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IMPACT OF STANDALONE PERSONAL HEALTH RECORD USE ON CLINICAL OUTCOMES OF PATIENTS WITH TYPE 2 DIABETES: AN INTERVENTION MIXED METHODS STUDY

by

Kevin T. Fuji

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IMPACT OF STANDALONE PERSONAL HEALTH RECORD USE ON CLINICAL OUTCOMES OF PATIENTS WITH TYPE 2 DIABETES: AN INTERVENTION MIXED METHODS STUDY

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University of Nebraska, 2013

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The purpose of this study was to assess the impact of using an online personal health record (PHR) on clinical outcomes of patients with type 2 diabetes. This study used an intervention mixed methods approach with a quantitative randomized, controlled trial combined with a qualitative exploration of how patients used the PHR. A total of 140 participants with type 2 diabetes were randomized to either receive a PHR and training to use the PHR, or to a control group who received usual care. Both clinical and social cognitive outcomes were measured and compared at baseline and follow-up, three to six months after baseline. A linear regression was also used to model the relationship between PHR use, social cognitive factors, and hemoglobin A1c (HbA1c). The quantitative analysis revealed no differences in diabetes clinical outcomes (HbA1c or blood glucose) from baseline to follow-up between either the control and intervention groups, or within the intervention group, between individuals who continued to use the PHR after baseline (PHR users) and individuals who ceased use after baseline (PHR non-users). Additionally, the linear regression revealed no significant relationships between PHR use, social cognitive factors, and HbA1c. In-depth interviews were conducted with all members of the intervention group to explore how patients used the PHR in their

diabetes self-management. Themes that emerged from the qualitative analysis were used to explain quantitative findings and identify continued research gaps that must be addressed in future research. Nine themes emerged from the qualitative analysis, seven of which expressed barriers that helped to explain the lack of quantitative difference between the groups. The additional two themes identified positive outcomes from PHR use that support hypothesized benefits from PHR use. Future research should focus on the integration of the PHR into patients' regular diabetes self-care routine and identifying which features of the PHR have the potential to lead to clinical improvement.

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IMPACT OF STANDALONE PERSONAL HEALTH RECORD USE ON CLINICAL OUTCOMES OF PATIENTS WITH TYPE 2 DIABETES: AN INTERVENTION MIXED METHODS STUDY

Chapter 1: Introduction

Diabetes is the seventh leading cause of death in the United States, and continues to be the leading cause of kidney failure, non-traumatic lower-limb amputations, and new cases of blindness (Centers for Disease Control and Prevention (CDC), 2011). There are currently 18.8 million Americans diagnosed with diabetes, with 40.3 million Americans (15.4% of the population) projected to have the disease by 2021 (CDC, 2011). This will increase annual health care spending for diabetes from $206 billion to $512 billion (CDC, 2011).

Despite the demonstrated efficacy of medical therapy in prevention of diabetes-related complications, most patients with type 2 diabetes mellitus cared for in the community do not reach recommended treatment goals for glycemic, blood pressure, or low-density lipoprotein cholesterol (LDL-C) control established by the American Diabetes Association (Casagrande, Fradkin, Saydah, Rust, & Cowie, 2013; Saadine et al., 2002; Saydah, Fradkin, & Cowie, 2004; UK Prospective Diabetes Study Group, 1998a; UK Prospective Diabetes Study Group, 1998b). Teaching patients to monitor their diabetes risk factors, increasing patients' knowledge about diabetes, and empowering them to collaborate with their physicians have been demonstrated to improve clinical outcomes (Anderson et al., 1995; Berikai et al., 2007; Heisler, Piette, Spencer, Kieffer, & Vijan, 2005; Rachmani, Levi, Slavachevski, Avin, & Ravid, 2002). Older trials have

attempted to accomplish these goals through the use of patient-carried paper reminder cards and mini-records designed to help patients track the results of their care (Dickey & Petitti, 1992; Turner, Waivers, & O'Brien, 1990). More recently, studies have used electronic tools to provide patients with personalized hemoglobin A1c (HbA1c) reports, glucose monitoring systems, and web-based case management (Cho et al., 2006; Levetan, Dawn, Robbins, & Ratner, 2002; McMahon et al., 2005). In particular, personal health records (PHRs) have emerged as an innovative tool to empower patients to take an active role in their own health management (Tang, Ash, Bates, Overhage, & Sands, 2006).

