Frail older adults' experience of participating in clinical trials

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FRAIL OLDER ADULTS' EXPERIENCE OF PARTICIPATING IN CLINICAL TRIALS

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ABSTRACT

Purpose: The purpose of this research was to address the gap in the literature related to frail older adults' experience of participating in clinical trials.

Background: Frail older adults are generally underrepresented in the population of research volunteers from which evidence-based guidelines are derived. To improve care for frail older adults, research must be expanded to specifically target this population. Most of the users of healthcare today are greater than 65 years old, use more health care services than any other age cohort and suffer from coexisting illnesses for which they take several prescribed medications. Since the number of elders is increasing within the general population, it is important to reach a more thorough understanding of frail older adults' experience. Acquiring a better understanding of their experience will give the investigator more insight into barriers of recruitment, retention, and factors affecting elders' decision to participate in research.

Method: Using a qualitative descriptive approach involving semi-structured interviews, a cohort of participants age 65 and older was asked about their experience of participating in research studies. Data analysis used an interpretive paradigm involving the methods of Miles, Huberman, and Saldana (2014).

Results: Participants identified the main factors influencing their decision to participate as the opinions and encouragement of family members with the strongest influence being a recommendation from their doctor. Participants were varied in the emotions evoked by their participation in the study procedures. The majority of participants stressed how important it was to them to receive feedback in the form of results of studies in which they had participated. The majority of participants stated that receiving feedback or research results was the exception.

Conclusions: Data generated from this study related to the experience of frail elder participation in clinical trials will be useful in designing future clinical trials to be more inclusive of this patient population.

Keywords: frail elders, research participation, clinical trials, chronic illness, qualitative, multmorbidity

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To my family and friends, thank you for being there and for pointing out the small successes which turned out to be as important as the milestones.

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Chapter One

Overview of the Study

A lack of understanding exists within the healthcare community related to the experience of participating in clinical trials among frail older adults. Chapter one introduces and provides the perspective for this problem. The significance of this issue is presented and the need to examine this phenomenon from a qualitative perspective is addressed.

Statement of the Problem

Frail older adults are generally underrepresented in the population of research volunteers from which evidence-based guidelines are derived (Dennis & Neese, 2000; Falk, Ekman, Anderson, Fu, & Granger, 2013; Mitka, 2003; Watts, 2012). While it may be important to have rigid controls and a sample population that is young and healthy to understand how medications, devices, and procedures directly impact outcomes, the reality of the practice environment is that most users of healthcare are greater than 65 years old. It is the frail older adults who are well documented in the literature as having several coexisting illnesses, many medications prescribed to treat varying conditions, undergo more tests, and use more health care services than any other population (Institute of Medicine, 2008). In a variety of situations it is unclear how the physiologic mechanisms of these coexisting illnesses impact one another or how the treatments used to address one health problem impact the treatments used for another. The presence of a surprisingly scant evidence base for frail geriatric care

along with this lack of understanding about co-occurring chronic conditions and treatments constitutes a major barrier to delivering optimum care to frail older adults (Bleijenberg, 2013; Falk, Ekman, Anderson, Fu, & Granger, 2013).

To improve care for frail older adults, the path is clear. First, expand research specifically targeted to this underserved population (Walston, Hadley, Ferrucci, Guralnik, Newman, Studenski, Ershler, Harris & Fried, 2006; Watts, 2012) and second, include frail older adults in both intervention and control groups of research cohorts of other studies related to the general population wherever appropriate and whenever possible. The decision to recruit frail older adults creates its own set of challenges and needs, one of which is to understand their experience of participation. Reaching a more thorough understanding of frail older adults' experience will allow the investigator a deeper insight into what the experience is like for frail older adults as research subjects and may help to recruit more.

Significance

Aging society. On January 1, 2011, the first of 78 million American Baby Boomers (individuals born between the years 1946 and 1964) marked a 65th birthday. Everyday thereafter through December 31, 2029, boomers will turn 65 years old at a rate of 10,000 people per day, swelling the numbers of individuals classified as elderly to one in five Americans and becoming 18% of the U.S. population (Boult et al., 2009; Cohn & Taylor, 2010). In parallel, the number of those over age 85 years is already the fastest growing population group in the U.S., with its size projected to double from the years 1995 to 2030 (U.S. Census Bureau, 2008). Globally, a similar phenomenon of a changing population demographic is occurring. For example by the year 2050 in

Taiwan, China, 40% of the population is predicted to be 65 years or older. At the same time in Europe, 19 countries are projected to have at least 10% of their population at least 80 years old (United Nations Department of Economic and Social Affairs [DESA], 2001).

Longevity. Human longevity is frequently associated with the development of chronic conditions, defined by the Center for Medicare and Medicaid Services as those conditions lasting a year or more requiring ongoing medical attention, and/or limit activities of daily living (Center for Medicare & Medicaid Services, 2011). Prior to the 1940s when the first antibiotics were used, people with complex chronic conditions often succumbed to pneumonia regardless of their age. Pneumonia, then known as the "old man's best friend," was considered a natural and peaceful way to die for anyone suffering from a chronic disabling condition (Gruenberg, 1977). By the 1970's many individuals with chronic conditions and complex care needs had developed a projected life expectancy to be well into their 60s. This lengthening life expectancy was due to public health improvements (Dans & Kerr, 1979), the effectiveness of antibiotics and vaccines (Schlipkoter, 2010), a model of care delivery steeped in the perspective of technological imperative (Gillick, 2007), and many other medical advances (Goldstein, M., Lubezky, N., Yushkov, Y., Bae, C., & Guarrera, J., 2012; Krishnamani, R., DeNofrio, D., & Konstam, M., 2010). Gruenberg (1977) raised concerns related to what this long life might be like in terms of overall health and quality of life for this group of individuals.

The term "failures of success" was coined at this time, specifically referring to those individuals with complex chronic conditions like "senile brain disease and

mongolism" who had survived "the old man's best friend" because of medical advances previously mentioned. These conditions were recognized at the time as needing large scale funding to develop mechanisms for prevention and management (Gruenberg, 1977). While the term "failures of success" has receded into the background, the concerns raised by Gruenberg in 1977 have not been completely addressed. Issues are more complex around best practices for evidence based care decisions, quality of life, and approach to death for those with complex medical needs in both the general population and among frail older adults (Center for Medicare Services, 2011; Lynn & Adamson, 2003).

Further, life expectancy has continued to increase. In 2013 the average life span of U.S. men and women was 76 and 81 years respectively (Organization for Economic Co-operation and Development [OECD], 2014). From 2010-2013, the average life expectancy at birth worldwide increased to 68.5 for males and 73.2 for females (Population Division of DESA, 2012). Given Gruenberg's framework almost fifty years later within the context of major medical advances, a society has emerged where multiple co-occurring chronic illnesses are commonplace with the accompanying complexities related to managing care particularly in older adults. This condition of multiple co-occurring chronic illnesses is termed multi-morbidity (American Geriatric Society [AGS], Expert Panel, 2012).

Chronic illness and multi-morbidity. Considering the demographics related to aging, it is no surprise that the incidence of both singular chronic illness and multi-morbidity has increased globally, accounting for approximately 63% of deaths across all continents (World Health Organization [WHO], 2013). The more surprising fact is

that out of this trend toward a societal state of multi-morbidity, an evolution of clinically recognized syndromes has occurred. Highly prevalent well known examples of multi-morbid conditions are metabolic syndrome and non-alcoholic fatty liver disease (NAFLD). Metabolic syndrome develops where obesity, hyperlipidemia, and hypertension are present. NAFLD is associated with type-2 diabetes, obesity, dyslipidemia, and hypertension (Brunt, 2007). Chronic illness components of multi-morbidity do not occur in isolation and one chronic illness often exacerbates another underlining the need for a more comprehensive care plan with integrated pharmacological intervention. Having recognized the high prevalence of multi-morbidity the AGS Expert Panel (2012) and the WHO (2013) have suggested a comprehensive care plan with an integrative step-wise approach to treatment for both the prevention and treatment of multi-morbidity.

Despite taking this step, much research is still aimed at testing biomarkers in isolation, and testing drugs or devices aimed to treat one condition (Vogeli et al., 2007). Not only is this thinking out of step with the holistic healing perspective of some health care professionals such as nursing, it also fails to address a reality of multi-morbidity and exclusion of this age cohort from the research sample that is testing the very treatment most likely needed by frail older adults (Falk, Ekman, Anderson, Fu, & Granger, 2013).

Treatment guidelines. Patients are often struggling at home with multi-morbidity. Treatment plans are often inadequately designed to manage geriatric physiology and unintended consequence such as side-effects of polypharmacy. Treatment guidelines have historically been based on evidence derived from clinical

trials using young, healthy males as the predominate group of research participants (Falk, Ekman, Anderson, Fu, & Granger, 2013). Clinical guidelines used in treatment for elders are not generally based on evidence from clinical trials where older adults, particularly frail older adults with multi-morbidity were included in the research population. Guidelines are not based on evidence generated from researching older adults and especially frail older adults who are often on several treatment regimens each targeted to individual diagnoses and not integrated with each other.

To address this discrepancy in care it is first important to understand the experience of older adults who do participate in clinical trial research. Essential to this is a need to understand what motivates frail older adults to participate and once enrolled to understand what the experience is like for them. Therefore, this study aims to explore the experience of older adults who participate in clinical trials. Even though the number of older research participants may be small, these participants can offer valuable insights to bridge the knowledge gap noted.

An urgent need exists for investigators to close this gap and develop therapies embedded with treatment options easily adaptable to accommodate fragile metabolism to reduce hazardous synergistic effects of overlapping medication mechanism of action. Toward the goal of correcting this disparity, not only must the inclusion and exclusion criteria be adjusted to accommodate frail older adults' advanced age and/or presence of multi-morbidity, but also validated tools are needed to provide guidance to investigators for decision making purposes related to the level of justification for excluding frail older adult potential research participants (Cherubini et al, 2011). As important and of great significance, is the need to resolve the lack of understanding

prevalent within the healthcare community related to frail older adults' perspective around participation in clinical trials (Dowling & Wiener, 1997; Witham & George, 2014).

Research Question

Despite the growing body of work published on older adults in general and on varying aspects of frailty in older adults, little is known about frail older adults' experience of participating in a clinical trial. In order to overcome barriers and increase representation, a compelling need exists to describe the overall experience of what it is like to be an older, frail participant in a research study. The purpose of the research described in this proposal is to explore the qualitative research question: "What is the experience of frail older adults who participate in clinical trials?"

An open-ended qualitative descriptive approach will be used to explore the research question. This approach is philosophically in line with the goals of nursing across the spectrum from the early nursing metaparadigm to more recent application of unity (Copp L. & Copp J., 1960; Fawcett, 1978, 1984; Flanagan, 2007, pp. 275-285; Newman, 1994, pp. 82-85; Newman, Sime, Corcoran-Perry, 1991; Torres & Yura, 1974, pp. 1-12; Watson & Smith, 2002; Willis, Grace, & Roy, 2008).

Summary

This chapter has introduced the problem related to underrepresentation of older adults in clinical trials, the results of which are often the basis for the care they receive. To date, little is known about the experience of frail older adults who participate in clinical trials. To understand what this experience is like for frail older adults, this study proposes to use a qualitative descriptive approach aimed at

understanding the frail older adult's experience of participating in clinical trials. The question to be answered is "What is the perception of frail older adults who participate in clinical trials?"

Chapter Two

Review of Literature

This chapter introduces the context for this dissertation and provides in-depth background supporting the significance of this research question. A discussion of the philosophical underpinnings is presented including an explication of the goals of nursing along with relevant results of pilot work. A description of the current demographics related to older adults is given followed by a discussion of frailty, polypharmacy, and the burgeoning recognition of a need for research aimed at understanding the experience of frail older adults who do participate in clinical trials.

Disciplinary Perspective of Nursing

Donaldson and Crowley (1978) began a scholarly discourse in the literature, which continues to date, related to nursing perspective and the definition of a discipline. Restating the definition, nurses were tasked to rethink their starting point when conducting research. Nurses were charged with placing this starting point among three themes consistently being used at the time by nurse scholars to explain essence of nursing or nursing perspective and which had the potential to make the discipline of nursing more explicit. The themes included: (1) concern with principles and laws governing life processes, well-being, and functioning of human beings; (2) concern with patterning of human behavior in interaction with the environment in critical life situations and (3) concern with processes which promote positive changes in health status. These themes added processes and patterns to the concepts—society, nursing, person, and health—identified in a National League for Nursing study of

baccalaureate curriculum framework (Torres and Yura, 1974). Fawcett (1984) later called the concepts of nursing: person, environment, health and nursing a metaparadigm. Since then a steadily unfolding of a professional identity has occurred accompanied by nursing knowledge accretion with a conceptual pluralism not previously valued. Nursing strove to distinguish and explore the difference in theories rather than embrace a unity of nursing (Watson & Smith, 2002). Where before there were no nursing theories (Fawcett, 1978), a 21st century nurse researcher can now choose from a number of Grand or Middle Range Theories depending on the level of abstraction of the area of concern under exploration (Smith & Liehr, 2003).

Related to this study in which hearing the patient's voice and understanding the patient's message is of paramount concern, it is the nurse investigator's interpretation of the patient message that needs to be placed within the nursing metaparadigm. In 1974, one year after the ANA published its first *Standards of Nursing Practice* and 24 years after the ANA *Code for Professional Nurses* was formally published, Johnson (1974) noted that "nursing is an occupation whose form of service, until recently, was not considered particularly socially valuable and certainly not critical in social life" (American Nurses Association, 1991; Johnson, 1974; Taylor,1991). Since then and fortunately for all concerned, a societal intellectual conversion has occurred related to attitudes regarding nurses' significant contributions to the patient experience occurring at the bedside.

