A Nonequivalent Control Group Before-After Matched Cohort Design: Use of Telehealth to Reduce
Rehospitalizations and LOS

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Acknowledgments

TO MY HUSBAND MANOJ

Who always believes in me…
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A Nonequivalent Control Group Before-After Matched Cohort Design: Use of Telehealth to Reduce Rehospitalizations and LOS

Specific Aims

The population of patients with chronic heart failure (CHF) is rapidly growing in the United States (U.S.). CHF is the most common cause of recurrent hospitalizations in the patient population above 65 years of age (Abraham et al., 2008). The 5.7 million people who have been diagnosed with CHF are contributing to the rising healthcare costs from requiring frequent medical care for symptom management (McGhee & Murphy, 2010). With current stringent changes occurring in the federal reimbursement and funding of healthcare, healthcare professionals are constantly seeking options to prevent poor patient outcomes in this vulnerable population. A tool that can assist in caring for these individuals is the telehealth telecommunications technology (The Institute of Medicine [IOM], 2012).

Over the last decade, the use of information technology (IT) has advanced in the healthcare industry. The IOM describes the use of IT as a core competency for all healthcare professionals including nurses. IOM encourages the use of effective technology, such as telehealth, if it plays a role in improving the six elements of healthcare delivery of safety, patient-centered, timely, equitable, effective, and efficient (IOM, 2012). Numerous studies have suggested that telehealth is a safe, reliable, proactive approach in monitoring chronic conditions such as hypertension and diabetes (Dewsbury, 2012; McGhee & Murphy, 2010; Artinian et al., 2007; Stone et al., 2010). However, more replication studies are required to study the impact of telehealth on conditions such as CHF, chronic obstructive pulmonary disease (COPD), and asthma to promote widespread use of the technology.

The U.S. Department of Health and Human Services (HHS) is currently supporting funding to evaluate the efficacy of telehealth programs. This organization along with the American Medical Informatics Association (AMIA) has established a national priority to develop and implement information systems that increase efficiency, promote safety, and improve overall patient care (AMIA, 2012). In addition, American Association of Nurse Practitioners (AANP) research agenda focuses on ways to improve patient outcomes (AANP, 2010). If research suggests the telehealth technology is beneficial in monitoring chronic conditions, medical providers will be more likely to adapt the use of the tool. Insurance companies will also be willing to provide full reimbursement of the care provided via telehealth, thus promoting the use of the technology.

While educating the patient and the family can prevent CHF disease exacerbations, the specific aim of this study is to evaluate if telehealth monitoring is an effective method to reduce re-hospitalizations in this population, thus improving patient quality of life, an overarching goal of Healthy People 2020 (HP 2020). The two directional research hypotheses for this study will be: 1) The use of telehealth will reduce in-patient re-hospitalizations in the CHF patient population and 2) If re-hospitalization is warranted, the length of stay (LOS) in the hospital related to a CHF exacerbation will be reduced for those individuals who receive telehealth services. The independent variable will be the use of telehealth monitoring system. The operational definition of the telehealth monitoring system is a device that monitors the patient’s vital signs of heart rate, blood pressure, and weight on a daily basis. The dependent variables will be re-hospitalization rates and LOS. The re-hospitalization rate is the percentage of times the patient is admitted as an in-patient (>24 hours) to the hospital. The LOS is termed as the amount of days the patient stays in the hospital before discharged home or to a rehabilitation facility.
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Background

The growing population of 5.7 million people in the United States (U.S.) who have been diagnosed with chronic heart failure (CHF) is drastically influencing the rising costs of healthcare. Despite the existence of effective treatments, median hospital readmission rate is 24.7% in the CHF diagnosis related group and about half of those readmissions are potentially preventable (Centers for Medicare and Medicaid Services [CMS], 2011; Goldfield, et al., 2008). The mortality rate is 50% within five years of CHF diagnosis and the reported costs per year is approximately $34 billion (American Heart Association [AHA], 2012). In October 2012, CMS recently adopted a plan supported by the Affordable Care Act that will reduce reimbursement to hospitals with excessive readmissions (CMS, 2012). Healthcare providers are actively exploring options of possible interventions to manage this vulnerable patient population group diagnosed with CHF.

Evidence suggests that verbal or written patient education about the disease process is not sufficient in managing disease exacerbations. In the U.S., more than 90 million Americans have difficulty understanding and utilizing health information (Wilson, 2003). Furthermore, a great portion of the disease education is provided in a stressful, time-constrained environment such as the doctor’s office or the hospital where patients are easily overwhelmed with information (Taylor-Clarke et al., 2012). Taylor-Clarke et al. (2012) evaluated the suitability and readability of 18 patient education materials on heart failure and analyzed that only two (11%) were adequate for the fifth grade reading standard recommended by CMS. Limited health literacy in combination with overall low literacy of the majority of U.S. population fosters nonadherence to treatment regimens, leading to decreased control of personal risk factors and undesirable health outcomes (Cho, Lee, Arozullah, & Crittenden, 2008). Patient education is suggested to supplement other monitoring strategy to better manage cardiovascular diseases (Taylor-Clarke et al., 2012).

