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Ethics in Research

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Ethics in Research

Abstract

Due to a history of unethical research studies, ethical codes were developed to address the treatment of humans during research. After World War II, the Nuremberg Code was developed to prevent research misconduct by establishing specific protective criteria for human subjects. The Belmont Report, developed in 1978 in the United States, regulates studies today. The Belmont Report contains three basic ethical principles: (1) respect for persons, (2) beneficence, and (3) justice. The Belmont Report provides research-based protective implementation for informed consent, risk/benefit assessment, and participant selection. This case study demonstrates how to implement ethical standards successfully during research with human subjects. The focus of the manuscript is to indicate how decisions are made and problems are solved to adhere to ethical standards.

Keywords

ethics, older adults, aging, physical activity, quality of life

Cover Page Footnote

Ethics in Research

Researchers are accountable and responsible to adhere to ethical standards in research. As the researcher explores phenomena with human subjects, it is mandatory that the rights and safety of participants are protected (Beauchamp, 2008). Older adults are a vulnerable population requiring diligent adherence to ethical standards of practice in research (Flaskerud, & Winslow, 1998). Aging is associated with physical and mental functional decline (Goncalves, Vale, Barata, Varejao, & Dantas, 2010); thus, older adults experience diminished vitality and loss of self-sufficiency (Vale et al., 2009) leaving individuals vulnerable to manipulation and exploitation.

Purpose/Objectives

This manuscript addresses ethical concerns relevant to a particular research question about older adults, specifically, what are the effects of physical activity on quality of life (QOL) and sleep in older adults in the southeastern United States. That research question is salient because the vulnerable population of older adults is expected to reach 20% of the general population by 2030 (CDC, 2013). The ethical issue exists between the researcher's passion for the study focus and the human rights of the participant. The ethical objectives for this paper include the following:

- Examine the researcher's perspective and personal beliefs regarding older adults and professional accountability toward study participants.
- Identify the process to recruit study participants to ensure confidentiality, informed consent, and anonymity.
- Identify the ethical principles involved in justice, respect of persons, beneficence, and nonmaleficence with older adults.
- Identify the ethical manner to disseminate information discovered in this study

The Context: Illustration

A nurse researcher spoke to a group of older adults while recruiting participants for a community research study to examine the effect of a yoga intervention as a physical activity on QOL and sleep in older adults. Mrs. Henry, aged 67, gave her telephone number and indicated she would like to discuss it further. The nurse researcher called her the next day and set up an appointment for the following week. Mrs. Henry, a widow for two years, lives alone in the rural home she shared with her husband for 45 years. Their three children live out of state. She is retired and living on a fixed income. Mrs. Henry attends church regularly, plants a vegetable garden annually, and enjoys socializing weekly with her peers at the local senior citizen community center. Upon meeting with Mrs. Henry, the nurse researcher notices she is wearing bifocals, a hearing aid, and ambulates without difficulty. She shares she has been diagnosed by her physician with arthritis and mild hypertension; she does smoke a cigar occasionally. Mrs. Henry listened carefully to the nurse researcher, read the detailed information about the study, and signed the consent. As she left the meeting, Mrs. Henry expressed she was looking forward to the yoga classes because she had trouble sleeping and tired more easily.

The Research Ethics Issue: Older Adults as a Vulnerable Population

The research ethics issue addressed in this manuscript centers on the vulnerability of older adults involved as participants in research studies. A vulnerable population may be at risk due to age, socioeconomic status, functional status, chronic disease, or disability status (CDC, 2014; Agency for Healthcare Policy and Research, 1998). Older adults face a change in finances when they retire, debility may increase with age, and physical or mental changes affect their functional status.

Physical and emotional inequities between researcher and older adult participant can compromise ethical principles. Older adults experience physical changes such as decreased muscle mass and breathing difficulties (Goncalves, Vale, Barata, Varejao, & Dantas, 2010). Disturbances in sleep patterns increase with aging including diminished day time alertness, disturbed sleep at night, and take longer to go to sleep (Neikrug & Ancoli-Israel, 2010; Lo & Lee, 2012). Chronic disease diminishes physical functioning, causes pain, and impairs QOL in older adults. The National Center for Chronic Disease Prevention and Promotion (2009) reported, "80% of older adults have at least one chronic condition and 50% have at least two" (p. 1). According to Andrew, Mitnitski, & Rockwood (2008), emotional inequities can be heightened by the social vulnerability of older adults.

Researchers should be vigilant regarding ethical communication with older adults. Older adults experience cognitive changes, diminished hearing, and diminished vision. (U. S. National Library of Medicine, 2014). Older adults may not be visually able to read consent forms or materials pertaining to the study; it may be difficult for older adults to hear the researcher explain the risks and benefits of the study. All written information should be in a clear font of an appropriate size for older adults to read easily (Kavanaugh, Moro, Savage, & Mehendale, 2006).