This conversion is illustrated through the types of research currently funded through the National Institute of Health and the National Institute for Nursing

Research. These federally funded institutes routinely call for abstracts focusing on chronic disease management, and currently are related to home based nurse-coached interventions and reducing risk of depressive symptoms in community-dwelling elderly (NINR, 2014). These are examples where the patient's voice must be heard within the context of the research.

In 2001, the Institute of Medicine released a landmark report, *Crossing the Quality Chasm,* calling for a redesign of healthcare in America for the 21st century. Among the recommendations and mandates for redesign is a section on "Ten Simple Rules for the 21st Century Health Care System." Of note is that Rule #1 states that patient care needs to be based on continuous healing relationships (IOM, 2001). Nurses have been doing this for over 150 years, since Florence Nightingale (Fitzpatrick, 1992). The power and significance of this one rule is that it rendered an official validity to and recognition of nursing practice, specifically the universal uniqueness of the patient's relationship to the nurse situated in the environment of care and moving along a healing path (Flanagan, 2007, pp. 275-285; Newman, 1994, pp. 82-85; Newman, Sime, Corcoran-Perry, 1991; Picard & Jones, 2005; Watson & Smith, 2002; Willis, Grace, & Roy, 2008).

Dawning Awareness

The statistics presented in chapter one on our aging population may seem startling; however, economists, administrators, policy makers, and educators have sounded a clarion call to action spanning decades. Accelerating the need for action is the increased awareness that the growing numbers of people over age 65 have several

chronic conditions that are considered health-resource intensive. Accompanying this concern is a concurrent projected shortage of physicians to care for these people and a potential lack of funding from Medicare (Anderson, 2010; Medicare, 2008).

In 1978, the Institute of Medicine (IOM) recommended a broadening of medical education programs to provide more coverage of geriatrics and gerontology (IOM, 1978). The report called for medical education faculty to teach an intensified geriatric-gerontology curriculum to the established primary care specialties, presumably upgrading the care of the elderly (IOM, 1978). The report did not recommend a formal specialty in geriatrics which invoked a strong response from critics and academics alike, from both the U.S. and Europe (Kane, R., Solomon, D., Beck, J., Keeler, E., & Kane, R.,1980). Critics and academics expressed fears that the strategy proposed would relegate the care of the elderly to secondary status. They echoed warnings of demographers, epidemiologists, and social scientists, with predictions of a looming shortage of physicians to manage healthcare needs of an aging population with chronic problems which would only become more complex. Strong recommendations were made to establish geriatrics as a specialty practice founded on the unique knowledge required to adequately care for older adults. Several models for medical education curriculum changes were proposed with a call for significant increase in funding devoted to research of older adults (Dans & Kerr, 1979; Kane, R., Solomon, Beck, & Keeler, & Kane R, 1980; Williamson, 1979).

Medicare, instituted in the United States in 1965 under President Lyndon Johnson as part of the Great Society, became the subject of intense examination

twenty years later. Projections of Medicare outlays indicated large future deficits. In the context of the economic and social trends at the time, the percentage of elderly in the total population had grown appreciably, with a sharp reduction in age-specific mortality, a sharp reduction of older men in the workforce, and an increase in consumption of medical care by the elderly during the last years of their lives (Fuchs, 1984). One important concept generated from this examination was the proposal to periodically revise the definition of "who is old" and to build an ongoing research focus targeting changes in life expectancy at older ages. For this, older adults would have to be included in the research population (Fries, 1989; Fuchs, 1984).

Now, more than 30 years after administrators, policy makers, and educators sounded their call to action, their administrator, policy maker, and educator successors are facing much the same issues, but at crisis proportions. A sense of urgency imbues the increased awareness of a need for research initiatives addressing many aspects related to the aging population: medical education, mortality and life expectancy, chronic disease, and avenues for social change. Several events have occurred to highlight the sense of urgency. In 2001, the IOM report from the Committee on Quality of Health Care in America published a critique of the U.S. healthcare system, *Crossing the Quality Chasm*, in which a major overhaul of the delivery system was demanded. The report included suggestions for improvement and models for redesign of all aspects of the healthcare delivery system (Committee of Quality on Healthcare in America, 2001). Additionally, at that point the fact was ever present that in 2011, ten short years away, the Baby Boomers would start turning age 65.

Turning 65

As noted the next two decades (2010 to 2030) will see a rapid rise in America's senior population as the Baby Boom generation passes the 65 year age marker. Historically, ages 65 and older have been associated with the highest rates of morbidity and disability. Whether or not the Baby Boom generation will enter later life with better or worse age-specific rates of morbidity and disability than earlier generations is unclear. The data on Baby Boomers are lacking to make this determination and research is needed in general on the question of trends in health and functioning during the decades leading up to retirement (Martin, Freedman, Schoeni, & Andreski, 2009).

Other aspects of the United States Baby Boomer demographic profile are notable for the need for risk assessments. Collectively many factors should be considered when designing research in the frail older adult population including family structure and social mores related to family care-giving at home. More grandparents over age 65 are the primary care-givers to grandchildren who live with them. Older women outnumber older men, 23 million women to 17 million men. 72% of older men to 42% of older women are more likely to be married.

This generation is more racially and ethnically diverse than its predecessors. Between 2010 and 2030 older minority older adults will increase in numbers by 160% and will represent 30% of the elderly population (Administration on Aging, 2011). Culturally diverse older adults can be considered as a cohort within the elder population. The elderly minority cohort has been shown to have specific research

needs requiring attention (Moreno-John et al., 2004), revealing a greater call to include older adults in research.

After 65

By 2030, the Boomers who turned 65 years old on January 1, 2011, will be 84. The fact that older people generally have medical needs different from younger adults implies that 75 year olds may have much greater medical needs than those who are 65. The average 75-year-old American has at least three chronic medical conditions (multi-morbidity) and regularly uses an average of five to twelve prescription drugs (polypharmacy), along with a number of over-the-counter remedies (Perry, 2002). The chronic medical conditions considered as standard to older people include some memory loss, urinary incontinence, depression, arthritis, and hypertension. Age alone is not a determinant of cognitive or physical function, yet there is bias in that far too often symptoms such as agitation, urinary incontinence, depression, memory loss, chronic pain and declined physical function are considered normal by many care providers and not symptoms that should trigger further investigation. As a result, these conditions result in marginalization, posing a threat to an elder's ability to function, and to live independently (Perry, 2002).

Polypharmacy

Polypharmacy is defined as the use of multiple medications and/or the administration of more medications than are clinically indicated, representing unnecessary drug use (Haijar, Cariero, & Hanlon, 2007). Polypharmacy continues to increase and is a known risk factor for important morbidity and mortality particularly

among the elderly. Although not directly intended to address polypharmacy, but rather adverse events in older adults due to physiologic change that occur with age and pharmacological properties of drugs that may be impacted by aging, the Beer's Criteria was developed in 1991. Now adopted by the American Geriatric Society (2012), this list now includes 53 drugs or classes of drugs that are listed as either ones to avoid or potentially contradictory for adults age 65 or greater. The Beer's list in itself is not a mandate for prescribers, but a guideline based on the best evidence to date. Despite this evidence, there is still widespread use of many of the medications on the Beer's list in the older adult population. This coupled with the issue of polypharmacy has many implications for the health and safety of older adults.

One current explanation, although not a justification for widespread use of polypharmacy, is actually an incrimination of pharmaceutical research. One source claims that a high enough level of sophistication in biomedical technology already exists to support development of medications designed for both multi-morbid syndromes and geriatric physiology. The missing ingredient is funding and a vision for advancing treatment of elders. The fact that multi-morbidity includes co-occurring chronic illnesses each of which requires medication intervention which then leads to an overlap of medication mechanism of action is alone a compelling justification to support funded research in this area. Stated more succinctly, large scale research is needed to create medications more selective for specific targeted conditions in the context of geriatric physiology thus reducing negative side effects and unintended consequences (Muth et al., 2013; Peron, Gray, & Hanlon, 2011). This is another area

where frail elders would directly benefit from evidence generated in this case from pharmaceutical clinical trials.

Frailty

The continuing lack of clarity with the concept of frailty has its roots in the etymology of the word "frail." A summary of "frail' is included for background. The Oxford English Dictionary devotes two thirds of a page to etymology of the word "frail," tracing the origins, definitions, and uses of the words "frail", "frailty" and "frailness." Early uses of the word "frail," (circa 1382), referred to the 30 to 75 pound quantity of figs, raisins, and so forth, packed into a basket made of rushes. At the same time (c. 1374) Chaucer used "frailness" to refer to a tendency to be broken or destroyed (Oxford English Dictionary, 2009).

Many believe that the presence of a state or trait of being frail is accompanied by the combination of increasing age and chronic illness. So, who is frail, what does frail look like, how does one "get frail," and what does being frail mean to the one who is labeled as "frail?"

Within 20th century healthcare literature, "frailty" as a concept grew for 30 years and in 1978 began to appear in research literature initially associated with significant age and debility (Hogan, MacKnight, & Bergman, 2003). In 1990, a position grounded in the statistics of epidemiology and demographics maintained that a significant percentage of the population would soon be old and become frail, thus entering a state of being frail (Anderson, Gilchrist, Mondeika, & Schwartzberg, 1990). At the same time, other academics described aging and development of frailty by

using a "compression of morbidity" model. This model placed aging and development of chronic disease on a continuum. Development of frailty was determined by the length of time taken to develop chronic disease (Fries, 1989). Frailty has also been considered as a trait in the category of a significant health problem that increases the probability of developing adverse health outcomes in the elderly (de Souto Barreto, 2011). One logical position holds that the prevalence of frailty among older people depends on the definition used (Gobbens, Luijkx, Wijnen-Sponselee, & Schols, 2010).

In the 21st century a number of both single and multidimensional models have evolved to describe frailty. Some use purely biomedical factors as the basis for definition and others stipulate that psychosocial factors cannot be ignored. After the appearance in 2001 of a "phenotype of frailty" (Fried et al. 2001) many researchers adopted the "phenotype" as a premise for further study. But among academics no consensus on the definition of frailty has yet been reached (Mohandras, Reifsnyder, Jacobs, & Fox, 2011). The debate continues not only about the fundamental definition of frailty, that is, whether or not frailty is a natural consequence of aging if one lives long enough, but also about how to approach assessment of the presence/absence of frailty and if present, then how to measure the degree to which someone is frail.

The unfortunate consequence of this continuing lack of consensus on both a definition of frailty and a unified approach to assessing and measuring frailty is the stunted development of effective interventions. In terms of the elderly, multi-morbidities, and frailty, there is a lack of development of effective interventions for managing care, reversing the progression of frailness, and educating patients and

caregivers. Most importantly, we have suffered a short-sighted failure to develop a focused research agenda leading to evidence-based guidelines targeting those issues as mentioned above.

Although there are several frailty models and some scholars have adopted Fried's phenotype of frailty, this author supports a more comprehensive approach as described by Searle and colleagues to determine frailty risk (Searle, Mitnitski, Gahbauer, Gill, & Rockwood, 2008). This model suggests data such as medical conditions, signs, symptoms, age, sex, functional decline, altered laboratory (including cardiac and radiology) findings, body mass index, grip and shoulder strength, walking pace, and the independent assessment of activities of daily living (IADL) should be considered in determining the level of frailty. For the purposes of this study, the approach of Bleijenberg and colleagues (2013) will be used to screen for people who may potentially be at risk for frailty. This includes screening for polypharmacy, multimorbidity, and greater than three year gaps in primary care.

Evidence-Based Guidelines

Evidence based guidelines are extrapolated from results of clinical research trials, the most rigorous of which is considered to be the double blind random controlled trial as scored by one of several Evidence Rating Scales (AHRQ, 2002; Evans, 2003). In this type of clinical trial an intervention group is compared to a control group of healthy volunteers. Historically, characteristics of research volunteers in the control group have been Caucasian healthy males, ages 18-55. While optimizing the availability of this group as a starting point for accumulating evidence for clinical

practice, researchers have spent long periods of time excluding segments of the general population, women and children for example, but in particular, those over the age of 65 (Hutchins, Unger, Crowley, Coltman, & Albain, 1999). With the segment of the aging population increasing, clinical decision making has become problematic for practitioners (Scott, & Guyatt, 2010). There is a growing body of literature concerned with the issue that best practice guidelines do not address the needs of the older individuals with complex multi-morbidity (Cox, Kloseck, Crilly, McWilliam, & Diachun, 2011; Mutasingwa, Hong, & Upshur, 2011). Practitioners must treat older adults, frail or not, using evidence-based guidelines that were developed using evidence accumulated from clinical trials where elderly research subjects were absent in both the intervention and control groups (Lee, Boscardin, Cenzer, Huany, Rice-Trumble, & Eng, 2011). When pondering the utility of evidence for practice, its measure lies in the integrity of the sample used to generate the outcomes with respect to the intended application (AHRQ, 2002; Hutchins, Unger, Crowley, Coltman, & Albain, 1999).