An emerging tool of telehealth monitoring (TM) not only efficiently assists with medical management, but also focuses on Healthy People 2020 goals of increasing access to care, improving patient outcomes, and providing cost-effective care. TM is defined as the delivery of healthcare services and education to individuals at a distance using digital technology (Wooten, 1996; Marineau, 2007). Remote patient monitoring for diseases such as diabetes, heart and pulmonary disease, and skin disease is estimated to save $197 billion over 25 years (Federal Communications Commission, 2010). Furthermore, the use of TM decreased emergency department (ED) visits by 38% and length of stay by 50%, and reduced $74 per day from the total cost of care (Spaulding, Velasquez, He, & Alloway, 2012). In order to compare previous studies’ outcomes on the evaluation of TM, a literature review is warranted. A summary of the literature review, in the form of a literature grid guide, is listed in Appendix.

Review of Literature

Marineau (2007) described positive and negative experiences of TM of ten participants who had been hospitalized with an infection and were transitioning home. The rising themes addressed that telehealth system was “easy to use,” “treatment changes were made in a timely manner,” and that this type of care allowed “more self-control” (Marineau, 2007). Participants verbalized the importance of recovering in the home, in a restful environment, where the care was constantly monitored by a nurse or a nurse practitioner who immediately advised appropriate treatment. The hospital atmosphere was perceived as suboptimal, in which the care delivered delayed the recovery process. This was due to constant interruptions in rest, nosocomial infections, decreased appetite, feeling of disempowerment and depression, and needs not achieved. One affirmative view of TM was the care model avoided the cost of copayments from the multiple clinic visits and the long waiting time periods. Physician wait times in an urban city can range from 11-15 days, further delaying the care and increasing the probability for deterioration of patient condition (Dehours et al., 2012). Some of the partakers in the TM care model were unenthusiastic about using the technology because they believed this type of care was “second choice care.” Yet other participants believed they were prematurely discharged from the hospital, and were encouraged to use TM at home for remainder of the recovery period (Marineau, 2007).
TM programs assist in early identification of symptoms of disease exacerbation, thus resulting in earlier implementation of medical care. A chronic prevalent disease, hypertension, effects one in three Americans and is associated with high rate of morbidity and mortality (CDC, 2011). Evidence-based interventions are highly in demand to control the adverse outcomes of the disease such as heart disease and stroke. A randomized, experimental, longitudinal study evaluated the effects of TM on reducing blood pressure (BP) values among 394 African Americans (Artinian et al., 2007). In addition to visiting primary care providers, the interventional group was requested to send BP readings to the TM nurse once a week via the TM device. After the readings were obtained, a phone call was made by the nurse to provide feedback in relation to medication adherence, lifestyle modification, and targeted goals. In one year, the TM group experienced both clinically and statistically significant reductions in SBP by 13 mmHg ($P = 0.04$), and clinically significant reduction in DBP by 6.3 mmHg ($P = 0.12$) than the control group who only attended the regularly scheduled doctor’s visits (Artinian et al., 2007).

The lack of knowledge of the management of the disease process can be a hindrance to those who are motivated to care for their health. TM provides substantial education during the monitoring process and is a bridge to this gap (McGhee & Murphy, 2010). In 2009, a study indicated that the TM model was successful in reducing hemoglobin A1C (HA1C) levels by $57.8\%$ ($P = <0.01$) and low-density lipoprotein (LDL) levels by $79.7\%$ ($P = 0.02$) in a 137 diabetic veteran population at a six month follow-up visit. Encouraging results of TM also illustrate that at six months, $20.3\%$ of TM group participants compared to only $5.5\%$ of control group participants achieved a HA1C level $<7%$ at six month follow-up ($P=0.01$) (Stone et al., 2010). Increased abnormal A1C levels are related to cardiovascular diseases and are a leading cause of morbidity and mortality (Miller, Safford, & Pogach, 2004). Substantial education is required to manage this disease process. The researchers incorporated the importance of education in the study conducted by Stone et al. (2010) by having a nurse practitioner constantly monitor, educate, and adjust medications as needed after receiving the daily transmitted values of blood glucose levels, BP, and weight of the TM group. The study illustrates that additional, ongoing education as well as the occasional scheduled office visit is beneficial in managing chronic diseases. Although not as rigorous, the comparison group also received education from a nurse educator once a month and the group was also noted to have lowered HA1C levels by $34.2\%$ ($P = <0.01$) and LDL levels by $59.4\%$ ($P = 0.02$) (Stone et al., 2010).

