80.00	135.50	3	95.4545	29.3408	135.4839
634	71.8636	31.9991	162.1538	128.00	82.00	102.00	4	70.5909	31.4324	159.2821
255	55.2273	23.7782	121.5000	126.00	58.00	72.00	4	55.5455	23.9152	122.1000
139	93.6364	36.5681	179.1304	140.00	68.00		4	94.0000	36.7101	179.8261
214	55.4545	29.4767	143.5294	140.00	60.00	177.00	5	55.1364	29.3076	142.7059
891	73.1364	26.0244	123.7692	110.00	70.00		5	73.8182	26.2670	124.9231
635	74.5455	27.3481	131.2000	120.00	60.00	129.20	3	76.5455	28.0818	134.7200
182	77.9191	27.7227	120.7042	140.00	80.00		5	77.9191	27.7227	120.7042
180	66.0909	23.5174	111.8462	128.00	82.00	144.00	4	65.6364	23.3556	111.0763
952	61.8182	24.1421	118.2609	122.00	80.00		4	59.7727	23.3433	114.3778
522	99.4545	37.5584	178.6122			189.20	4	95.5455	35.5982	171.5918
770	69.3636	23.9507	103.1081	110.00	56.00		3	69.3636	23.9507	103.1081
661	101.3727	30.3012	143.8750	110.00	60.00		5	101.3727	30.3012	143.8750
918	80.2727	30.3615	147.1667	150.00	72.00	130.00	5	80.1818	30.3271	147.0000
338	56.5909	22.8189	113.1818	142.00	64.00	182.00	3	57.5455	23.2038	115.0909
424	100.2727	39.1599	191.8261	120.00	60.00	233.00	4	98.3636	38.1429	188.1739
245	57.2727	18.6459	78.7500	100.00	68.00	131.50	5	57.2727	18.6459	78.7500
501	92.8182	39.9631	204.2000	142.00	74.00		4	92.8182	39.9631	204.2000
680	63.6818	27.4183	140.1000	140.00	62.00		4	65.4545	28.1812	144.0000
292	53.0909	20.0904	97.3333	130.00	60.00	161.88	5	53.0909	20.0904	97.3333
195	61.4545	26.4594	135.2000	126.00	76.00		5	61.0909	26.3028	134.4000

Table 4 (continued)

Subject	Systolic Blood Pressure (mmHg) Week 18	Diastolic Blood Pressure (mmHg) Week 18	Blood Glucose (mg/dl) Week 18	Albumin (g/dl) Week 18	Hemo-globin (mg/dl) Week 18	Hema-tocrit (%) Week 18	Diet Satisfaction Week 18	Hemo-globin A1c (%) Week 0	Hemo-globin A1c (%) Week 2	Hemo-globin A1c (%) Mid-weeks	Hemo-globin A1c (%) Week 18
289	128.00	72.00	152.00	3.50			4			5.70	
265	122.00	70.00	142.43		11.50	33.10	3	6.30			5.20
634	138.00	80.00	101.00	3.40	12.60	37.40	4	6.00	5.80		5.70
255	130.00	70.00	109.00	2.60	11.70	33.10	4	6.20		7.00	
139	130.00	64.00	93.00	3.70	13.30	39.60	5	5.50	5.50		
214	130.00	72.00	189.00	2.90	14.80	44.00	5	6.80			
891	128.00	72.00					5				
635	128.00	74.00	124.00		11.60	33.00	3	9.10			6.80
182	140.00	80.00		3.60	13.00	37.80	5				
180	128.00	78.00	136.00	3.70	13.20	39.90	4		6.10		6.00
952	132.00	70.00					4				
522	130.00	78.00	285.00		12.00	36.40	4	8.10		8.30	
770	110.00	56.00	78.00	3.30	12.80	36.20	3				
661	110.00	60.00		3.30	13.50	40.20	5				
918	150.00	72.00	99.00		11.00	30.60	5			5.50	5.30
338	120.00	54.00	178.00	4.30	13.20	40.50	4	7.50			7.40
424	148.00	80.00	176.50		11.40	34.10	4	6.90		7.00	
245	100.00	68.00	218.00	3.30	12.10	35.60	5			5.40	
501	142.00	74.00		3.50	12.40	36.90	4				
680	110.00	62.00					4				
292	128.00	80.00	154.00	3.90	14.70	43.20	5	5.70		7.00	6.50
195	150.00	70.00	200.00	4.40			5		6.40	6.70	6.50