Barriers to participation

In the literature on barriers-to-elder-participation, some frequently cited reasons for this under-representation in research are (a) difficulties with the informed consent procedure related to decisional capacity (Jefferson, Lambe, Moser, Byerly, Ozonoff & Karlawish, 2008), (b) a failure of the message in the recruitment materials to acknowledge personal goals or to address knowledge gaps of potential research volunteers (Brown & Topcu, 2003; Chinn, White, Howel, Harland, & Drinkwater,

2006), (c) insufficient flexibility with follow up options related to longitudinal studies (Strotmeyer et al., 2010), (d) high rate of refusal due to lack of interest based on a perception that study participation is too time consuming (Marike et al., 2008), and (e) presence of confounding comorbid conditions that exclude subjects (Townsley, Selby, & Siu, 2005).

A search on PubMed using the terms “older adults experience in research/clinical trials,” “older adults participation in research/clinical trials,” “frail patients/participant’s/ subject’s experience and research/clinical trials” revealed no studies related to understanding the experience of the few older adults who actually do participate in clinical trials. Given the fact that many older adults do live with chronic illness, the presence of which excludes many of them from participating and is considered confounding when designing research studies, a significant disconnect has been created in the evidence used to base guidelines for the care of this vulnerable population.

Summary

This chapter has introduced context and background of the phenomena related to the under-representation of frail elders’ participation in clinical trials and the lack of understanding of elder participants’ experiences among healthcare professionals. An impressive set of statistical trends for aging both in the United States and globally was presented underlining an increasing need for research to keep pace with health issues that have evolved as a result of the trend in a global lengthening longevity. A discussion related to goals of nursing was presented as to underpin a qualitative

descriptive approach to exploring the research question.

To date, little is known about the experience of frail older adults who participate in clinical trials. The next section will explicate the method by which this phenomenon will begin to be described. To understand what this experience is like for frail older adults, this study proposes to use a qualitative descriptive approach. The question to be answered is “What is the experience of frail older adults who participate in clinical research trials?”

Chapter Three

Method

Introduction

Chapter Three introduces the qualitative method used to explore the research question central to this study. Philosophical underpinnings of the qualitative descriptive method, a description of relevant pilot study results influencing decisions around selection of the sample, approach to data analysis, and system for data management are each discussed.

A primary goal of nursing research is to explore fundamental areas of concern or interest relevant to nursing practice which include the nurse-patient relationship and the patient experience. Qualitative descriptive inquiry is an appropriate approach to use when little is known about a phenomenon of concern (Sandelowski, 2000). To date, I have found no reported studies in the literature that seek to understand why frail elders might participate in clinical trial research and/or what the experience of participation is like for them. The main focus of this study was to explore the experience of participating in a clinical research trial among frail elders. Due to the lack of understanding about this experience, a qualitative descriptive method was an appropriate approach for gaining an understanding of what it is like for frail older adults to participate in clinical research trials.

To begin to close the gap in knowledge related to understanding the older adults' experience of participating in a clinical research study, an open-ended questionnaire was utilized. This approach is consistent with a qualitative method and allowed participants to

discuss their experience to the degree to which was comfortable for them and was both self-limiting and self-expanding. Data analysis of the participants' verbal expression related to their perspective provided insights into the experience of frail older adults who participate in a clinical research trial.

Pilot Study

A pilot study was conducted with two frail older adult participants. The purpose of the pilot study was to test the open ended questions for suitability in prompting the older adult research volunteers to describe their experience, to provide the author with the experience of conducting this type of inquiry, to test the best way to least intrusively record the sessions, to test the recording equipment, to determine the most appropriate setting for the interview (either in person or by telephone), and to determine if the questions developed for the open ended inquiry would actually provide findings which would meet the aim of the study.

I developed the open ended questions for the qualitative inquiry with input from colleagues. I am an experienced advanced practice nurse with over 30 years of patient care nursing experience and 6 years more recently on a clinical research unit. I also have experience with frail elderly family members who were interested in volunteering several years ago for 2 studies but were excluded because of age. These family members have also suffered from effects of polypharmacy resulting from conflicting treatment plans related to multimorbidity.

To develop the questions, I first considered the overall aim of this investigation and what questions would best help to provide insights into frail older adults' experiences

in clinical research. After developing the questions, I described the purpose of the study to 6 peers on the Clinical Research Unit. Each was an experienced research nurse with a range of 10 to 25 years of experience. The expert peers were asked: “Do you think these questions would help me to understand the experience of frail older adults who participate in a clinical research trial?” Some of the questions were modified based on their feedback.

The next step involved asking several frail older adult research subjects if they thought the questions would ascertain the information sought in this investigation. Their suggestions helped to modify the questions further. Lastly, the questions were brought to the dissertation committee who is comprised of a distinguished nurse theorist and faculty member, the academic Program Director of the Adult Gerontology Program who also maintains a nurse practitioner practice on the Clinical Research Unit, and a doctoral prepared Nurse Scientist who is a clinical expert in the care of frail older adults. The committee further reviewed the questions and consensus around the questions was reached. Questions used in the pilot are listed in Appendix A.

Institutional Review Board approval was obtained through the expedited process and ceded review. Potential participants were approached by their research nurse or study coordinator to determine interest in this research project. For those interested in hearing more, I discussed the study with the potential participant, answered questions, and obtained verbal consent when applicable. One interview was conducted by telephone with the investigator using the speaker option to digitally record the interview as well as a conferencing service that both recorded and transcribed the interview. The other

interview was conducted at the hospital during the participant's study visit and was only digitally recorded.

The pilot was valuable for several reasons. First, the experience provided me, a novice researcher, the opportunity to practice open-ended qualitative interviewing techniques specific to the qualitative descriptive perspective. Second, the results of the interview revealed that the questions were appropriately worded to elicit descriptions of the participants' experiences of participating. The results also indicated that additional questions were warranted: one question quantifying the number of medications that the participants routinely took to inductively relate to level of polypharmacy and co-morbidities; two, a description of living situation inductively related to level of independence; and three to ask them to categorize themselves as frail or not.

Lastly, the pilot study helped to clarify the setting for the study. At the outset, it was unclear if participants would want to interview face to face or by telephone. It was also unclear if one setting would be preferable in terms of participant convenience, comfort, and overall potential for distractions. Pilot interviews were held at the place chosen by the participant. One was conducted face to face at the hospital in a private office setting on the day of an already scheduled doctors' appointment. The other interview was conducted via telephone with the participant in his own home. The hospital setting was rushed, distracting, and had several environmental interruptions as compared to the one conducted by telephone. Further, the telephone interview was relaxed, allowed the participant to feel like he had lots of time to describe his experience in as much detail as he could remember, and no environmental distractions occurred. Therefore it was

decided that interviews would be conducted via telephone or in the person's home or in another place determined to be suitable and convenient.

Method

The qualitative descriptive approach is an appropriate method to use when little is known about the phenomena of concern (Miles & Huberman, 1994; Morse & Field, 1995; Sandelowski, 2000). The goal of qualitative descriptive research is to provide an objective, rich description about the experience with the goal of informing knowledge development. The purpose of this study was to describe the overall experience and what the experience was like for frail elders who participated in clinical research trials. Specifically for this purpose the study questions used resulted from modifications made to those used in the pilot (Appendix A). Modifications were made so that the questions were better suited to the goals of the study. The questions are as follows:

1. How did you find out about the study?
2. Have the experiences of family or friends influenced your decision to participate?
3. How many studies have you participated in?
4. Were there things about being a participant that you found enjoyable?
5. Were there things about being a participant that were not enjoyable?
6. Was the study participation difficult for you for any reason?
7. Were there things about being a participant that surprised you?
8. Did the experience meet your expectation?
9. I am interested in understanding the perspective of older adult research

participants. Is there anything about being older that makes this experience unique for you?

Study Procedures. Both Partners IRB approval (protocol number: 2013P001428/MGH) and Boston College IRB approval through Ceded Review were obtained. For the purposes of this study "elders" were defined as individuals who were age 65 years and older. Frailty was defined as presence of two or more chronic illnesses present for a year or more and 5 or more regular prescription medications.

Inclusion criteria.

1. Men and women
2. Frail, as defined by having 2 or more co-morbid conditions and 5 or more regular medications
3. Age 65 or older
4. Currently participating in a research study or have been a participant within the last 12 months.

Exclusion criteria.

1. Individuals younger than 65 years old
2. Cognitively impaired as reported by clinicians directly involved in their care
3. Those who had no experience with participating in a research trial or who had participated more than a year ago. Subjects were not excluded from the study on the basis of race or ethnic background.

Sampling process. This study used purposive convenience sampling to meet the study aims focused on understanding older frail adults' experience of participating in a clinical research study. Study coordinators interacting directly with potential participants used eligibility criteria to invite all potential participants during routine study visits. The study coordinators or the nurse caring for the patient invited and provided interested patients with a letter from the medical director and the PI for review. The recruitment letter (Appendix B) provided an explanation of the study purpose, expected risk and benefits to the participant; study procedures with timeframe, assurance of confidentiality, an opt-in check box, and my contact information as the PI. The opt-in box which when checked, recorded the patient's preference to participate. If the participant opted-in, then within two weeks of being identified, I telephoned the participants, obtained verbal assent, completed the demographic questionnaire (Appendix C), and interviewed each interested and eligible participant via telephone according to the interview guide (Appendix D). Based on the literature for this method, it was expected that initial interviews would last 30 to 45 minutes.

Setting. The setting where recruitment for this study took place was a large teaching medical center in the northeastern United States which sees an estimated 2000 study participants per year, 100 of whom are age 65 and older. The study procedure took place over the telephone with the participant situated in their location of choice.

Data collection and management procedure. In general, data collection and data analysis used in qualitative designs involve an iterative process, the steps of which inform each other in an ongoing basis and requires that the researcher make

frequent decisions that can alter the course of the study. This iterative cycle allowed me to immediately commence the process of dwelling in the data and also provided an important opportunity for reflection. I engaged in an ongoing review of data in order to (1) observe the pace of questioning, (2) determine whether or not the questions asked met the aim of the study, (3) determine if there was a need to conduct follow up interviews, (4) note any unintended bias from me, and (5) determine whether or not there was a need for prolonged engagement in the field or if no new themes (data saturation) were emerging. I was aware that I needed to make adjustments when indicated in the data collection process and then to also record these observations and changes in a reflexive journal which was later used during data analysis.

As such, there are many sources of data in qualitative descriptive studies. For this study the sources included recordings of the interview, transcribed data, my field notes of observations made during data collection, and my reflexive journal, which detailed thoughts, questions and ideas which were very helpful in linking aspects of data collection to the data analysis. The several steps involved with the data collection process involved with this study are described below.

A beginning step for any qualitative researcher is to be aware of personal bias and to state up front why a topic is of interest. The topic of frail elders' participation in clinical research is of particular interest to me for two reasons. First, I have had personal experience with family elders who were excluded from research based on their age of 67 and were not frail based on criteria used in this study. Time has passed and these same elders have become frail and have suffered greatly from effects of polypharmacy

prescribed as part of treatment regimens attempting to manage their multi-morbidities. Second, I have been a nurse working with acute care inpatients for greater than 30 years. In that time I have cared for many frail elders with complicated treatment plans where physician consults had difficulty reaching consensus related to the best practice for the clinical situation. While these two experiences have caused me to be interested in this topic, they also represented sources of potential bias.

In order to reduce the influence on my thinking of potential bias as described above, I had to consider the following. First, I was genuinely interested in the stories of the participants, but in order to be open to hearing their stories and not imposing bias or influence, I needed to take time for quiet reflection and centering prior to the commencement of each interview and throughout data analysis. I did this by meditating, praying or walking both before and after each interview and prior to and after analyzing each case. My dissertation committee also served as an objective group, hearing my thoughts about the study, data, and redirecting me as needed.

During data collection, as noted above, I made observations about the process that formed the basis of the field notes. Additionally, a reflexive journal was kept which details my thoughts and emotions occurring throughout the process. After each interview, I listened to each recording before reading the transcription. This listening to the recording allowed me to note any sense of missed opportunities or of rushing the interviewee during the call. This listening also provided an opportunity to note the general pacing of the interview and the presence of any unintended bias from me during the interview. These notes were kept in the reflexive journal, and served to inform the

iterative process of data collection/analysis. For example, initially I noted that I seemed awkward and afraid to ask questions, but then I could hear the change as I became more comfortable with the interview process. At times, I was too conversational and did not allow participants enough time to talk. I noted these things in my journal and made adjustments to my interview technique.

The next step in the data management process was to read the transcribed interview data and then re-read the transcript while listening to the recording with the intent of identifying initial themes. Due to the iterative process of data collection these initial themes served as a way of verifying information with new participants as enrollment continued and new data was collected. The iterative process also served to inform me when adjustments to data collection procedures were necessary such as the need for a follow up interview. Additionally the iterative process allowed me to recognize when data saturation had occurred. The literature suggested that between 13 and 15 participants were required to reach saturation. In this study data saturation was achieved at 12. I continued to enroll to 16 participants because of my inexperience with the approach and the fact that I did not want to close enrollment without being sure I had exhausted the information I could gain.

Risks and benefits

Participants were free to decline or withdraw from the study at any point during data collection and analysis. I personally obtained all consents and then reviewed each participant’s information for completeness during data collection at the end of each interview and monthly. To date, the potential risk from participating in this study is and

was believed to be no more than minimal. The risk may have been that discussing and recounting their experiences of participating research studies would invoke a negative emotion. Research participants were free to decline to answer any of the interview questions and were free to withdraw from this study at any point during data collection even after completion of the interview.