Healthcare providers realize that TM is a short-term intervention to medical management. In fact, previous numerous studies purpose that TM promotes patient self-management and results in lifelong lifestyle changes (McGhee & Murphy, 2010; Radhakrishnan & Jocelon, 2011; Gellis et al., 2012). Individuals require repetition to establish an understanding of the importance of disease management education (Taylor-Clarke et al., 2012). TM assists with delivering cost-effective teaching by nurses, instead of physicians, in the community rather than in a hospital or a clinic setting. Gellis et al. (2012) recruited 115 subjects with CHF or COPD to examine if TM education intervention improved general and mental health. The control group received education on the management of the disease three times a week with a face-to-face encounter with a home care nurse whereas the experimental group received an ongoing daily education via TM in addition to the home care nurse visits. The education provided included medical symptoms, adherence to medication regimen, monitoring of vital signs, increasing physical activity, and ways to solve daily problems associated with the medical condition which may affect their psychological distress. At the three month follow-up, the TM group improved significantly in depression symptom scores on the PHQ-9 scale, an average of 7.5 point increase compared to 1.6 points in the control group ($P=<0.005$) and CES-D scale, an average of 9.5 point increase compared to 1.8 points in the control group ($P=<0.004$). The TM group also experienced greater increases in social functioning ($P = < 0.014$) and general health ($P=<0.016$). In 12 months, a statistically significant correlation supported that the control group had $75\%$ ($P = 0.03$) more visits to the ED than the TM group. There was an observed trend for fewer rehospitalization days in the TM group (7.5 days versus 10.5 days in the control group), but the relationship was not significant ($P = 0.06$) (Gellis et al., 2012).

By 2030, the number of people aged 65 years old and over is expected to double (U.S. Census Bureau, 2008). Implementation of new delivery care models, such as TM, is necessary to provide cost-effective care to
this frail population and to ensure that the quality of care is not sacrificed. The structure of TM model is the solution for possible higher rates of nurse shortages that will occur in the next few decades (Sanner, 2004). A TM project that was implemented in Pitt County in North Carolina included 107 participants who were considered as high risk for rehospitalization and were diagnosed with, on average, 12 chronic illnesses (most common diseases included hypertension, heart failure, osteoporosis, and diabetes) and were prescribed 15 medications daily. The study compared pre and post enrollment data and demonstrated positive impacts of using TM in all the areas that were under study. Individuals who used TM had a 54% reduction in ED visits, 36% reduction in ED costs, 69% reduction in hospital admissions, 60% reduction in hospital costs, and 64% reduction in hospital LOS \( (P = <0.05) \) (Duke, 2005). Because of the outcomes of the study, the Pitt County Memorial Hospital in North Carolina has established a Geriatric Telehealth Case Management program as a permanent service for those who are at risk for fragmented, costly health care.

Prior studies on TM suggest on targeting a variety of subpopulations to test the efficacy of the TM technology. Although some studies have included the CHF patient population in TM studies, more studies are indicated that isolate this patient population for further examination. Furthermore, the CHF population is uniquely characterized with having complex medication regimens with poor adherence and multiple other highly prevalent co-morbidities (i.e. hypertension, diabetes, COPD, etc.). Future recommendations for studies incorporate controlling these possible confounding variables to better assess the effect of TM. This study will follow the same cohort to analyze the before and after intervention results, rather than randomly selecting individuals to the treatment (TM) group and control group as have been previously done in studies.

**Theoretical Model**

CHF is a progressive condition that requires repeated hospitalizations and results in impaired quality of life (AHA, 2012). Transitioning care from the hospital to home is a stressful event to both patient and family caregivers (Pressler et al., 2009). Time-consuming responsibilities of monitoring signs and symptoms of heart failure, identifying a change in condition, and following up with appropriate daily care can lead to physical, psychological, and financial stressors and dissatisfactory outcomes (Chiang, Chen, Dai, & Ho, 2012). To explain the role of TM in reducing re-hospitalization rates and LOS days in the CHF population, Bandura's Social Cognitive Theory can be applied.

A behavioral change is the result of environment, people, and behavior (Bandura, 2001). The theory's concept of behavioral capability is gained by increasing patient's knowledge of the CHF disease process by educational components of TM. In addition, patients interact with healthcare providers, such as TM nurses, who are often the source of reinforcing healthy and poor self-care behaviors. These expectations result in either increase or decrease in the likelihood of the occurrence of behaviors. The goal is to promote self-efficacy, or the confidence to perform a specific behavior, by providing constant education and feedback, through TM, on markers of CHF disease status (i.e. BP, heart rate, body weight) (Bandura, 1997; Bandura 2001; Ciere, Cartwright, & Newman, 2012). Stronger self-efficacy beliefs are associated with increased self-control, or purposive behaviors, that enhance disease self-monitoring and problem solving (Bandura, 1997). Acquiring knowledge and self-efficacy on the management of CHF disease leads to increased self-care behaviors such as greater adherence to medical regimen, dietary recommendations, monitoring of signs and symptoms. These important behavioral changes learned by the patient subsequently result in improved patient outcomes and decreased occurrence of rehospitalizations and shorter LOS.
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Research Design