The Personal Health Record

The PHR is nationally-recognized as an electronic tool to facilitate patient self-management of their health information, and subsequent sharing and exchange of that information with health care providers (Tang et al., 2006). While there are many formal definitions of a PHR, what is common across all definitions is that the PHR is electronic, controlled by the patient, used for health information management, and should be secure and private (Fuji et al., 2012). The PHR facilitates the existing interest by patients in tracking their personal health data, including self-treatments such as non-prescription medications and nutritional supplements, and self-monitoring results about health maintenance or progress (e.g. minutes exercised or weight loss) (Harris Interactive, 2004; Markle Foundation, 2003). The PHR is expected to be a key component of the patient-provider information network because it is patient-controlled and may contain information that is not available in the provider-based record (e.g. self-care behaviors, use of non-prescription medications or herbal supplements, etc.). The PHR should provide a comprehensive view of the patient's past and current medical history, including

treatment and care given by multiple providers (including non-traditional individuals such as herbalists), throughout the patient's life.

There are a wide range of diverse PHR architectures and functions, ranging from "standalone" PHRs that do not integrate with any other electronic systems, to "tethered" PHRs that connect with a patient's health care organization or health insurer (Tang et al., 2006). Tethered PHRs are expected to become increasingly used by patients as these types of PHRs are often connected to electronic health records (EHRs). The "Meaningful Use" program, which has provided economic incentives to health care systems and providers to adopt and use EHRs, is designed to increase quality and safety of patient care through universal provider access to comprehensive patient information (Hillestad et al., 2005). However, while this national initiative may lead to increased adoption of tethered PHRs, standalone PHRs will still be needed by patients whose provider does not utilize an EHR.

Regardless of architecture type, PHR use has been advanced as a strategy to facilitate improvements in diabetes self-management and achieve treatment goals (Grant et al., 2006; Hess et al., 2007; Osborn, Mayberry, Mulvaney, & Hess, 2010. PHRs have the potential to enhance patient health knowledge, allow patients to better manage their medical conditions, and empower patients to become more involved in their care and share in decision-making with their providers, ultimately leading to better health outcomes (Nagykaldi, Aspy, Chou, & Mold, 2012; Solomon, Wagner, & Goes, 2012; Tang et al., 2006; Wagner et al., 2012). Studies have also shown that patients believe the use of a technology such as a PHR will enable their health care providers to gain easier access to their health information, and will open channels of communication with other

health care providers and entities (Ball, Smith, & Bakalar, 2007). It is even estimated that PHR use can result in health care cost savings. A cost-benefit analysis of PHR use over 10 years demonstrated that although all PHR architectures have initial negative value, PHR use could yield annual savings of $13-21 billion per year (Kaelber & Pan, 2008). The promise of PHRs holds particular value for patients with chronic conditions such as diabetes, who have complex health needs; taking multiple medications and performing a variety of self-care behaviors to manage their condition(s) (Kaelber, Jha, Johnston, Middleton, & Bates, 2008; Solomon et al., 2012; Tang et al., 2006).

Despite these proposed benefits, it is estimated that only 10% of the consumers in the United States are using a PHR (Keckley & Coughlin, 2012). It has been proposed that cost, concerns that information is not private or protected, inconvenience, design shortcoming and inability to share information across health care systems and organizations are potential barriers to PHR adoption and use (Kahn, Aulakh, & Bosworth, 2009). However, many of these barriers are purely theoretical as there have been limited studies examining barriers experienced by actual PHR users. Additionally, there has been limited research examining the impact of PHR use on clinical outcomes of chronic conditions amongst PHR users, and the studies that have been conducted have demonstrated inconsistent findings (Grant et al., 2006; Wagner et al., 2012).