Adverse events (AEs) were not anticipated in relation to this study. No AEs occurred and if any had occurred as a result of this study, I would have notified the IRB immediately. There were no expected benefits to participating in this research. The expectation was that the findings would provide information and be informative about the experience of elders who have participated in a research study. There was no remuneration for participation in this study.

Ethical considerations

The institutional review board (IRB) of the facility where the study participants were recruited approved the study protocol and a Ceded Review for the academic institution was obtained via a partnership agreement between the two institutions. I obtained verbal consent from each participant after explaining in detail the study procedure, risks, benefits, and their option to withdraw at any time without consequence even if the interview had been completed. I am CITI certified in the Protection of Human Subjects Research and am knowledgeable in methods to protect confidentiality and I also understand the importance of that protection.

Throughout this investigation, I assured privacy and confidentiality for all research participants. All interviews were digitally recorded using AT Conferencing or

No-Notes Conferencing and were also recorded with a portable digital recorder as a backup. I coded all data (digital recordings and demographic information) and kept documents, transcriptions, and digital recorder in a locked file in a locked office. A master list contained the names of study participants and their corresponding code numbers. This list was kept in a locked file and was made available only to the research team. The master list and recordings will be destroyed at the earliest possible time after all data are collected, analyzed and published. No reference to individuals will be made in any published reports of the study. Participants have been given pseudonyms that will protect them from being identified in all published reports of the study. Data that was obtained and analyzed will only be used for research purposes.

Safety was assured by conducting the phone interview with the participant in the comfort of their location of choice. I maintained all data and reviewed it with the methodologist at pre-determined intervals throughout data collection to review and/or adapt the process when needed. The study methodologist and I met on a monthly basis to determine if changes in the protocol were necessary for any reason. Data was transcribed verbatim and then analyzed according to the steps described by Miles, Huberman and Saldana (2014).

Data Analysis

The process of qualitative descriptive analysis involves a cyclic inductive and deductive approach with the purpose of understanding the whole. Along with understanding the whole, there is also an implied purpose to understand the intent and meaning of the individual participants. Elo and Kyngas (2007) suggest that the aim of the

study and questions used in the interview should guide the level of analysis.To this end, the approach to analysis as described by Miles, Huberman and Saldana (2014) is most consistent with the aim of this study which is to understand what the experience is like for frail elders to participate in a research study.

The data analysis process is described next and involves 13 tactics to generate meaning. It is important to note that these are not 13 serial and consecutive steps, but rather parts of an iterative process. Initially, when using content analysis individual cases are reviewed in isolation to determine categories and themes within cases and then re-reviewed to determine categories and themes across cases. Together, all these processes provided me with adequate time to dwell with the data. The 13 tactics are:

1. Noting patterns and themes
2. Seeing plausibility
3. Clustering
4. Making metaphors
5. Counting
6. Making contrasts/comparisons
7. Partitioning variables
8. Subsuming particulars into the general
9. Factoring
10. Noting the relations between variables
11. Finding intervening variables
12. Building a logical chain of evidence

13. Making conceptual/theoretical coherence

In listening to, reading, and reviewing the digital recordings and transcribed data, I noted patterns of responses and themes. At times, this process literally involved counting words which were repeated both within and across cases. However, with counting, the goal was to isolate themes, phrases, and/or patterns. After isolating these initial themes, I then determined which of the phrases and responses belonged together to inform the whole. The next phase in seeing plausibility involved objectively considering the findings to determine if the findings made sense and if they fit into the picture that was emerging. Equally important in this process was determining when things did not fit or did not make sense. Given the concurrent nature of data collection and analysis, this information informed me when to ask different questions or to follow up with participants to gain more insight into the responses.

The next step was to cluster the findings. In this process I determined what went with what thus beginning the initial categorization of the findings. Often this involved choosing one word that captured the category. The process often involved categorizing many things such as shared experiences, similar responses, or relationships which may be categorized in a hierarchical fashion from most frequent to least frequent or from most important to least important or incidental. This study did involve both the horizontal and hierarchical categorizing of the many aspects of the data collected. For instance within the category ‘Decision to participate,’ the responses of participants who learned of the study from their doctor and who also recommended that they participate were low in frequency but high in importance. These responses were high in importance because they

also contributed to the data for the initial patterns of 'Respect for authority' and 'Obligation.' The presence of these patterns provided insight into the process through which some older adults became aware of their study and the influences affecting their decision to participate.

The process of making a metaphor is a way to look at the data abstractly to determine what phrase, if any, captures what is going on with the participants. While this is an important process, Miles, Huberman and Saldana (2014) caution that this should not be forced. Like making metaphors, counting is an important step in that in helps with managing the data and in determining what are the prevalent themes or patterns. Most importantly, this part of the process allows the investigator to "step back" from the data and determine what are the dominant themes or categories. This distinction is important because sometimes fewer frequent categories can be impressive or in line with the investigator's thinking so that they might overshadow dominant themes. Counting categories requires objectivity thereby reducing potential investigator bias. In this study, counting categories and "stepping back" from the data were essential steps to ensuring my objectivity as the investigator and in determining the dominant themes. For example, an initial pattern 'Telling past history,' was eventually removed as a category based on the process of confirming the findings using "stepping back" as one of the methods to ensure objectivity.

Making comparison was yet another tactic that helped to reduce my bias because I needed to objectively examine the data and note how cases were similar or different. This process also helped to identify extreme cases. In all, this process forced me to "see

what they had" in yet another objective way. Partitioning variables is a process in which the data was re-considered in multiple ways. For example, one may further divide the categories of an outcome into further variables such as short-term impact versus long-term consequences. This process decreased the tendency to blur findings and lead me out of linear thinking in order to consider the plausibility of the findings. Sometimes during the process of data analysis, the investigator can be left with what seems to be loose ends. By subsuming particulars into the general, the PI examines these particulars with a new lens and makes decisions about within what categories these seemingly stray findings may fit. My study was no different and I did have loose ends that needed to be placed into categories. By subsuming these particulars into the general, I was able to "see" additional aspects of these data and allow the data to assign themselves to categories

For example, the pattern 'Age discrimination' seemed to be a stray finding in that only one participant elaborated on this topic. However, her description was such that it provided insight into her experience and is a topic that needs more exploration. This participant had been excluded from several studies because of age. She started misrepresenting her age to meet inclusion criteria of several focus groups she was interested in joining. As a participant in those focus groups, she heard other focus group participants' opinions which reinforced her feelings. Although this is speculation, age discrimination may have been a topic that many of the participants in my study had noticed at some point, but were not necessarily related to the studies in which they were participating. After using the tactic of subsuming the particular into the general I decided

to keep this pattern (‘Age discrimination’) and place it in the category, ‘Feelings evoked by participation.’

In factoring data, I again re-examined data to determine if the categories required further subdivision to create categories within categories. In this process, I began to condense the data from many categories to fewer, more descriptive themes. Another tactic described by Miles, Huberman and Saldana (2014) is finding intervening variables whereby the PI is encouraged to consider variables that seem as if they should be linked. For example, after determining initial patterns and clustering into categories, the category ‘Feelings evoked by participation’ encompassed seven patterns. By testing the relationships of the initial patterns to the category, two intervening variables were noticed: ‘Study procedures’ (feelings evoked by study procedures) and ‘Study visit schedules’ (feelings evoked by study visit schedules’). With the establishment of the intervening variables, a clearer understanding of the participant responses to these aspects of the studies was appreciated. This is an example of where other variables may be present but are not initially considered by the investigator. However, at some point, the fact that the relationship among the variables may not be clearly direct, further analysis will uncover the intervening variables.

In building a logical chain of evidence I was at this point, making the case for bringing the story together to form the big picture. This process details the relationships, factors, or parts of the story and demonstrates how these interrelationships together form the whole. In this study, I needed to bring the story together of how the frail older participants found out about the study and influences affecting their decision to move

forward. The story includes reactions to the structure of the study, visits and procedures, for example, and their thoughts on how this experience of participating was made unique by their advanced age. Lastly, the data analysis process involved making theoretical conceptual coherence. This process involved examining both the observable and non-observable and making the conceptual link to the notion of what it all means in terms of telling the big picture and developing knowledge.

In this study the big picture in terms of developing knowledge is related to the older adults' experience of participating in research studies. The logical chain of evidence starts with the participant responses related to how they became aware of the study and the influences or factors affecting their decision to participate. Participant responses describing their reactions to overall study experience, including study visits, study procedures, consenting, and how they were treated- feeling cared for, among others, provide the details of relationships that are tested during the process of building the logical chain of evidence.

Trustworthiness

Miles, Huberman and Saldana (2014) address trustworthiness and suggest several ways to do so. The steps aimed at assuring trustworthiness are described next.

Checking for representativeness suggests that the findings are typical for people who are similar to the participants in this study. One way this was addressed in this study was by the sampling techniques. I received support from researchers enrolling participants who met my study inclusion criteria. I did not directly recruit the potential participants. Rather, study coordinators across research settings were instructed to use

convenience sampling to identify participants in their studies who met my inclusion criteria in my study. Study coordinators provided potential participants with a recruitment letter and an opportunity to "opt-in" to hear more about my study. I then contacted those potential participants to obtain verbal consent. By using this process, a representative sample of participants was enrolled.

After stating up front why this topic is of interest to me, I began to address the second criterion, *checking for researcher effects* on the case. During the process of data collection I took several deliberate steps to reduce potential bias including taking time to center myself both before data collection and during analysis. I kept a reflexive journal and analyzed the data concurrent to data collection. In addition, the several steps (as seeing plausibility, clustering, making metaphors, counting, making contrasts/ comparisons, partitioning variables, subsuming particulars into the general, factoring, and noting the relations between variables) described in the previous section helped to address this area of checking for researcher effects. In using a variety of data sources such as digital recordings, transcribed data, field notes of observation and a reflexive journal *triangulation* of the data is addressed.

Many of the following steps to assure credibility were achieved by the iterative process of ongoing data collection and analysis. Miles, Huberman, and Saldana (2014) suggest that data collection and analysis be a concurrent process so that attention can be given to potential researcher bias *outlying, negative, extreme*, and *surprise* cases. Examining data for typical cases, and counting categories were two ways in which this study assured the process of *deciding which kinds of data are most trustworthy*.

In considering data from the perspective of *if that then this,* I was developing a picture of the whole and contributing to theory development. It was also important in this process that *extraneous variables* be considered and either categorized into previously defined categories or considered a spurious relation to the whole. Steps described previously in data collection such as making metaphors, counting, making contrasts/comparisons, partitioning variables, and subsuming particulars into the general assured credibility. I also completed these steps in assuring credibility by reviewing the data with the dissertation team and making sure all possible explanations were considered in the data analysis. This process also helped to address potential bias.

Replication of the findings is an important step in qualitative research. In this study, it demanded that I be clear about the steps in the process of data collection and analysis. The previous sections provide this detail. Replication of the findings also suggests that the researcher spend enough time in the field collecting data so that presumptions are avoided. Rich descriptions of the analyzed data are also essential so that a reader of the data can get a true feel for the experience. By working closely with the dissertation committee and following an iterative process of data collection and analysis I assured that the findings in this study met this standard. Because the data analysis was to the level of relationships and thematic explanation, it was imperative that I step back from the data and be reflective about *rival explanations.* To do so, I needed to review the data analysis with the dissertation committee on an ongoing basis.

There are several ways that I planned to *get feedback from participants***.** First, I collected data and analyzed it in an iterative fashion allowing me the opportunity to check

ongoing findings with participants. For example, if in the first few cases, participants described the fact that their decision to participate was made solely on recommendation from their doctor, then I subsequently stated something like: “The first several participants in this study described making a decision to participate in research only at the recommendation from their doctor, is this something that makes sense to you? Can you tell me how or how not this may be the case?”

Other ways to obtain feedback include bringing the data back to the participants, but Miles, Huberman and Saldana (2014) suggest this should be completed only after the data is completely analyzed. They also state this approach may be problematic for the participants and therefore not advisable given the potential sensitive nature of the findings. My approach to determining if findings were plausible was to review findings with other research subjects not enrolled in my study but who otherwise met study criteria to determine if findings resonated with them. This proved to be an effective method.

Summary

Chapters One, Two, and Three have described the essential elements of this dissertation study. The background and significance were described with an explication of the literature supporting both the significance of the research question and the study procedures. Chapters Four and Five will present the findings and conclusions.

CHAPTER 4

FINDINGS AND DISCUSSION

Introduction

This study sought to understand what the experience of clinical trial participation is like for frail older adults. The steps for data collection and content analysis as described in Chapter 3 (Elo & Kyngas, 2008; Miles, Huberman, & Saldana, 2014) were used to identify themes. Sixteen older adult participants shared some similarities in their experiences but they also had many differences. Initially, the PI asked general questions to ease the participant into the interview. As a result, each of the participants began by describing how they heard about the study and what influenced their decision to enroll. As they became more comfortable with the process and I asked more probing questions, the participants went on to describe different aspects of their experiences including associated personal history, memories, and previous healthcare encounters they had.

Description of Sample

After screening 24 potential participants, 16 met inclusion criteria. Of those found ineligible, 4 were excluded based on the number of medications taken or number of co-morbidities, which were the parameters used for this study to assess for frailty (5 medications, 2 co-morbidities). Four who initially gave verbal consent decided not continue.