To evaluate the effectiveness of telehealth to reduce rehospitalizations and length of stay (LOS) in chronic heart failure (CHF) population, a quantitative, quasi-experimental, nonequivalent control group before-after matched cohort design is used in this study. Due to the lack of randomization, this study is quasi-experimental rather than experimental (Polit & Beck, 2008). The nonequivalent control group before-after study design was chosen instead of the one group before-after design. In one group before-after designs, observations are made before and after implementation of an intervention, but this type of study has many weaknesses. Unlike a one group before-after design, a nonequivalent control group before-after study design has a concurrent comparison group available to diminish the effects of external factors (e.g. new technology, policies, or standards of care) which can influence the outcomes of the study and provide erroneous conclusions (Polit & Beck, 2008). To ensure that both the experimental and comparison groups are comparable at baseline, the concept of matching was adopted. Matching allows both groups to be similar in key variables that can be associated with the outcomes, therefore controlling intrinsic confounding factors. This process will avoid other possible variables that can interfere with the true association of the independent and dependent variables. The process of matching will allow researchers to differentiate between statistically significant results and flawed data (Polit & Beck).

This study observes two groups of participants before and after the implementation of the treatment, telehealth monitoring (TM). Both groups contain equal participants from Blackstone Home Care, a home health care agency based in Columbus, OH and Dayton, OH. The comparison group consists of participants from Dayton, OH where TM has not yet been implemented. Participants from Columbus, OH are in the experimental group that has implemented TM in the care of CHF patients. The key variables that were matched are rehospitalization rates and the LOS of the total CHF population of the agency. Blackstone Home Care – Columbus (BHC-C) group had a rehospitalization rate and average LOS of 32.6% and 12 days, respectively. The comparison group, Blackstone Home Care – Dayton (BHC-D), had a 31.9% rehospitalization rate and average LOS of 12 days. In addition, the standards and guidelines of care are also matched since both groups have staff employed by the same home health care company, thus eliminating external confounding variables.

Participants

Participants were recruited from Blackstone Home Care (BHC) agency from two locations in Ohio: Columbus and Dayton. This agency was chosen because of the vast number of CHF patients it contained under its care. Since the implementation of telehealth was in a trialing phase and was not implemented company wide, it was also easier to perform baseline matching of the key variables. The inclusion criteria consisted of: CHF diagnosis in medical chart, intention to remain under BHC care for six months, access to land-based analog telephone line, and able to learn the use of TM system. The exclusion criteria included: cognitive impairment, physical impairment preventing use of TM, and non-English speaking. From the inclusion criteria, 97 out of 494 total BHC-C patients were eligible for the study. Each eligible participant was contacted by phone by the primary researcher for a maximum of three times to explain the motive of the study and to solicit participation. Of the 97 patients, 14 were unreachable and 11 refused participation. A total convenience sample of 72 participants was recruited for the experimental group. In the comparison group, a total random sample of 72 patients from a total of 533 was obtained with a random numbers table from the BHC-D cluster.

The primary researcher contacted interested participants in the experimental group who met the inclusion criteria to attain informed consent (copy attached in the Appendix). Each person was given $40 for participation in the study. Although no known, legal, physical, or psychological potential risks of the treatment were identified, the benefits of telehealth were explained. The research procedure was reviewed and the participants were made aware that a potential benefit of daily monitoring and education by a telehealth nurse to manage CHF disease process will be provided. Ethical principles were integrated in the study design and were reviewed with the informed consent with the participants. The principle of respect for human dignity was
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upheld to allow for the right to self-determination of participation and informed consent. Full disclosure of the experiment was elucidated by the primary researcher. Each participant received fair, equal treatment, without judgment in accordance with the principle of justice. A pledge of confidentiality was maintained to protect each participant’s right to privacy and to ensure information gathered from the study will not be shared and will only be used for the sole purpose of the study. Research data were collected in an anonymous manner by coding methods to protect the identity of the patients. The overarching aim of the study reflected on the principle of beneficence, right to protection from potential harm and maximizing good.

Data Collection

The Wright State University’s IRB approved quasi-experimental study was conducted at two locations of BHC, an agency accredited by the state of Ohio. The experimental group in Columbus, OH received the TM intervention. The control group in Dayton, OH received the usual care (UC) treatment consisting of weekly face-to-face home visits to provide health education on CHF disease process. Both groups had access to the nurse assigned to the case for concerns or questions. All of the care was delivered in the participant’s home.