Studies Examining the Impact of a PHR on Clinical Outcomes of Diabetes

To date, five studies have examined the use of a PHR (either alone or in combination with other interventions) and its impact on diabetes clinical outcomes, with mixed results.

Grant et al (2008) randomized 244 patients from 11 primary care practices into two tethered PHR groups (126 patients in the intervention group and 118 patients in the control group). Intervention practices received access to a diabetes-specific PHR that allowed patients to view their clinical and medication-related information; provided patient-tailored decision support; and enabled the patient to author a "Diabetes Care Plan" for electronic submission to their physician prior to upcoming appointments. Control practices received a PHR that allowed patients to update and submit family history and health maintenance information. After one year, there was no difference in HbA1c improvement between the intervention group (Δ = -0.16%) and the control group (Δ = -0.26%) (p = .62).

Ralston et al (2009) randomized 83 patients to receive either web-based case management for diabetes along with access to a tethered PHR, or to usual care. A total of 74 patients completed the study (39 in the intervention group and 35 in the control group). After one year, HbA1c improved significantly in the intervention group compared to the control group (Δ = -0.7%, p = .01). However, the researchers were unable to determine to what extent the PHR specifically contributed to this change.

Holbrook et al (2009) studied the impact of a tethered PHR with an automated telephone reminder system on diabetes quality of care. The PHR contained a personalized diabetes tracker with identified treatment goals, and the telephone reminder system was used to remind patients of upcoming laboratory and physician visits. The researchers randomized 511 patients to receive the intervention (n = 253) or to a control group (n = 258). After six months, the intervention group had demonstrated a small but significant decrease in HbA1c compared to the control group (Δ = -0.2%, p = .029).

Similar to the study by Ralston et al (2009), the researchers were unable to determine to what extent the PHR specifically contributed to this change.

Johnson & Singal (2006) examined the impact of a web-based health management system (which included a PHR) on diabetes quality of care outcomes in 254 patients (91 in the intervention group and 163 in the control group). The health management system provided patients with a personalized diabetes report card outlining treatment goals and progress toward achieving those goals, and also provided this information electronically to the patient's health care provider. After six months, patients in the intervention group saw their HbA1c improve significantly ($\Delta = -0.8\%$, $p = .039$) compared to the control group ($\Delta = +0.4\%$, $p = .498$).

Tenforde et al (2012) conducted an observational study of patients with diabetes who used a tethered PHR with a secure messaging component and health reminders, compared to a control group of non-users. A total of 4,036 patients were PHR users with 6,710 patients comprising the control group. After one year, patients who were PHR users demonstrated a lower HbA1c compared to patients who were not users ($p < .01$). However, as an observational study, the researchers could not make causal claims about PHR use and diabetes control.

Current Gaps in the Literature

Given the limited number of studies examining the impact of PHRs on diabetes outcomes and the difficulty in assessing the relative impact of PHRs compared to interventions it is often combined with, there is a need for further evaluation of the effectiveness of PHRs in patients with diabetes and an exploration of the unique contribution of PHRs. Additionally, a focus should be placed on studying standalone

PHRs. While tethered PHR adoption is increasing as EHRs are being adopted at a rapid rate, it is estimated that approximately 50% of physician offices and 20% of eligible hospitals still do not have EHRs, making further research on standalone PHRs an imperative (Kaelber et al., 2008; U.S. Department of Health and Human Services, 2013).

Given the limited number of patients who have adopted a PHR, it is clear that health care is in an early phase of PHR use. Thus, there is an opportunity to better understand the perceived value and challenges of PHR use from actual users (Kaelber et al., 2008). There are few prospective studies designed to identify factors leading to sustained PHR use and barriers that lead to ineffective or non-use (Archer, Fevrier-Thomas, Lokker, McKibbon, & Strauss, 2011; Kaelber et al., 2008; Ralston, Coleman, Reid, Handley, & Larson, 2010; Tenforde, Nowacki, Jain, & Hickner, 2012; Wagner et al., 2012). A major question encompassing many of these issues is: How do patients engage with a PHR? The proposed research will help to address above described gap in knowledge about the role PHRs play in diabetes-specific outcomes.