The types of studies in which the volunteers were participating included Phase 1 and Phase 2 clinical drug trials; a rehabilitation and impairment study of the elderly; a genetic study examining acute response to medications used to treat diabetes; a

longitudinal study looking at serial changes in brain anatomy correlating the structural changes with changes in memory and early markers of Alzheimer's disease; a study exploring lipodystrophy in those positive with HIV; and a study to evaluate life style with encouragement to make life style changes to positively impact specific physiologic markers. One participant was participating in both the longitudinal study and a Phase 2 drug study for osteoporosis. The longitudinal study looking at serial changes also included several sub-studies. Many of those who participated in the main study also participated in the sub studies. During data analysis, I did not segregate those responses related to the sub-studies because the participants themselves thought of the sequence of sub-studies as different visits for the same study. The information around the types of studies from which the participants were recruited is captured from the recruitment log and is reported in Table 1.

Table 1: Types of Studies Represented and Number of Participants in Each

Studies	# Participants
RISE: Rehabilitation Impairment Study of the Elderly	1
Phase 1: Pulmonary Hypertension Harvard aging brain	8
Phase 2 drug study for multiple myeloma	1
SUGaR study	1
Lipodystrophy with HIV	1
BeFit	3
Phase 2 drug study for osteoporosis	1

Each of the 16 people who met inclusion criteria participated in telephone interviews with me (principal investigator). All were either currently participating in a research study or had participated within the past year at the time of the interview. Several had participated in multiple studies at different points in their lives.

Descriptive statistics were applied to the data. The range of ages of the 16 participants in the study sample was 65 to 84 years with a mean of 71.5 years. All of the participants had some level of formal education. The majority of the participants were college graduates 69% (n=11); 13% (n=2) had an associate degree; 13% (n=2) had a high school education; and 6% (n=1) had finished the 9th grade. Sixty nine percent (n=11) of the participants were female and 31% (n=5) were male. Thirty eight percent (n=6) were married and lived with their spouses; 31% (n=5) were single and lived alone; one of those who is single lives with her boyfriend; 13% (n=2) were divorced, one living in a multigenerational household, the other living with his girlfriend; 19% (n=3) were widowed and lived alone with one of them living in the independent living section of a retirement community.

The mean number of medications taken was 5.8 rounded to 6, ranging between 5 and 12. The number of co-morbidities ranged from 2 to 5 with a mean of 4. Fifteen of the 16 participants responded “no” when asked the question of whether or not they considered themselves as frail. One participant stated that she did not necessarily see herself as frail but she felt “at risk” because she had developed high blood pressure recently and had experienced a fall. All of them had seen their primary care doctor within the last three years.

The number of studies in which each had participated ranged from 1 to greater than 10 with a mean number of 5. This demographic had two outliers, participants 12 and 14. Each of them had participated in greater than 10 studies, estimated by the participants to be 20 and 15 other studies respectively, giving them a mean of 17.5 rounded up to 18

total other studies in which they had participated. Reporting the mean of all of the participants including the outliers was 4.6, rounding up to 5. Removing the data for the outliers to calculate the mean number of studies for the others, the mean was 2.5 rounded up to 3. See Table 2 for the demographic information. All but one participant lived within 90 minutes of the research site. One participant lived in a Mid-Atlantic state and commuted to Boston for study visits.

Table 2: Demographic Characteristics		**N=16 (%)**
Cultural Heritage	Race	2 (6%) African American
		14 (87%) Caucasian
	Ethnicity	16 (100%) non Hispanic
Gender	Male / Female	5 / 11
Age(years) Mean 71½	65-69	8
	70-74	3
	75-79	3
	80-84	2
Level of education	8 to 11th Grade	1 (6%)
	High school graduate	2 (13%)
	Associate degree	2 (13%)
	College graduate	6 (38%)
	Graduate degree	5 (31%)
Marital Status	Single	5
	Married	6
	Divorced	2
	Widowed	3
Employment	Part time / Part time plus volunteer	3 / 1
	Full time	4
	Retired / Retired plus volunteer	9 / 2
Living situation	Alone	7
	Spouse / Partner	7
	Extended family	2
Type of home:	Apartment/condo	5
	House	10
	Independent in Retirement Comm	1

# of Medications		Range 5-12; mean=6
Co-morbidities		Range 2-6; mean=4
Self Report as Frail		15 "No"
		1 “at risk”
3 Year Gap in Primary Care		0
Number of Studies		1 to >10; mean=5

Coding

Sources of qualitative data for this study included transcribed materials, digital recordings of the interviews, reflexive journaling, and field note observations. To ensure rigor in data analysis, a content analysis approach was used following the approach suggested by Elo and Kyngas (2007). The approach required listening to all of the digitally recorded interviews followed by reading all of the verbatim transcriptions of the recordings. Then the iterative process of reading the transcriptions while listening to the recordings occurred to accomplish first cycle coding. In vivo coding was used extensively at first to get a sense of what the participants had to say. In vivo coding is appropriate to use when the priority is “honoring the participants voice” (Miles, Huberman, & Saldana, 2014, p. 74). During first cycle coding, initial codes were identified as the reading of the verbatim transcriptions and the listening to the participants’ own words occurred.

Using an iterative process to progress through several levels of data analysis then clusters and patterns were identified followed by themes, which captured the overall experiences. Several types of first cycle coding were used: descriptive coding; in vivo coding, process coding, and emotion coding. An example of first cycle coding is displayed in Table 3.

Table 3: First Cycle Coding			
In vivo	Process Coding	Descriptive Coding	Emotion Coding
"My doctor told me about it. He thought I should join, so I did." "I wanted something to do"	Finding out about the study Respect for authority Seeking answers Vacillating between hope & resignation Filling the void – Community Feeling whole Feeling safe Having a voice Telling past history	Compensation Might help me Obligation Age perspective Age discrimination Contribution	Inconvenience Annoyance

To facilitate moving from first cycle coding to more general levels of abstraction to theme identification, I explored the specific instances of participant experiences by asking myself if these experiences could belong to a more general class. The methods used included seeing plausibility, clustering and subsuming the particulars into the general. The goal was to organize and cluster the first cycle codes in order to determine patterns and interrelationships that would then form the basis for developing categories. In second level coding, categories were expanded to themes that captured the gestalt of the experiences.

First cycle coding of the 16 participants' data generated 17 initial codes (1) 'Finding out about the study' (2) 'Compensation' (3) 'Respecting authority' (4) 'Might

help me' (5) 'Seeking answers' (6) 'Community-filling a void' (7) 'Vacillating between hope and resignation' (8) 'Inconvenience' (10) 'Annoyance' (11) 'Feeling whole' (12) 'Feeling safe' (13) 'Having a voice' (14) 'Telling Past History' (15) 'Age perspective' (16) 'Age discrimination' (17) 'Contribution.'

To illustrate how I moved from initial codes to clusters and then to categories, I will describe the process used for the code 'Finding out about the study.' After identifying this code, I clustered the responses that fit within this code. Three of the participants recounted that their doctors had recommended the specific research studies.

Two of these particular subjects went on to say that they would not participate in research unless a doctor or someone who knew about the topic gave the recommendation to them. Next, these in-vivo comments were placed into both codes of: 'Respecting authority' and 'Finding out about the study.' However, not all participants reported needing authority. For example, other participants learned of the study and then made their decision to participate based on recommendations of family or friends, rather than a suggestion from their doctor. One participant who exemplified this stated; "My daughter saw a notice in the newspaper and told me about it because they are studying memory and I am always forgetting things." This was more closely aligned with the code of "Might help me." Another person described: "Somebody in my church group told me about it; she works on the study and thought I would be a good candidate."

These codes of "Might help me" and "Finding out about the study" were similar in that there was an underlying illness that others (family, friends or a physician) were aware of and therefore recommended participation. These codes were related in the sense

of finding out about the study because of symptoms or an illness, but different in that an authority as opposed to a concerned friend may have served as the conduit to the individual participating in a clinical trial. This step in the process helped to determine patterns and interrelationships.

Some participants did not seem to make the decision to participate based on either authority or the recommendation of others. In these cases, compensation was the primary motivator. As one participant described; “I am always looking for cash and it sounded easy.”

The next step in the process was to examine the codes “Finding out about the study”, “Might help me”, and “Compensation” and determine how they were related or not, what patterns existed and to reduce the codes to a broader category of ‘Decision to participate’ recognizing and respecting that the reasons to do so were varied.

Continuing the iterative process, the digital recordings and transcriptions were further examined paying particular attention to each of the codes to determine other clusters, plausibility and establish initial categories and then themes. Plausibility within this data set, presented itself as an impression or pointer to the reaction, feelings, and perspectives of the participants related to their experiences of participating in the research studies. The 17 codes were clustered into 5 categories. Lastly, 4 themes were identified.

1. Participation is influenced by authority persons I trust to make good decisions for me,
2. Participation is a choice I make because it may benefit me or others I care about

3. Unsure of my future at this stage in my illness, participation makes me feel cared for and safe
4. Age in perspective: I choose to participate to be heard and understood

The recordings and transcriptions were again explored with a particular focus on seeing plausibility of these themes. At this juncture, in particular, I consulted with other older adult research participants not enrolled in my study, in order to determine if the themes resonated with them. I also gave myself frequent timeouts while I reflected on the participants words to allow for adequate time to dwell in the data. This process ensured that the themes captured the intention and spirit of the participant responses representing their experiences. Lastly, a metaphor,'Hope in the future because I am participating in this research now,' was created as interplay of the broader themes. This represented the overall experience of frail older adults' participation in clinical trials. Table 4 demonstrates the process of moving from codes to categories to themes to metaphor. This next section describes in more detail each of the themes.

Table 4: Progression thru Coding to make the Metaphor.

First cycle coding – Initial codes	Categories	Themes	Metaphor
Finding out about the study Compensation Respecting authority Might help me Seeking answers Vacillating between hope and resignation Community – filling the void Inconvenience	1. Finding out about the study – authority based 2. Finding out about the study – self 3. Hope when there is little 4. Age related, making a difference 5. Feelings evoked by participation a. Study visit schedule and	Participation is influenced by authority persons I trust to make good decisions for me. Participation is a choice I make because it may benefit me or others I care about. Unsure of my future	Hope is in the future because I am going thru this now.

Obligation Annoyance Feeling whole Feeling safe Having a voice --- Telling past history Age perspective Age discrimination Contribution	b. Study procedures	at this stage in my illness, participation makes me feel cared for and safe. Age in perspective: I choose to participate because I want to be heard and understood.	

Theme 1

Theme 1, Participation is influenced by authority persons I trust to make good decisions for me, was the term derived from the following codes after patterns were examined: Finding out about the study; Respecting authority; Might help me; Obligation; and Seeking answers.

When the participants were each asked to share their experience of how they found out about the studies and what influenced their decision to actually participate, 4 of the responses were “my doctor recommended it” (participants 1, 2, 12, 13) and 5 described receiving a letter in the mail (from their doctor) “I got a letter in the mail.” (participants 5, 6, 9, 14, 15). Within the aggregate of the responses related to deciding whether or not to participate, coding of the initial data of those who enrolled in response to physicians’ recommendations also revealed a sense of respect for authority and a sense of obligation to their doctor (participants 1, 2, 12, 13).

Two of the four participants who enrolled because of the recommendations from their doctor stated that they would not enroll in any medical research without this

recommendation. On exploring further, each of these participants elaborated on the fact that they had a complicated personal medical history as well as a lengthy family medical history and so felt the need for their physician or someone with knowledge of the topic to review both the research protocol and the consent form before agreeing to participate (participants 1, 2.) “I wanted someone who had authority to tell me if it was a good idea or not” (participant 1). “With my diagnosis, I would not go ‘willy-nilly’ signing up for stuff” (participant 2). Participants had complicated personal medical histories and described needing an authority to recommend the study, but also but had additional reasons for deciding to participate. The decision to participate based on trust in authority had two perspectives. One was that people still felt they were autonomously making the choice as partners in their care. To date, clinical trial research has resulted in extending their life with overall good quality of life. One participant who had lived with HIV for > 25 years described his decision to participate in this way;

> Participant 12: I join everything they tell me to….been doing this for 25 years since the beginning (being diagnosed with HIV)….alive today because I joined….back then I was young and stupid and did it for the cash….don’t get me wrong, I still do it for the cash, but they keep finding stuff……joining one soon where I only have to take one pill….maybe next year the pill will only be once a week….wouldn’t that be something.

The experience for people who were living with a chronic illness was different from those more recently diagnosed with a life limiting acute illness, limited options and no prior of history of having had life extended through clinical trials. These participants expressed having fewer treatment choices, more urgency, desperation and a need to participate based on deferring to the opinion of the experts

> Participant 13: …this (being so sick) is new for me….been a master swimmer since I qualified for the category (swimming level) …then last year I got this (multiple myeloma). The doctor explained the protocol, then I found out that if I joined, the company (pharmaceutical) would pay for the meds (study medications), otherwise I have to go through my insurance…nuh uh, spent enough time on the phone with menus, not doing that, so I said sure, glad I did.

In addition to the reasons stated above and physician recommendations, all of the participants (participants 1 through 16) said directly or indirectly that they believed that the results of the studies "…might help me…," "get answers…" and one in particular stated: "I want to be in a position to benefit if the medication works" (participant 2). The fact that participation in the research may have been of benefit to them was a strong motivator for them to participate.

One aspect that seems to have been neglected was the timeline for when some of these participants expected to gain a benefit from participating. Those participants in the Phase 1 and Phase 2 trials spoke openly about their hope for a cure at some point in the future (participants 2, 9, 13) but were also counting on an immediate (within a couple of months) benefit or remission of disease progression. Participant #13: "They told me that if I could just hang in there long enough the side effects would pass (from stem cell transplant) and I would begin to feel better."