The environment should be well lit and quiet to enhance older adult's ease of visibility and hearing. Intellect diminishes with aging; therefore, researchers should be proactive in ascertaining the individual's ability to comprehend information (APA, 2014a). Clear, articulate communication and explanation is mandatory between researcher and participant to achieve accurate understanding in order to truly have ethical consent.

Older adults are at risk for isolation due to retirement, the loss of friends and family, and the loss of independence (Cornwell & Waite, 2009). These losses may increase feeling of

powerlessness in older adults (Cornwell & Waite, 2009). Loss of support systems may heighten the potential for older adults to feel pressured and eager to please others. The nurse researcher must be careful to avoid the appearance of coercion when describing the social benefits of yoga classes (Kavanaugh et al., 2006).

Points of Conflict

Justice, respect of persons, beneficence, and non-maleficence. When examining the ethical considerations of research with a vulnerable population, it is vital that the nurse researcher strictly adhere to the standards of justice, respect of persons, beneficence, and non-maleficence (Beauchamp, 2008). Older adults can be at risk physically, psychologically, socially, or a combination of the three (Aday, 2001). Thus, there is a social obligation to respectfully attend to the health of older community members (Aday, 2001). Researchers must build trust, honor confidentiality, and demonstrate respect to participants (Beauchamp, 2008) in order for older adults to feel comfortable to communicate their needs.

Researcher/participant personal behavior. Another potential point of conflict is researcher and participant personal behavior or response to the subject matter of the study. Kamenou (2007) defined double subjectivity as "the process whereby the researcher's and the research participants' perceptions and views can affect the research itself, their behaviors and responses" (p. 2003). Researchers have the responsibility to avoid actual or perceived power imbalances that could lead to response bias, thus, diminishing the integrity of the study (Rich, 2013; Beauchamp, 2008). Establishing trust between researcher and participant is important to decrease response bias or double subjectivity in research involving vulnerable populations like older adults.

Age-bias. A third point of conflict to consider is age-bias or bias towards older people. Daniels (1995) stated, "The elderly are portrayed as a minority that is treated in unfavorable, even discriminatory, ways by the more powerful majority" (p. 89). With older adult participants, researchers must continually examine and seek justice in order to diminish the potential for ethical conflict (Ludwick & Silva, 2004). The devaluing of the older adult may be due to sociofunctional processes, i.e. society has become independent and autonomous, but as humans age, they become more dependent upon others (North & Fiske, 2013). The physical appearance of the older adult may heighten the awareness of mortality in others (North & Fiske, 2013). The devaluation of this vulnerable population and fear of personal mortality may contribute to age-bias.

Disciplinary & Federal Ethics

The American Nurses Association (ANA) Code of Ethics guides the practice of nursing and of nursing research in the United States (ANA, 2001). From the perspective of the scenario given earlier, the nurse researcher would adhere to the guidelines of nursing ethics by preserving integrity in the study, maintaining quality of care to the older adult, delegating tasks appropriately to a certified yoga instructor, and remaining committed to the older adult participants throughout the study (ANA, 2010). The ANA Position Statement upholds ethical standards of ongoing informed consent and risk versus benefit assessment throughout the study (ANA, 2010). In 2012, the Institute of Medicine (IOM) identified older adults as a diverse, vulnerable population with unique care challenges (IOM, 2012) which further confirms the ethical the ethical concern of vulnerability of older adult populations addressed in this paper.

Philosophical & Moral Principles

The philosophical ethical principles of justice, respect for persons, beneficence, and non-maleficence are the strengths providing the foundation in research ethics. Beaumont (2008) reported that justice was specifically important for vulnerable populations. Justice is simply fairness in sharing the risks and benefits of research among participants. The literature has demonstrated the vulnerability of the older adult (IOM, 2012; Aday, 2001; U.S. Department of Health and Human Services, 1979). The nurse researcher should carefully weigh all options to arrive at the ethical decision for older adults in the development and implementation of any study. Justice requires that older adults are treated ethically, equally, and fairly (U.S. Department of Health and Human Services, 1979). Choosing older adults as research participants simply because of ease of availability or manipulability is a breach of the principle of justice and should be avoided (U.S. Department of Health and Human Services, 1979).

Respect for persons means the researcher acknowledges the participant's right to make choices and decisions autonomously (Beaumont, 2008). Ethically obtained informed consent requires full disclosure of the study to an individual with the capacity to understand and voluntarily participate (Beaumont, 2008). Human dignity is respected when a vulnerable population is afforded respectful opportunities to make informed decisions. The nurse researcher is accountable to continue informed consent throughout the study, known as process consent (Munhall, 2010), acknowledging the older adult's right to withdraw at any time.