Experimental group participants were contacted by the primary researcher to schedule an initial in-home visit to have a telehealth nurse set up the monitoring system and provide a detailed one hour tutorial session on its use. As part of teaching practice protocol, the nurse required feedback demonstration of the equipment by each participant. The telehealth nurses were trained for one week on the use of the telehealth system and on problem-solving strategies related to the CHF disease process. This study used the Honeywell “HomMed” Health Monitoring System which is a small, tabletop in-home monitor (illustration in Appendix). The participants were required to take daily vital signs which included weight, blood pressure, heart rate, and oxygen saturation at a predetermined time of convenience. A selection of modifiable yes/no questions regarding the CHF disease process were prompted on the monitor and instructed patients to respond with a single key press. The data collection process took approximately 5-10 minutes daily. All transmitted data were encrypted and sent via a telephone line to the central station located at the home health care agency where three trained telehealth nurses reviewed the data daily. Participants with abnormal readings were contacted by the telehealth nurse for further evaluation. The telehealth nurse would provide education tailored to the participants’ needs and included counseling on the importance of daily monitoring of body weight, proper low salt and fluid restriction diet, smoking cessation, medication compliance, and monitoring of symptoms indicating worsening CHF. If warranted, the nurse was available for urgent home care visits and also collaborated with the primary care provider to case manage the care.

The data was collected using a tool created by the Centers for Medicare and Medicaid Services (CMS) called the Outcome and Assessment Information Set (OASIS) (CMS, 2012). The data were extracted from the OASIS section “Transfer to an Inpatient Facility” (questions M0080-M0100, M1040-M1055, M1500, M1510, M2004, M2015, M2300-M2410, M2430-M2440, M0903, M0906) to measure the quantity of times and the specific reason the patient was admitted to the hospital. The reliability and validity measurements of the OASIS tool are not available in the current literature review. A rehospitalization reason only related to the CHF disease process (e.g. weight gain, increased shortness of breath) was included in the data. When patient returned home from the hospital, the patient was resumed on prior homecare services. The hospital discharge summary that was sent to the homecare agency by facility case managers was reviewed to obtain the LOS days in the hospital. Due to the nature of the study, the telehealth nurses were not blinded during the data collection process but the primary researcher was. Data of the number of times the patient was admitted to the hospital from a CHF exacerbation and the LOS days were collected for a period of six months before the TM intervention implementation and again at six month post intervention for both experimental and control groups.

Data Analysis
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To test for both hypotheses, the independent $t$-test was chosen as the test of choice. The $t$-test allows testing of differences in group means and can be used with two independent groups (i.e. experimental and control groups), and when the sample is paired as in a pre-post treatment study (Polit & Beck, 2008). $T$-tests are useful in establishing if the group differences are reliable or if the differences occurred due to chance fluctuations. The formula of a $t$-test consists of group means, variability, and sample size. When comparing between two groups, a $t$-test considers the differences in group variation and group size of the two groups (Polit & Beck, 2008). The value $p<0.05$ was set to be considered significant.

To test for hypothesis one, a null hypothesis is established that states there is no difference in the rehospitalization rates in the CHF patient population between the experimental and control groups. Then an upper limit will be calculated as a $t$-statistic which will determine the probability of the null hypothesis being true. If the calculated $t$-value is higher than the upper limit $t$-statistic, it can be supported that the results are statistically significant (Polit & Beck, 2008). A similar process will be used to test the second hypothesis. The null hypothesis will state there is no difference in the LOS between the experimental group receiving TM services and the control group receiving the UC services.
Appendix