Those who did not have such a life limiting diagnosis expressed their expectation of benefit as "…it might help me," and "I need something to get myself in gear to make changes." Except for those participants in the study exploring lifestyle change they were not specific about when their expectation might be fulfilled or how the benefit would manifest. On the contrary, those individuals participating in the lifestyle change study

(participants 3, 11, 16), expressed definite goals and had high expectations for change. Participant #11 expressed the expectation in this way: “I wanted to see if I could lose some weight and get my cholesterol down. I am getting into a walking program and getting my food on a routine.”

Theme 2

The second theme, Participation is a choice. I choose to participate because it may benefit me or others I care about, was developed after examining these codes: Might help me, Seeking answers, Compensation, and Contribution. Participants described hearing about the study from family and friends or at work (participants 3, 7, 8, 10, 11, 16). Influences on their decision to actually participate included: I needed the cash, (participants 12, 14); I thought it might help me, I'm looking for answers (participants 2, 3, 12, 13, 15, 16); I was looking for something to do, and I wanted to contribute.

The participants who learned of the study through friends, notices in a newspaper, or having received a card in the mail used the following statements to describe aspects of their decision making process (participants 3, 4, 5, 6, 7, 8, 9, 10, 11, 14, 15, 16): “I was looking for something to do, you know, fill the void;” “I needed extra cash;” “The topic seemed interesting;” “All I had to do was answer some questions.”

The pattern ‘Contribution’ was initially coded into the category cluster named ‘Age perspective.’ During a phase of confirming the findings, the tactic of getting feedback from participants was used to test whether or not this pattern belonged in ‘Age perspective.’ Feedback was that it belonged in the category ‘Decision to participate’ and should be moved. Using the tactics as suggested by Miles, Huberman, & Saldana (2014,

p. 296) for confirming the findings I found that there were researcher effects and that I had a preconceived notion that contribution would be age related. Returning to the iterative process of listening and reading, the participant data showed that a desire to contribute was present but was not uniformly age-related. It was more related to making the decision as to whether to participate or not. Two participants expressed a desire to contribute related to age, one directly and one indirectly. Those responses are included below (participants 4, 5). Based on the feedback and results from tests to confirm findings, the pattern of 'Contribution' was moved to 'Decision to participate.'

Ten of the sixteen participants spoke directly about contributing, giving something back, doing something for the future, wanting to do something right, or maybe adding something (participants 2, 3, 4, 5, 6, 7, 9, 10, 11, 12). The following exemplifies the desire to participate with the hope of helping others, particularly family.

> Participant 6: "We have a family history of cancer and heart and I know that my husband and my daughter all have cancer and these studies (that I am participating in) don't have to involve cancer but if I can do something to help the medical field solve some problems, I will feel that I am helping them."

> Participant 7: "Well actually my ex- husband family's has a history of Alzheimer's and he now actually has it. He'll be 68 tomorrow and he had a cousin who died in her fifties with complication from Alzheimer's; her mother (his aunt) died same thing, and one of her sisters, and one of her brothers. So I think what kind of got me interested in it, is trying to find information that I can share with my daughter, because I obviously feel that they are in jeopardy. I think that it is genetic and I think that the more information that I can gather about my aging process it might help them."

Among the six participants not included in the category 'Contribution,' two spoke at great length about their motivations for participation, which were not related to hoping to help family or others (participants 13, 14).

> Participant 14: "I do it for the cash and it (the study) might help me, I might learn something (about my disease). I do a lot of studies, but if they don't pay, I don't sign up, I live on a fixed income and I need the cash."

The sense of authority captured in theme one was not present within the responses of those who joined for other reasons (participants 3, 4, 5, 6, 7, 8, 9, 10, 11, 14, 15, 16). This nuance does not infer that these participants disrespected authority or felt no sense of obligation. It indicates only a lack of data to support assigning their responses to those initial patterns.

Theme 3

Theme 3 was labeled**, "**Unsure of my future at this stage in my illness; participation makes me feel cared for and safe. Each of the participants was able to express their feelings about different aspects of the studies in which they participated. 'Vacillating between hope and resignation' was identified during first level coding. This pattern was particularly present in the responses of participants with grave illnesses. Each was participating in a phase 1 or 2 drug trial at the recommendation of their doctors. They each realized the significance of their diagnosis but harbored hope for something beneficial for themselves resulting from their participation. One participant described;

> Participant 2: The illness I was diagnosed with, there is no effective treatment. My doctor found this study and recommended it because it is specifically targeted to the diagnosis. ….the protocol is really clear that I shouldn't expect any benefit. But I hope and expect that if this moves on to stage two (Phase 2 clinical trial) and eventually stage three (Phase 3 clinical trial) given that I have already participated I would be considered a good candidate to go into those further trials and if the drug proves to be efficacious I'll be there to get it, so on one hand I want to do something like just to do something right but on the other hand I am hoping that it might benefit me ultimately. Yeah although no promises were made to me, I don't even know that we've discussed this but that is certainly my hope. (In response to the question: So one of the influences in your decision was

> that the hope was that this would go on to clinical intervention and that you would be able to benefit from that after having participated?).

While this response reflects hope, there was also a sense of searching for answers and hope despite having a terminal illness. While participants did not describe a sense of lost hope, they did describe a need for answers and frustration with knowing something is wrong and time is limited. One participant stated:

> I can't even count (number of studies participated in) because of my condition anything that is pertinent to me I sort of want to pursue, if it's something that I qualify for I pursue just out of curiosity; they might find stuff..like stuff that I don't know about; Well the things that surprised me is the results, results that they found, found spots on my lungs, found spots on my pancreas and deficiencies, found things that need to be fixed by my doctor. If I keep doing these, they'll find something to fix it (HIV).

Another participant described the physical and emotional challenges to clinical trial participation in this way:

> They have you talk to a psychiatrist before the start to make sure you won't bail during the treatment...I was so sick after the infusion (stem cells). I thought I would rather have it now than when I was 35, I must admit. Again let me go back to the guilt I was trying to get through with the psychiatrist, I call it cancer "light" (diagnosis). I kept thinking thank God this didn't happen when I was 35-40. That could be a whole other level of depression. Then I'm thinking this is happening now, I have to deal with this. But one of the things Dr. B made sure I understood at the very beginning was they have some very encouraging protocols, different treatments that are out there. He said, five years ago we would have given me three to five years life expectancy, even then we didn't have the cure, just control, and he said we would probably give you ten and I said okay great. Let's get this "me" decade started. He said there are three or four other protocols out there that are very promising right now and there is a good chance that within those ten years we will give you another ten. I said that's great let's get through the first ten and see how we do.

Yet another participant described the sense of knowing something is wrong, and a simultaneous loss of control as detected in this statement:

> A number of words, just plain old you know, meaningless words, and I had to remember a whole list of them. And I couldn't string them together in any way that I could make associations, and so that particular one I didn't like because I didn't do well on it, and it makes me feel bad…for me it was, you know, failure upon failure.

The category 'Feelings evoked by participation,' that was eventually represented by the third theme: Unsure of my future at this stage in my illness, participation makes me feel cared for and safe represents a cluster of seven of the initial codes.They are: 'Vacillating between hope and resignation,' 'Inconvenience,' 'Annoyance,' 'Feeling whole,' 'Feeling safe,' 'Have a voice,' and 'Age discrimination. However during the latter phases of data analysis this category seemed to have an inconclusive relationship with its component patterns. Intervening variables around inconvenience, annoyance, scheduling, study visit procedures captured frustrations about participation, but did not add to the overall understanding of choosing to participate in the same way other clusters such as "Feeling safe did. The intervening variables initially clustered here 'Study visit schedule,' evoked the following comments related to 'Inconvenience' and 'Annoyance" as represented by the comments below really reflect a frustration with processes of study participation and a lack of feeling cared for and a lack of feeling safe. Participants who expressed frustration with the process of research and/or scheduling seemed to be reflecting a sense of not being cared for and a sense of not being an equal partner in care. Two participants expressed their frustration in this way:

> Participant 4: "I got there and there was some kind of a delay…. What do they think, just because I'm retired doesn't mean I have all day."
>
> Participant 16: "Well, I had to rearrange my work day; fortunately I could do that sometimes; not sure what people do if their schedule is inflexible, I

> guess they drop out, too bad; they should have some kind of alternative so they could get the information."

The codes 'Feeling safe' encompassed participant expressions of how they felt in relation to the study team (nurses) during the study procedures. Participants reported feeling cared for and their needs being addressed. One participant described how the nurses provided a reassuring presence that he needed during stem cell transplantation in this way:

> Participant 13: I had to be in the hospital for the stem cells…and I was so sick….I made myself stay awake….I am so used to being the strong one….finally she came in and sat with me and told me that they were always there, to be there was their job; I must have been confused or something, I forgot I was in the hospital but she explained she was the nurse and reminded me where I was. I thought, oh yeah, now I remember;…I have been trying to forget….then I fell asleep. I woke up later and there was a guy there; he told me he was the night nurse, I thought to myself, 'ok you are here, you mean what you say', then I fell asleep again.

Theme 4

Theme 4, "Age in perspective: I choose to participate because I want to be heard and understood," was the last theme to be identified and originally encompassed three codes: 'Contribution,' 'Age perspective' and 'Telling past history.' During a phase of confirming the findings, using the tactic of getting-feedback-from-participants (Miles, Huberman, Saldana, 2014, p. 309), the response was 3-fold: to move 'Contribution' to the larger category of 'Decision to Participate,' to leave 'Age perspective' as a category further developed into the theme, Age in perspective - I choose to participate to be heard and understood. Telling past history' as an individual was subsumed within this theme.

This fourth theme encompasses thoughts and opinions that had a wide range of focus. When asked the question “Is there anything about being an older participant (in research) that makes this experience unique for you?” Those who experienced discomfort expressed their thoughts in terms of the discomfort or feeling vulnerable, yet others expressed their perspective in terms of what they found interesting or what they felt good about (study procedures). Others were able to express a broader view and reflect on how researchers require a broad range of humanity in order to progress their science or made either direct or indirect references to how much time they had left (in their lives). One provided a practical aspect of commuting to and from study visits; another provided perspective on how important it is to be able to see the consent form. They also talked about how important it was to have accurate information and to feel safe. Despite being in clinical trials were data is collected, but only reported to participants if life threatening, many participants still felt they would receive more information about their overall health. This suggests people may have entered the trial to seek answers about health concerns that were not being addressed through routine care. One participant exemplified this in this way:

> Participant 8: “ They need to tell us how we are doing, I mean they have interacted with a lot of people on these memory tests, and you know, be nice if they could at least give you a hint if you are falling below the level; they say they will call your doctor, I haven’t heard anything so that is good news I guess; but at this age, we’re all worried about that (losing memory)….you know they (younger people) don’t think about those things.

Participants also described being worried that the aches and pains they felt or their inability to answer some tests questions should also be explained in terms of what is normal and what is not. One person described:

> Participant 10: …I couldn't do all the tests, I couldn't remember stuff; I had to stop that scan because I was so uncomfortable. I mean if you are 30 and cannot do things, you get say oh, well; but at this age, you start to think is it because I'm going downhill and am different than I was yesterday…we are all worried…

Some participants described reaping the rewards of clinical trial research and expressed a strong desire to give back and contribute to medical science.

> Participant 12: …you know, young guys are not worried like we were; it used to be a death sentence, still is sort of; but we would join everything to help to get a cure; today, they join for the money, me too, but I seen the difference it's made since 20 years; my best friends dropping like flies.

Other older participants described wanting to participate because the study filled a void in their life. Being in a research intensive environment albeit as a participant was more stimulating than other activities ascribed to older persons. More importantly though, others described that not including older adults was erroneous given the longer life span many experience today.

> Participant 11: well, I think lots of them (studies) are just too tight on the age bracket, I mean, if you have someone who comes along and fits everything except the age, then what's the problem; I'm not talking about the ones for babies or pregnant women, but the general ones; also, I think that they need to look at what does 65 mean today as opposed to 40 years ago. We are healthier population, we are more active population and I wouldn't dismiss an age based on what you think your great grandmother did, I think that you need to be fairly open and understand that this very active aware population is not the Alzheimer's group that it used to be thought off. Yes, we are worried about that but not all of us are demented.

Lastly, others described discomfort about being amongst younger people who were facing death and knowing that they (the participant might live many more total years than

the younger person (s). One participant tried to make light of this in stating;

> Participant 13: …well, certainly see the horizon; where before, I didn't even think about it. I got into this (research) because of my diagnosis. If it weren't for that, I wouldn't be doing it (the research), I would be living my life; now I count every day. The young people I see there (at the infusion center)….they also count every day but its different, they're angry. They talk to me in that room (infusion room), and I feel guilty because I've had another 25 years more than them…; another thing has to do with my eyes…I tried to make a joke with the doctor the other day but no way….I am having trouble with my eyes since I got sick with my depth perception…like going downstairs, and driving, it's a real problem….so he says to me….so you are having trouble with your depth perception?….I said, well yes, a lot of trouble, but there is absolutely no trouble with my death perception….I cleared the room on that one….."

'Telling past history' was a pattern composed of responses from each of the participants where they described past events and elaborated on details about themselves in addition to answering the interview questions. This suggests a need to be known by providers and was re-coded as it belonged in each of the larger themes.