Study Purpose and Research Questions

The purpose of this study was to quantitatively assess the impact of a standalone PHR on clinical outcomes of patients with type 2 diabetes, qualitatively explore how patients with type 2 diabetes use a PHR to manage their diabetes-related health information for self-care, and use qualitative results to explain the quantitative findings. This will be accomplished through the following research aims:

> Quantitative Research Question: How does the use of a standalone PHR impact the clinical outcomes achieved in patients with type 2 diabetes compared to patients who use other methods of health information tracking?

Qualitative Research Question: How do patients with type 2 diabetes describe their use of a standalone PHR for managing their diabetes-related health information, including barriers to use and strategies for overcoming those barriers?

Mixed Methods Research Question: How does the way in which patients with type 2 diabetes use the standalone PHR explain the impact of the standalone PHR on clinical outcomes of patients with type 2 diabetes?

Chapter 2: Methods

Research Design

This comparative effectiveness pilot study utilized an intervention mixed methods study design, combining a randomized, controlled trial (quantitative component), with follow-up in-depth interviews (explanatory qualitative component) (see Figure 2.1). It compared the effect of a PHR vs. traditional means of personal health information record-keeping in achieving recognized clinical diabetes outcomes (primary outcome: change in HbA1c). This study was approved by the Creighton University Institutional Review Board (IRB #09-15470).

Intervention mixed methods design. An intervention mixed methods design occurs in two phases, a primary quantitative phase that emphasizes the importance of statistical tests, examination of relationships between variables, and cause-and-effect (often typified through the conduction of a randomized controlled trial); and a qualitative phase designed to explain the results of the quantitative phase (Creswell & Plano Clark, 2011; Song, Sandelowski, & Happ, 2010). The quantitative phase takes priority over the qualitative phase, and quantitative data is collected and analyzed independently of

qualitative data. The qualitative phase of the study is then conducted; collecting and analyzing the qualitative data. Mixing of the data occurs during the data interpretation, after both the quantitative and qualitative data has been collected and analyzed. Qualitative findings are used to provide a deeper explanation for the quantitative results.

Song, Sandelowski, and Happ (2010) identified limitations with the use of a randomized controlled trial when studying socially complex interventions, which may necessitate the use of an intervention mixed methods design. Socially complex interventions are ones that are defined as having a large number of interacting parts; require complex behaviors for researchers providing the intervention and for participants engaging with the intervention; and a large number of different types of target outcomes resulting from intervention use (Craig et al., 2008). Limitations to the randomized controlled trial in socially complex interventions include: 1) it is difficult to conduct a truly rigorous randomized controlled trial with random sampling and assignment, mutually exclusive study groups, and double blinding; 2) by definition, socially complex interventions are difficult to control and standardize, so the process of randomization itself may introduce a variable that impacts internal validity; and 3) it is difficult to generalize the results of a randomized controlled trial which is typically conducted in well-controlled settings, to understand the effectiveness of the intervention in a complex real-world setting (Song et al., 2010).

Understanding these limitations, and identifying the PHR as a socially complex intervention, an intervention mixed methods design was chosen for this study. While it is acknowledged that statistical changes in clinical outcomes are important because they can identify important relationships between variables and degrees of change, they are

incomplete on their own. The addition of a complementary qualitative exploration to identify and explain reasons for the change (or non-change) is necessary (Creswell & Plano Clark, 2011). This is particularly useful in the study of the PHR, a technology with limited evidence about its impact on clinical outcomes. In this case, having a qualitative component also allows the researcher to explore a complex technology more in-depth and generate research questions for future study.