**Literature Review Grid – Telehealth**


<table>
<thead>
<tr>
<th>APA reference</th>
<th>Problem statement</th>
<th>Purpose or Specific aims</th>
<th>Research Question or Hypothesis and Key concepts or variables under investigation</th>
<th>Theoretical/conceptual framework</th>
<th>Research Tradition; Research Type</th>
<th>Setting, Population (sample), Sampling Plan, Inclusion/exclusion criteria, Informed consent, Data collection procedures, Instruments used to measure data, and Data analysis</th>
<th>Results or Findings (include descriptive and inferential statistics)</th>
<th>Limitations of the study (stated by author(s) and Recommendations for further study)</th>
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<tr>
<td><strong>Study 1</strong> Marineau, 2007</td>
<td>There is limited research on patients’ perceptions of using telehealth (TH) technology although a growing trend of using this technology is evident.</td>
<td>Describe “lived experiences” of individuals with acute infections transitioning in the home with support by an advanced practice nurse (APN) using TH.</td>
<td>“What are the risks and benefits of TH from the patient’s perspective?” Key concepts: TH and patient experience</td>
<td>N/A</td>
<td>Qualitative</td>
<td>Setting: participant’s home Sample: 5 men, 5 women 49-81 yrs of age who are on TH at home and were discharged from the hospital with an acute infection diagnosis Sampling Plan: convenience sample recruited by phone from the TH pilot program located at a HMO in Hawaii. Inclusion criteria: included in TH program over the past 2 yrs and discharged with an acute infection Exclusion criteria: non-english speaking Consent: reviewed with participants during 1st interview Data Collection: audio tapes were used during 3 different interviews Instrument: open-ended questionnaire was implemented until data saturation occurred Data Analysis: Colazzi’s (1973) 7-step process utilized; tapes were listened to and transcripts were read numerous times to obtain thick descriptions of the perceptions of TH</td>
<td>Overall, positive experience of TH. 1 negative experience 3 themes emerged: Initial response: excitement and trusting TH care of model, relief at the possibility of being monitored at home, feeling like a guinea pig in new care model Engaging in care: Viewing family as a substitute nurse, feeling good to be monitored by APN, feeling confident in care delivered, feeling dislike for hospital environment Experiencing the downside: Feeling too sick to go</td>
<td>Recommendations -Interviewing family members’ views of TH Limitations: -Interviewed only participants who volunteered to enter TH program to promote earlier discharge -Diverse ethnic population leads to limited transferability -Possible skewed data because the researcher was also an APN providing TH care</td>
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<td>Home, being sent home too early, receiving second choice healthcare</td>
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<td>Study 2 Artinian et al., 2007</td>
<td>Hypertension (HTN) is one of the largest risk factors for CVD and it is growing in prevalence, especially among African Americans (AA)</td>
<td>To compare usual care given to patients with blood pressure (BP) TH monitoring plus usual care to determine which leads to greater reduction in BP from baseline to 12 months follow-up than individuals who received usual care only.” Variables: Independent Variable (IV): use of TH Dependent Variable (DV): BP</td>
<td>N/A</td>
<td>Quantitative 2-group experimental longitudinal design with block stratified randomization</td>
<td>Setting: subjects' homes Sample: 394 urban AA Sampling Plan: recruited through free BP clinics at community centers, thrift, or grocery stores on East Side of Detroit Inclusion criteria: ≥18 yrs of age, SBP ≥ 140 or DBP ≥ 90mmHg, access to a land-based telephone, oriented to person, time, place, English-speaking, intent to remain in Detroit for 1 year Exclusion criteria: arm circumference ≥ 17.5 in., history of dementia, mental illness, terminal cancer, advanced liver disease, on hemodialysis, drug or alcohol use Consent: Written consent before start of study Data Collection: BP readings sent from home via TH to RN once weekly x3 months, and once monthly x9 month Instrument: Electronic BP monitor Omron Hem-737 Data Analysis: Data compared with baseline data using SAS Version 9.1, SPSS Version 14.0, Independent t-tests, chi-square statistics, cross-tabs, ANOVA</td>
<td>Hypothesis partially supported: 3 months follow-up: TH group on average decreased SBP by 8.7% and DBP by 7%. The usual care group on average decreased SBP by 3.5% and DBP by 2.6% (P=0.001). 12 months follow-up: In the TH group, SBP was 13mmHg lower than usual care group (P=0.04), and DBP was 6.3mmHg lower than the usual care group (P=0.12).</td>
<td>Limitations: BP monitoring not consistent during the 12 month period -Obese (arm circumference ≥ 17.5 in.) excluded from study</td>
<td>Recommendations -Determine lasting effect of TH and if effective in reducing BP associated complications - If TH is useful in reducing the number of medications used to treat BP -Explore cost-effectiveness of TH -Test theoretical explanations for the efficacy of TM on BP</td>
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<td>Study 3</td>
<td>CHF and COPD often co-exist and are disabling medical conditions. This frail population consists of homebound older adults that lack access to care and integrated services, which contribute to readmissions to the hospital.</td>
<td>To test the impact of TH intervention on general and mental health outcomes of homebound medically ill older adults diagnosed with CHF or COPD who receive homecare services.</td>
<td>“Patients enrolled in the tele-HEART Intervention would receive significant better quality of care for CHF/COPD using chronic disease management protocols resulting in improved health-related quality of life (QOL), mental health status, and satisfaction with care at 3 months follow-up and decreased ER use and hospital admissions at 12 months follow-up.”</td>
<td>Patient Centered Care Model</td>
<td>Quantitative experimental randomized control trial</td>
<td>Setting: subjects’ homes Sample: 115 homecare patients under care of St. Peters Home Health Care (HHC) in New York – 81% with HF, 19% with COPD Sampling Plan: Recruited from hospital discharge planners or from eligible list of patients admitted to HHC agency who expressed interest. Inclusion criteria: ≥65 years, diagnosed with CHF or COPD, patient either hospitalized two or more times in last 6 months or seen in ER at least twice, willing to learn TH monitoring device Exclusion criteria: physical disability preventing use of TH, cognitive impairment, behavioral issues Consent: Written consent before start of study Data Collection: Daily weight, BP, heart rate, temperature, oxygen saturation transmitted to RN via TH device using encryption Instrument: Honeywell “HomMed” Health Monitoring System, CES-D Scale and PHQ-9 Scale (Depression scores) SF-36 Survey (QOL measurement), Patient Satisfaction Survey (for patient satisfaction scores)</td>
<td>3 months follow-up: TH group showed greater improvement in depression scores on PHQ-9 scale (P&lt;0.005) and CES-D scale (P&lt;0.004) compared to control group: Mean PHQ –9 scores (Baseline/Posttreatment) for TH group: 19.9/10 for usual care group: 15.2/13.6 Mean CES-D scores (Baseline/Posttreatment) for TH group: 14.9/7.4 for usual care group: 19.5/11.5</td>
<td>-Examined the variable of patient motivation for behavioral change Limitations: -Unclear which aspect tele-HEART (TH or protocol) impacted the results -Relationship between TM care coordinator and the patients was not studied.</td>
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<td>Data Analysis: t-tests, chi-square tests, random effects regression model (RERM)</td>
<td>points vs. 0.5 points) (P&lt;0.016) and social functioning (improvement by 9.9 points vs 1.6 points) (P&lt;0.014), but not bodily pain (improvement in 2.5 points vs 1.9 points)</td>
<td>Both groups were equally satisfied with the care they received 12 month follow-up -control group had 75% (P=0.03) more visits to the ED than TH group -TH group had fewer hospitalization days (7.5 days) than control group (10.5 days), but the relationship is not significant (P=0.06)</td>
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USE OF TELEHEALTH