Discussion

In total, 4 themes capture the experience of older adults participating in research studies. These themes evolved directly from their responses and descriptions given during the telephone interviews. The four themes serve as the basis for making the metaphor in an effort to understand and capture the unique experience linked with a broad perspective. "Metaphor is one of the most important tools for making sense of our experience and for trying to comprehend partially what cannot be comprehended totally: our feelings, spiritual awareness, aesthetic practices, and moral awareness" (Miles, Huberman, & Saldana, 2014, p. 281; Lakoff & Johnson, 2003). Alternating between the metaphor and the underlying themes, I like to think of as looking through binoculars

while turning the knob to alternate the focus first on the detail of something near and then turning the knob to then focus on something faraway.

As a novice qualitative researcher, it was my experience with the data that I did not create the metaphor for this study, but rather the metaphor revealed itself to me. It came in the phrase: 'Hope is in the future because I am going through this now.' I was surprised because my novice investigator bias wanted it to be a more concrete and obvious connection with the participant data (in-vivo). I also thought that this study deserved more than one metaphor to explain the phenomenon of the participant experience that was being explored. In the abstract, metaphors are useful in qualitative research as tools for condensing data, making patterns, stepping back to find out what is going on at a more analytical level (de-centering), and to connect findings to theory (Miles, Huberman, & Saldana, 2014, p. 281). After 'Hope is in the future because I am going thru this now' popped into my head, I returned once again to the iterative process of listening to recordings and reading transcripts to determine its plausibility and to see if this phrase really did condense the data, make sense of the patterns, and connect findings to theory as claimed by Miles, Huberman & Saldana.

The truth is that this iterative process, which had been a dependable and valuable tool for making sense of the data, did not help me much at this time. I needed to spread out all the "scratch paper" of my data analysis in the form of a network display to see how the components interconnected. This included all tables, drawings and charts of participants' responses linking first cycle codes to second cycle patterns; the reflexive journal and field notes; the myriad matrices of cross-cases where, for example, I

compared participant 7 to 14 and then continued comparing with other participants; I needed to retrieve from the trash the "participant wheel" that I had made after interviewing #7 and which was patterned after an Indian "medicine wheel" with an inner circle representing first cycle coding and the outer circle representing second cycle patterns. By turning the circles counterclockwise, patterns and categories could be matched as a way to determine plausibility. This tool has not been validated or calibrated but it was another useful mechanism for me to view the data with a different lens.

With all of this spread out on the floor in front of me I started with the metaphor 'Hope is in the future...now,' and reversed the analytic process to unbundle my thinking. I examined the conceptual connections I had made and generally searched for something to discount my revelation. During this process what I found was that very slowly my list of well known metaphors which I had thought might be representative of the participants' experience began to fall away. For example in relation to the cluster categories: 'Decision to participate,' 'Feelings evoked by participation,' and 'Age perspective,' three metaphors had been lined up as candidates to represent them: 'Nothing ventured, nothing gained,' 'Expect the unexpected,' and 'Wisdom of the ages,' but each of them turned out to be a little bit off.

At first, 'Nothing ventured, nothing gained' seemed to accurately represent the patient experience of the themes within the category of 'Decision to participate.' But, embedded in the expression 'nothing ventured, nothing gained' is the concept that if you do not take risks, you will not accomplish anything. On the surface one could make an argument that 'Nothing ventured, nothing gained,' could be applied to participating in

clinical trial research, or any research for that matter. If no one volunteers for the "experiment" then no information is collected or analyzed and the science cannot progress.

In order to keep myself analytically honest and to verify the hunch or hypothesis that 'Nothing ventured, nothing gained' was a valid representation, I started with the "counting" intervention as described by Miles, Huberman, & Saldana (2014, p. 282). Counting requires an examination of the in-vivo data to determine how often a word or phrase actually occurs. Results of counting the words "risk" and "taking a chance" showed that one out of sixteen participants mentioned risk: "…..what choice do I have, I know it's a risk, but my diagnosis, ….there is no cure, I don't have a lot of options." Another participant alluded to risk with her response related to the question of how she decided in which studies she would participate: "Well, I don't want to be a guinea pig, but I mean, if no one ever volunteers, then what about progress, how can that happen?" With only one participant directly mentioning risk as a concern related to participation in research, the metaphor of 'Nothing ventured, nothing gained,' seemed to need more evaluation. I went back to the recordings and the transcription of this participant. I realized that "hope" was the more important message that he was conveying. His participation was really not about risk: …" there is no cure, what have I got to lose; I want to position myself in case the medication works…if this (the research) gets to stage 2 or stage 3 (phase 2 clinical trials or intervention)."

'Expect the unexpected' was initially thought to be useful to represent 'Feelings evoked by participation. Embedded in this phrase is a heightened sense of eternal

vigilance or being on guard to avoid getting "blind-sided" or experiencing something which is usually negative and which appears to have no origin or to "come out of nowhere."

As a participant in a research study related to study visits and related to the mechanics of the study operations, the Institutional Review Boards and other regulatory bodies are in place to assure patient safety and to require that the investigators minimize unexpected events as much as possible. The majority of the unexpected aspects described by the participants in this study were related to inconvenience of scheduling, physical discomfort from lying in an MRI, having an IV placed, or as in the case of Participant 13, experiencing side effects of a medication. "I was so sick after the treatment (stem cells) and the drugs just dropped me. I really could not do anything; needed help to get up to the bathroom. I was surprised by that." When I asked him if he felt "blind-sided" or uninformed that side effects might occur, he responded:

> Well, no; there is that 25 page paper they have you read with them; they do a tag team, with doctor, NP, somebody in street clothes maybe pharmacist-not sure, psychiatrist, and end up with the doctor again; takes several hours. Thing is, they told me all this stuff, I asked lots of questions; but I thought that it wouldn't happen to me. I had been so healthy that I was surprised, but I knew that others had felt bad after.

Other participants also made the distinction between being surprised and having something unexpected happen.

> Participant 8: They called me on the phone and wanted me to come in so they could explain everything before we got started. I said I wanted to ask my doctor about it, so she said she would send it in the mail. Well, it was long, maybe 20 pages and you had to initial most of the pages. So I took it to my primary doctor and he went over it; he said not to do the lumbar puncture part of it. But he thought the rest of it was a good idea. So then I went into Boston and the research doctor and the little girl (study

> coordinator) did the whole thing all over again. He got another paper, well, the same paper she had sent me, just another copy, because he wanted to sign it at the same time as me. I got my questions answered and I asked the same questions that I asked the primary doctor and got probably the same answers but it was in research talk. The thing I was surprised about was how I did on those word tests….no, I knew what they were going to do…

Additional aspects of the study procedures which came as a surprise to some participants were performance related with how they thought they scored on the memory tests, or in the case of Participant 1 who was surprised that she could keep her balance with the "walking test" (tandem gait); for others the surprise was how they felt when in the CT scanner or the MRI, the hardness of the table or the claustrophobia. However, these aspects cannot be considered as unexpected events related to participating in the research study.

'Wisdom of the ages' represents the third metaphor which needed testing for confirmability and which had initially been matched with the category of 'Age perspective.' As previous mentioned, several sources of data are required for a thorough data analysis. In examining my reflexive journal and field notes, I had several instances where after having completed an interview, I had written about my own bias related to how I expect elders to think. This bias is something that I struggled with throughout the data collection phase and the analysis. I have a bias that I think older people in general should have a perspective that reflects a life time of experience and can be less ego centric in their thinking than other age groups. In addition to the comments of the participants described earlier, there were several outliers and contrary cases. Four of the participants responded negatively to the question related to being an older participant

relative to the experience being unique for them. They said, “no, I don’t think so, younger people probably wouldn’t be any different or they wouldn’t do it (the study) because they would not have the time.” The combined researcher effect of bias and contrary cases was the negative evidence against this metaphor to be used as a generality for this category.

‘Hope is in the future because I am going through this now’ is the phrase that came to me as I was mediating over the network of data spread out before me. The data sources, as mentioned previously, before me included participant recordings, transcriptions of the recordings, reflexive journal, field notes, and the ‘participant wheel. In re-exploring the data, including listening and reading, I came to appreciate that each of these participants harbored an expectation of hope although the feeling may not have been expressed explicitly. Participant 12: “.... joining one soon where I only have to take one pill….maybe next year the pill will only be once a week….wouldn’t that be something.” Participant 11: “I wanted to see if I could lose some weight and get my cholesterol down. I am getting into a walking program and getting my food on a routine.” Participant 2: “there is no cure, what have I got to lose; I want to position myself in case the medication works so I can get it…if this (the research) gets to stage 2 or stage 3 (phase 2 clinical trials or intervention).”

Several of these participants had a life limiting diagnosis and their reasons for participating were clear. Others were participating to get motivated to make life style changes. However, none of the participants made any reference to dropping out of the studies. Some expressed strong feelings of annoyance about scheduling or having to wait but did not speak about ending their participation. There was an expectation of because I

am doing this now, then maybe something will be better because of it. In looking at the participant data, this logic also can be traced to their reasons for deciding to enroll. The logical chain of evidence was intact for this phrase to represent the participants' experience.

Summary of the Findings

The results of this study provide insight into what the experience was like for a cohort of 16 frail older adults. They were considered frail because they met the inclusion criteria of taking at least five medications and having at least 2 co-morbidities. Meeting inclusion criteria is separate from whether or not they considered themselves as frail. This mind body connection (or disconnection) does have nursing implications, which are discussed in Chapter 5.

The findings of this study provide an understanding as to how the participants learned about the study and the influences affecting their decision to enroll. The findings also include and provide insight into their expectations of benefit, and the feelings evoked by the study procedures and the study visits. They were concerned about safety but had an overall feeling of hope in the future because of what they were doing now.

The findings from this investigation provide a more holistic perspective of the older frail adult's experience in clinical trial research. Gaining this perspective is important to nursing knowledge development in terms of understanding the entirety of the human experience as opposed to treating frail older adults as subjects who have little to contribute to the experience. The knowledge gained from this study is congruent with the core values of nursing. Findings from this investigation can encourage development

of research protocols carefully targeted to this population and result in studies more aligned and reflective of the frail older adult's experience. In doing so, clinical trials research has the potential to address this lack of evidenced based care that exists for frail older adults and begin to close a health disparity gap.

CHAPTER 5

IMPLICATIONS AND CONCLUSION

Introduction

The purpose of this study was to address the gap in the nursing knowledge related to accounts of what the experience is like for frail older adults' who participate in research studies. Using a qualitative descriptive approach involving open-ended semi-structured interviews, I asked a cohort of 16 frail older adults to talk about what it was like for them to participate in a research study. Hearing directly from older adults who were participating in clinical trials provided the most reliable avenue for gaining a deeper understanding and a greater appreciation of the complexities impacting older adults who participate in clinical trials.

The data resulted in 4 themes and a metaphor to capture the experience of this group of older adults' experience of participating in research studies. The four themes were: (a) Participation is influenced by authority persons I trust to make good decisions for me. (b) Participation is a choice I make because it may benefit me or others I care about. (c) I am unsure of my future at this stage in my illness, participation makes me feel cared for and safe. (d) Age in perspective, I chose to participate because I want to be heard and understood. The metaphor was expressed as Hope is in the future because I am participating in this research now.

In this chapter I will discuss the study findings related to implications for research, advancement of nursing theory, education clinical and practice.

Research Implications

The research findings of this study and its limitations provide avenues for further research. Replicating this study with a more racially, educationally, and geographically diverse background may reveal additional themes of concern for this population and may also deepen the understanding of their expectations of benefit and motivations for participating in research studies. An additional characteristic of this study sample that should be considered relates to those individuals who are enrolled in research during an inpatient hospital stay or who are enrolled in research but experience an overnight stay as part of the research. The inpatient research participant experience in particular may provide more insight into the bridge of clinical care with research protocol. As shown by Participant 13's comments about his inpatient stay, studying this aspect of an elder research participants' experience would also expand the knowledge of the nurse patient relationship and would add to the literature of how a patient perceives being "known" by the nurse (Zolnierek, 2014).

> Participant 13: I had to be in the hospital for the stem cells…and I was so sick….I made myself stay awake….I am so used to being the strong one….finally she came in and sat with me and told me that they were always there, to be there was their job; I must have been confused or something, I forgot I was in the hospital but she explained she was the nurse and reminded me where I was. I thought, oh yeah, now I remember;…I have been trying to forget….then I fell asleep. I woke up later and there was a guy there; he told me he was the night nurse, I thought to myself, 'ok you are here, you mean what you say', then I fell asleep again.

Relative to the fact that the number of elders is increasing globally, the need is present to examine a redefinition of aging, to develop a better understanding of multi-morbidity and the precursors of decline. Although the definition of frail in this study has room for expansion, the findings in this study show that there are those elders who may

score as frail but who may not consider themselves or "see" themselves in that category. How one sees oneself does not necessarily have to match with the reality of one's physical condition. However, in the 65 and older age group, this disconnect may place individuals at risk if they are either unaware of their limitations or they do not accept the changes in their physical status. Additionally, there is a need for research on the possibilities for reversing the progression of being frail. As evidenced by the findings of this study that none of the participants considered themselves as frail, a research question that may be asked is this: is being frail a state or a trait?

Nursing Theory Implications

With respect to theoretical foundations of aging and the fact that age groups for elderly people are currently categorized as "old (65-74), old-old (75-84), oldest-old (85-100), and elite-old (>100 years of age) (National Institute on Aging, 2011), the logic follows that more than one category of development or decline is present. Erikson's (1998) eight stages of psychosocial development describe the conflict for old age, as ego integrity versus despair (Erikson & Erikson, 1998). With respect to the 5 categories of aging mentioned above and described by the NIH (2011), there is room for evolving a finer distinction to characterize the aging process from a psychosocial perspective. Peck expanded on Erickson to provide ego differentiation vs. work role preoccupation; body transcendence vs. body preoccupation; and ego transcendence vs ego preoccupation as an extension of Erickson's work (Peck, 1968). The season's of life focus on relationship of physical changes to personality with the premise that an individual needs to ultimately come to terms with the inevitability of end of life.