Beneficence refers to contributing for the good and promoting well-being of another. In ethics, beneficence is a standard of care in which the researcher protects the rights of participants involved in a study (Holm & Harris, 2008). Non-maleficence guides researchers to avoid intentionally causing harm to others (Holm & Harris, 2008). Researchers have a moral obligation

to work diligently for the benefit and safety of participants, while avoiding every intentional wrong or disregard for human safety with older adults. A medical release from a physician will be required for each older adult participant involved in the study to avoid physical harm or emotional distress.

Richardson (2013) defined moral reasoning as the practical reasoning that differentiates right and wrong in a situation or develops a moral judgment regarding what one should do. Essentially, moral reasoning refers to the manner the researcher will address moral conflicts and reach a conclusion (Richardson, 2013). In the case illustrated earlier, the researcher will face the moral conflict of recruiting a vulnerable population to participate in physical exercise in a safe and healthy manner. However, previous studies have demonstrated the successful participation of older adults in studies examining the effects of physical activity on the population (Jancey, Clarke, Howat, Maycock, & Lee, 2009; Sun, Norman, & While, 2013; Koeneman, Verheijden, Chinapaw, & Hopman-Rock, 2011).

Specific Responsibilities in Ethical Conduct of Research

There are several ethical considerations the nurse researcher is responsible in the aforementioned case illustration. Institutional Review Board (IRB) would be obtained for this study. The role of the IRB is to assess the risks and benefits to participants, ensuring that risks are minimized, equitably distributed in relation to benefits, and benefits are maximized (USDA, 2018). Participants must never be exposed unnecessarily to potential harm. Researchers are to strictly follow the guidelines set forth in the IRB application and the standards adhered to by the IRB (USDA, 2018). *Case illustration: Mrs. Henry has rights that must be protected by the IRB review; careful attention should be given to her age, physical and emotional health, and socioeconomic status. The nurse researcher fully disclosed to the IRB how Mrs. Henry will*

receive justice, beneficence, non-maleficence, and respect as a person. All of the forms in the information packet described below must have IRB approval before dispersion. With a medical release from a physician, Mrs. Henry may be able to safely participate in yoga exercise to determine if this physical activity would affect her QOL and sleep.

After IRB approval, a cover letter accompanied by an information packet will be sent to all local churches, senior community centers, and retirement communities in the identified geographic region requesting permission to meet with older adult members and residents. The information packet will give a detailed explanation of the study, reason for the study, plans for a certified yoga instructor, meeting place and times for classes, length of study, explanation of procedures for participant confidentiality and anonymity, copy of informed consent form, copy of the Patient-Reported Outcomes Measurement Information System (PROMIS®) tools (PROMIS, 2019), and description of plans to publish study findings. Follow-up phone calls will be placed to confirm meeting times/dates with potential participants. *Case Illustration: During the initial informational meeting, the nurse researcher would take the opportunity to share and fully explain all of the data in the information packet with potential recruits. Mrs. Henry voluntarily shared contact information and met with the nurse researcher for further clarification of the study purpose and procedures. After her questions were addressed to her satisfaction and comprehension, she signed the informed consent. As described in the scenario, she was fully capable of making the decision for herself.*

At the recruitment meetings, each participant will receive the same information packet. Informed consent will be signed only after explanation and disclosure of the study had been discussed to the participant's full understanding. Once the informed consent process is completed, the participants will be randomized into two groups, a control group and an

intervention group. Both groups will be administered the PROMIS® tools and will submit saliva samples for cortisol and alpha-amylase levels; the nurse researcher will score the tools and run data on the saliva samples. The intervention group will begin yoga classes with a yoga instructor certified in yoga for older adults. The control group will participate in weekly health care classes. *Case illustration: Mrs. Henry is capable of reading and writing, thus, she can complete the instruments easily. The nurse researcher would be attentive to the fact that she wears glasses and a hearing aid. Therefore, special attention would be given during communication of instructions for use of the tools. Her earlier statements regarding trouble sleeping and tiring easily indicate she may benefit from physical activity. Mrs. Henry has equal chance of being placed in either the control group or the intervention group.*

Ongoing informed consent and continual risk versus benefit assessment will be performed throughout the study. Confidentiality of participant data will be maintained at all times. Participants can withdraw from the study at any time. At the end of the eight weeks, both groups will be administered the PROMIS® tools the second time and submit saliva samples. All data will be placed in SPSS for analysis.

In conclusion, this illustration exemplifies that ethics in nursing research requires minute attention to the details of caring for the safety and welfare of study participants. Nurse researchers must work diligently to prevent harm, either intentional or unintentional, to vulnerable populations that may not be able to readily advocate for themselves. Many resources are available to afford researchers guidance and direction to support ethical nursing research to benefit the profession. The moral obligation to protect confidentiality, autonomy, and justice is of paramount importance.

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