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<thead>
<tr>
<th>APA reference</th>
<th>Problem statement</th>
<th>Purpose or Specific aims</th>
<th>Research Question or Hypothesis and Key concepts or variables under investigation</th>
<th>Theoretical/conceptual framework</th>
<th>Research Tradition; Research Type</th>
<th>Setting, Population (sample), Sampling Plan, Inclusion/exclusion criteria, Informed consent, Data collection procedures, Instruments used to measure data, and Data analysis</th>
<th>Results or Findings (include descriptive and inferential statistics)</th>
<th>Limitations of the study (stated by author(s) and Recommendations for further study)</th>
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<tr>
<td>Study 4</td>
<td>About 500,000 veterans are diagnosed with diabetes nationally, and about 28% of that population has unfavorable glycemic control with A1C levels ≥8%. Increased abnormal A1C levels are related to cardiovascular diseases and morbidity and mortality.</td>
<td>To compare the efficacy of home telemonitoring with active care medication management by an APN (ACM+TH) with a lower-intensity care coordination intervention (CC) consisting of monthly telephone contact with a diabetic nurse</td>
<td>There will be a greater reduction in A1C levels in both 3 and 6 month follow-up for the ACM+TH group than the CC group.</td>
<td>Variables IV: use of active care medication management in combination with TH</td>
<td>DV: A1C levels</td>
<td>Setting: subjects’ homes/VA Pittsburg Healthcare System (VAPHS) &lt;br&gt;Sample: 137 Veterans with with A1C levels ≥ 7.5% &lt;br&gt;Sampling Plan: Recruited from VAPHS electronic medical and pharmacy records, approved by primary care providers &lt;br&gt;Inclusion criteria: at least 1 visit in primary care clinic between 6/1-12/31 2005, received pharmacological treatment for diabetes for ≥12 months, no referral to the Diabetic Clinic in past 18 months, A1C ≥ 7.5%, &lt; 80years of age &lt;br&gt;Exclusion criteria: &lt;6 months of life expectancy, participant in another study, resident of an institutional setting, did not have a land based analog line &lt;br&gt;Consent: Written consent before start of study &lt;br&gt;Data Collection: Participants sent blood glucose levels, BP, and weight daily to APN for review. Participants also presented to VAPHS at baseline, 3 month, and 6 month follow-up to measure A1C levels. &lt;br&gt;Instrument: Viterion 100 Monitor, DCA 2000 analyzer (to test A1C levels) &lt;br&gt;Data Analysis: 0.05-level two-sided test, t-test, Pearson correlations, mean and difference</td>
<td>3 months follow-up: &lt;br&gt;-Lower A1C levels in ACM + TH group than CC group (1.7% vs 0.7% (P&lt;0.001) &lt;br&gt;6 month follow-up: &lt;br&gt;-Lower A1C levels in ACM + TH group than CC group (1.7% vs 0.8% (P&lt;0.001) &lt;br&gt;-20.3% of ACM+TH and 5.5% of CC participants achieved A1C &lt;7% (P&lt;0.01) -LDL levels were decreased by 79.7% in ACM+TH and 59.4% in CC (P=0.02) -More ACM+TH than CC participants reached A1C levels of &lt;8% and &lt;9% at both 3 and 6 month</td>
<td>-TH nurses nor the participants were blinded &lt;br&gt;-Use of only one provider in the study &lt;br-Unclear if improved A1C levels are cause of education, medication</td>
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| Study 5 Duke, 2005 | The older population (>65 years) is expected to double by the year 2030. This patient population will require increased access to healthcare resulting in increased consumption of healthcare resources. New models of | To investigate the effects of community-based case management composed of TH technology for the frail elderly population and what effect this would have on healthcare utilization among this | The use of TH technology in addition to face-to-face nursing encounters will allow earlier identification of health-related outcomes, an overall decrease in ED visits, hospital admissions, and LOS, and reduction of health costs for this population compared to only receiving face-to-face nursing encounters. | N/A | Quantitative Retrospective Matched cohort study, Quasi-experimental design | Setting: subjects’ homes Sample: 107 elderly residents aged ≥65 years of Pitt County, N.C. Sampling Plan: Recruited convenience sample who received care at the BSOM Geriatric Clinic and were identified by the primary care provider as individuals who would benefit from intense monitoring Inclusion criteria: >65 years and older, reside in private home or in assisted living facility (ALF) in Pitt County, receive healthcare at BSOM Geriatric Clinic Exclusion criteria: cognitive impairment or enrolled in hospice care Consent: Written Data Collection: past medical records that contained inpatient and outpatient data, face to face nursing assessments, TH assessments consisting of transmitted daily values of BP, HR, weight, blood glucose, oxygen saturation, costs of healthcare | The TH group had a 54% reduction in ED visits, 36% reduction in ED costs, 69% reduction in hospital admissions, 60% reduction in hospital costs, and 64% reduction in hospital LOS (P<0.05) | Recommendations -Limit study in only an ALF and study the impact of providing education to ALF staff on disease processes in addition to providing TH. Study the impact of each of these interventions on patient outcomes. Limitations: -Regression to the mean of healthcare use. -Selection bias since sample was not randomized. -Study not limited to a specific diagnosis,
### USE OF TELEHEALTH