One study participant in particular seemed to have difficulty adjusting to her chronological age (75 years). This difficulty surfaced as she described her experience of misrepresenting her age so that she was not excluded from participating in several focus groups that she was interested in joining. Although she tended to marginalize the act of age misrepresentation, it does indicate that some individuals who may be considered as "elderly" and who also tend to engage in the behavior of age misrepresentation may benefit from use of a "finer screen" when academics describe psychosocial development of elders.

Nursing Education

Continuing to educate the incoming generations of new nurses is key for fostering optimum health for those who are entering the 65 and older age group. If you consider that the last of the Baby Boom generation will have turned 65 by December of 2030, then a nurse who is entering the field at age 21 in 2014 will be 37 years old and will be starting to "hit her stride" by the time the last of the Baby Boomers turn 65. The implication is that the need is present to have nurses in the field who can build the patient centered relationships and who have internalized the goals of nursing (Picard, C., & Jones, D., 2005; Willis, D., Grace, P., & Roy, C., 2008). Findings from this study validate the fact that patient centered care should continue to be a focus of the discipline of nursing and that the patient-nurse relationship is key regardless of the setting (research or clinical care).

One of the study participants was an inpatient during his research experience. This patient required clinical care and hospitalization. The research protocol in which he

was participating was offered to him during his hospitalization and also offered him a potentially better outcome for his illness. In this type of situation, the nurse is charged with a dual allegiance, that of fidelity to the research protocol, and that of following thru with the clinical plan of care. The success of the nurse to fulfill her dual allegiance was evidenced by the experience of the patient who expressed the fact that he could go to sleep because he knew that the nurse was there and would keep him safe. Several other study participants expressed how important it was to them to know that someone was listening to them, to how they felt and to the kinds of things that concerned them or caused them anxiety. Each of these expressions of the study participants' need to be heard, indicates the importance of having nurses present who can also "be present" with a caring consciousness. This caring consciousness is fundamental and universal to effective nurse-patient partnerships across all care environments (Cowling, Smith, & Watson, 2008). The tenants of knowing the patients and being well schooled in the goals of the discipline of nursing will enable nurses to provide the best of patient centered care (Flanagan, 2007).

Nursing Practice

The results of this study have the potential to contribute to the development of mid-range theory to describe older adults' experience as research subjects. The care provided by clinical research nurses, a fairly new specialty in nursing, would benefit from the knowledge generated by the four themes generated in this study. The data identify the particular experiences of frail older adults and their views which could be used to construct an elder-friendly approach to clinical trials.

Furthermore, this knowledge could be integrated with two existing sources. The North American Nursing Diagnoses Association International (NANDA-I) provides a comprehensive list of twelve domains of nursing practice with corresponding points under each domain categorizing nursing diagnoses. (Herdman, 2012; NANDA-I, 2011). For human subjects research, *International Conference on Harmonization Good clinical practice: Consolidated Guideline* defines and provides a unified standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects (DHHS, 1997). Compliance with Good Clinical Practice provides public assurance that the rights, well-being, and confidentiality of trial subjects are protected and that trial data are credible." (Department of Health and Human Services, 1997). Understanding that research patients are "patients" first and then research patients, just as the person who is post-operative gall bladder surgery is a patient first, there is room for generation of care plans for research patients that would be widely used by clinical research nurses in the research setting. Using the complete list of nursing diagnoses and the tenants of the Good Clinical Practice Guidelines further development of this mechanism would generate care plans for elderly research patients.

Study Limitations

The limitations of this study include sample demography; recruitment, definition of frailty used for inclusion/exclusion criteria, and missed opportunities by the investigator.

The findings are limited by homogenous sample characteristics of education, race, and geography. Only one participant was non-Caucasian (African American) and only

one participant had less than high school level of education (finished 9th grade). The African American participant was not the same participant as the one with the 9th grade education. Although not all of the participants were involved in the same study, they were all recruited from the same research center of an urban tertiary care medical center. Participation in eight research studies was represented with participation skewed because 7 of the participants were enrolled in the same study. One participant was concurrently enrolled in two studies. All of the participants were enrolled in outpatient studies where no overnight visits were required. One study participant happened to be an inpatient when the research protocol was offered to him. Because he was hospitalized for clinical care, his experience was not counted as inpatient research. The age range of the sample was skewed with 8 (50%) of the participants aged 65 to 69 with no participants over the age of 85. Because of these limitations the research study findings and knowledge acquired from this study are limited to this group of participants and ought not to be generalized to a broader group of elder participants.

An additional limitation to this study has to do with the two missed opportunities related to investigator interviewing technique. As pointed out in chapter 4, the investigator missed an opportunity during the telephone interviews to further explore participant responses related to their expectations of the timeline for when they thought they would benefit from participating in the research. This lost opportunity is important to note. It can be reframed into future research questions to elicit more meaningful and specific data on participant expectations of benefit.

Nevertheless, this study provides a beginning and important inquiry into older adults' participation in clinical trials that form the basis of medical care for millions of Americans.

Conclusion

Millions of older adults take medications and receive medical treatments that are based upon research that did not include older adults as subjects. For reasons not entirely understood, older adults are grossly underrepresented in clinical trials. As noted earlier, older adults are the major consumers of medical care, and as they are living longer with more chronic disease, this trend will continue for the next 20 years, or more.

This study is a beginning inquiry into the experience of older adults who do participate in clinical trials. The findings suggest a variety of reasons that this sample of older adults chose to participate, from altruism to hope for a successful treatment for their own disease. The fact that a physician suggested that they participate in the study reveals that this endorsement is an important motivator.

It was also demonstrated that participants had a variety of experiences, once enrolled. These revealed important, and possibly modifiable experiences, that, when corrected, may encourage other older adults to participate. The participants wished to be respected and be efficiently taken through the research experience. They identified some vulnerability on their part, by having to remember and repeat a string of words, that could have been humiliating for them, if they could not answer appropriately. This description showed that participation may cause embarrassment, which was mitigated by the staff's encouragement and acceptance. Several individuals in the sample were "repeat"

participants. This suggests that, for some, the experience was gratifying in some way. Knowledge gained from this study provides important insight into the experiences of older adults as research subjects. What has been discovered from this small of participants is greater knowledge of the motivations and experiences of older adults which could impact the future direction of clinical trials. Importantly, it can significantly influence the nursing care of clinical subjects in the way that hope is supported, that recognition is given for their altruistic service, and that greater efficiencies are provided to respect their time and, possibly, functional/cognitive decline. Clearly, encouragement by nurses mitigated feelings of vulnerability and helped participants feel safe.

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Appendix A: Pilot Study Interview Guide

I would like to know why you decided to participate in a research study.

1. Would you please tell me what made you decide to participate in this study?
    a. Potential follow up questions.
        i. Have you participated in other research studies?
        ii. Have the experience of family or friends influenced your decision?
2. What has the experience of participating in a research study been like for you?
    a. Potential follow up questions.
        i. Did the experience meet your expectations?
        ii. How did it or did not meet your expectations?
        iii. Were there things about being a participant that surprised you?

Appendix B: Recruitment Letter

MASSACHUSETTS GENERAL HOSPITAL

HARVARD MEDICAL SCHOOL

The MGH Clinical Research Center
A member of the Harvard Catalyst CTSC
55 Fruit Street, White 13, Boston, MA 02114-2696
http://www2.massgeneral.org/crc

HARVARD CATALYST
THE HARVARD CLINICAL AND TRANSLATIONAL SCIENCE CENTER

Dear Clinical Research Volunteer

As Director of the MGH Clinical Research Center (CRC), I am writing to tell you about a study being conducted through the CRC in case you would like to participate. This study is being conducted by Catherine Griffith, RN, PhD(c), ACNP-BC.

Catherine Griffith is studying the experiences of people aged 65 and older who have participated in research studies. This research project is designed to find out what the experience of participating in research has been like for you. Very little is known about the actual experience of participating in a research study among the group of people aged 65 and older. We hope that the results will help us understand your experience better and benefit other research volunteers and investigators in the future.

Participation will involve one telephone call with Catherine Griffith which will be scheduled at your convenience. You will be asked to discuss your experience in the research study on the CRC. We anticipate that the phone call interview will take approximately 45 minutes. All of your answers will be kept confidential and will not be discussed or shared with the investigators in the study in which you are participating. If you would like to learn more about the study, please contact the investigator, Catherine Griffith, at 781-820-4839.

You will not receive any personal health benefits as a result of your participation in this research study. There are no medications involved and there is no payment for participation. Whether you participate or not will have no effect on the medical care you receive here at Massachusetts General Hospital.

Your participation is voluntary. If you would like to participate, please check the "OPT-IN" box below and return this letter with your contact information to your nurse or study coordinator or you can mail the letter back in the envelope provided. If you are not interested, then no action is required.

Thank you in advance for considering this request,

David M. Nathan, MD
Director MGH Clinical Research Center
Phone: 617-726-2875; Fax: 617-726-6781
dnathan@partners.org

Catherine A. Griffith, RN, PhD(c), ACNP-BC
Staff Nurse MGH Clinical Research Center
Phone 781-820-4839
cgriffith@partners.org

OPT-IN ☐ I would like to participate in this study: Name:_____
Phone number: _____ or Email_____

Appendix C: Demographic Questionnaire

1. What cultural heritage do they most closely identify with?
    a. Race
    b. Ethnicity
2. Gender
3. Age
4. Level of education
5. Marital status
6. Employment
7. Living situation:
    a. Alone
    b. Spouse/Partner
    c. Others in household
8. Type of home:
    a. apartment/condo
    b. house
    c. Retirement community
    d. Assisted living
9. How many medications are you taking?
10. What kinds of medical problems do you have?
11. Do you see yourself as frail?
12. How long has it been since you have seen your primary care doctor?

Appendix D: Telephone Script

Thank you for agreeing to participate in the study addressing "Older research subjects' experience of participating in a research study." Your participation in this research project is voluntary and you may withdraw or stop your participation at any time even if you decide after you have completed the interview. If you decide to stop, contact me, and all information connected to you will be destroyed. The purpose of this study is to help researchers understand what the experience is like for people over 65 to participate in a research study.

Participation in this study involves one telephone call with me, Catherine Griffith. The telephone call will be scheduled at your convenience or can occur today if you chose to do so. You will be asked to discuss what your experience was like to participate in research from the perspective of someone age 65 or older. The interview will be audio recorded. We will also ask some questions about your educational background and work experience. We anticipate that the phone interview will take between 30 minutes to one hour. Most people take about 45 minutes. If you feel like you have more to say, we can schedule an additional telephone interview as a follow up. All of your answers will be kept confidential and will not be discussed or shared with the investigators in the study in which you are participating.

You will not receive any personal health benefits as a result of your participation in this research study. There are no medications involved and there is no payment for participation. Whether you participate or not will have no effect on the medical care you receive at Massachusetts General Hospital.

Do you have any questions?
Is this a good time to talk about your experience or would you like to schedule time within the next week?

The purpose of this study is to explore the perception of what the experience is like to participate in a research study among adults over age 65.

1. How did you find out about the study?
2. Have the experiences of family or friends influenced your decision to participate?
3. How many studies have you participated in before?
4. Were there things about being a participant that you found enjoyable?
5. Were there things about being a participant that were not enjoyable?
6. Was the study participation difficult for you for any reason?
7. Were there things about being a participant that surprised you?
8. Did the experience meet your expectation?
9. I am interested in understanding the perspective of older adult research participants. Is there anything about being older that makes this experience unique for you?

Partners Human Research Committee
116 Huntington Avenue, Suite 1002
Boston, MA 02116
Tel: (617) 424-4100
Fax: (617) 424-4199

Initial Review: Notification of IRB Approval/Activation
Protocol #: 2013P001428/MGH

Date: May 21, 2014

To: Catherine A. Griffith, RN, MSN
MGH
Central Admin-COO / Nursing

Jane M Flanagan, Ph.D, NP
MGH
Central Admin-COO / Nursing

From: Partners Human Research Committee
116 Huntington Avenue, Suite 1002
Boston, MA 02116

Title of Protocol:	Older adults' perception of participating in a clinical trial.
Version Date:	7/11/2013
Sponsor/Funding Support:	None
Study Population:	Adults
Consent/Authorization:	Required
Documentation of Consent:	Written Documentation Waived
Informed Consent From:	Adult Subject
Informed Consent By:	Non-Physician Investigator
IRB Review Type:	Expedited
Expedited Category/ies:	(7)
IRB Approval Date:	5/21/2014
Approval Activation Date:	5/21/2014
IRB Expiration Date:	5/21/2015

This project has been reviewed by MGH IRB . During the review of this project, the IRB specifically considered (i) the risks and anticipated benefits, if any, to subjects; (ii) the selection of subjects; (iii) the procedures for obtaining and documenting informed consent; (iv) the safety of subjects; and (v) the privacy of subjects and confidentiality of the data.

Please note that if an IRB member had a conflict of interest with regard to the review of this project, consistent with IRB policies and procedures, the member was required to leave the room during the discussion and vote on this project except to provide information requested by the IRB.