| care must be evaluated for cost-effective delivery of care. | population group. | DV: ED visits, hospital admissions, LOS, health costs | services participants used Instrument: Logician database Data Analysis: logistic regression analysis, ordinary least squares regression analysis, 2 tailed tests, SAS version 8.0 | on average participants had 12 diagnoses. Unclear if the outcomes are impacted by TH or nursing visits or a combination of both interventions |
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Informed Consent Form

I understand I am being asked to participate in a research study conducted by a Wright State University’s graduate student. The study conducted will evaluate if the use of a medical technology called telehealth will help in lowering the amount of times a patient with a heart failure problem gets sent to the hospital. The study will also look at if this technology can lower the number of days the patient spends in the hospital.

I realize I was chosen as a possible participant for this study because the homecare company I am using for healthcare services is trialing a new technology to see if the technology is beneficial to those who have heart failure.

If I agree to participate in the study, I understand that I will record my blood pressure, heart rate, oxygen level, and weight every day at home using the telehealth device for six months. Along with those recordings, I also will respond to simple yes/no questions on the device which ask about my heart failure condition every day. The above stated procedure will take me about 5-10 minutes every day. The results will be sent to the nurse without any identifying information using my telephone line connection. I will be taught by a nurse on how to use the device. The device will be kept in a safe place for the entire duration of the study. If I have any questions or concerns about the device or my health, I will contact the nurse for help. There are no possible risks in this study. The benefit that will be gained is the close monitoring of my disease condition by a trained nurse. I will receive $40 for completing this study.

I realize the information collected in the study will be kept confidential. However, the information may be shared in nursing journals to help other providers to establish better practices. If this happens, specific identifying information will not be made known.

I understand that my participation in this study is completely voluntary and there will be no penalties if I choose to withdraw at any time during the study period. I will be offered the alternate treatment of the usual homecare services at that time. I will continue to be treated and respected in the same way.

If I need to, I can contact Dr. Mary Beth Kaylor, Ph.D. at Wright State University, School of Nursing, at any time during the study at (937) 775-3848 or via email at marybeth.kaylor@wright.edu.

This study has been explained to me in detail and all my questions have been answered. I have read and understand the information on this consent form. I agree to participate in this study.

_______________________________________  __________________________
Signature of Participant                          Date

_______________________________________  __________________________
Signature of Witness                             Date

_______________________________________  __________________________
Signature of Investigator                        Date
Illustration of Honeywell “HomMed” Health Monitoring System

(HomMed, 2011)
**CITI Training Certificate**

**CITI Collaborative Institutional Training Initiative**

Human Research Curriculum Completion Report
Printed on 1/20/2013

**Learner:** Roshini Mathew (username: roshini914)

**Institution:** Wright State University

**Contact Information** Phone: 6148935407
Email: roshinitpunjabi@gmail.com

**Social/Behavioral Investigator:**

**Stage 1. Basic Course Passed on 01/20/13 (Ref # 9517404)**

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<td>7/10 (70%)</td>
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<td>History and Ethical Principles - SBR</td>
<td>01/18/13</td>
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<tr>
<td>Defining Research with Human Subjects - SBR</td>
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<td>The Regulations and The Social and Behavioral Sciences - SBR</td>
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For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator
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References


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Wilson, J. F. (2003). The crucial link between literacy and health. *Annual Internal Medicine, 139*(1), 875-878.