Theoretical Framework

A conceptual framework utilizing Bandura's social cognitive theory (SCT) in health promotion was used to guide this study (Bandura, 1998). Three study concepts were identified (modifying factors, diabetes knowledge, and self-efficacy) and then mapped to SCT concepts: modifying factors = outcome expectations + perceived facilitators; diabetes knowledge = knowledge; and self-efficacy = self-efficacy + goals. Modifying factors encompass perceived barriers which may interfere with managing diabetes care; and diabetes education and social support to assist patients in achieving optimal management of their diabetes. Diabetes knowledge focuses on patients' understanding of their condition and the improvements that can result from self-care behaviors. Finally, self-efficacy is crucial as a patient with a high-degree of self-efficacy is more likely to engage in beneficial self-care behaviors compared to a patient with a low-degree of self-efficacy due to their confidence in being able to impact and change their diabetes self-management.

Within this framework, adoption and use of a PHR is hypothesized to have multiple effects. The PHR provides a tool for patients to systematically track their health information. Through the tracking of this information patients have the opportunity to

become more knowledgeable about their diabetes outcomes, recommended self-care behaviors, and how their actions can directly impact their outcomes or disease management (e.g. changes in blood glucose levels over time). Observing positive changes resulting from improved self-care behaviors enhances patients' confidence in their ability to self-manage their diabetes care and results in higher levels of self-efficacy. Thus, it is hypothesized that there is a linear relationship between PHR use, social cognitive factors, and improved HbA1c.

Study Setting

This study was conducted in three clinics located in a metropolitan, Midwest city. These three clinics consisted of two internal medicine practices and one endocrinology practice. There are 13 practitioners at the clinic who provide regular diabetes care for patients (11 internal medicine physicians, 1 endocrinologist; 1 nurse practitioner).

Participant Recruitment

Medical record review was used to identify patients meeting the inclusion criteria: a diagnosis of type 2 diabetes with a hemoglobin A1c (HbA1c) value of ≥6.0, no concurrent diagnosis of impaired cognitive function (e.g. dementia), and English-speaking. Eligible patients were contacted via phone or met in-person immediately prior to their provider visit. The study was described to patients who were asked to self-report if they had access to a computer and felt comfortable using a computer. Those responding positively and were interested in participating provided informed consent and were enrolled in the study. Participants were randomized to either the control group, who continued to receive usual care, or the intervention group, who were signed up for and trained on the use of an online PHR to manage their diabetes-related health information.

Study Intervention

PHR selection followed a four step process: 1) identification of standalone PHRs that were free-of-charge and web-based; 2) identification of features that patients most desired in a PHR using an in-depth literature review; 3) creation of a checklist for evaluation of the identified PHRs; and 4) PHR evaluation using the checklist. This process resulted in the selection of Microsoft HealthVault© as the study PHR. An in-depth description of this process was published (Fuji et al., 2012). While there are a number of PHRs that are fee-for-use, a free-of-charge PHR was chosen under the assumption that with the large number of PHRs available, patients were likely to select a PHR that does not incur personal expense.

The Microsoft HealthVault PHR can be accessed online at: http://www.healthvault.com. It allows users to enter in a wide range of health information from laboratory values to self-care behaviors. Users can produce a visual graph of this information to track their progress over time. Users can also choose to share selected pieces of health information with others of their choosing (e.g., their physician or a family member). The PHR also has the ability to connect with a limited number of glucometers, allowing users to upload their blood glucose readings directly into the PHR, and to connect with some health-related applications. The PHR does not provide any customized information to the individual and cannot be personalized in any way for use.

Data Collection Tools

Diabetes Care Survey. The Diabetes Care Survey was constructed as a hybrid instrument by: a) extracting relevant questions from previously-validated instruments; b)

using an unpublished instrument measuring knowledge of medical conditions and prescription medications; and c) developing new items.

Three existing instruments were identified that were relevant to the study aims: the Diabetes Care Profile, Diabetes Attitude Scale, and Diabetes Empowerment Scale (Anderson, Fitzgerald, Funnell, & Grupen, 1998; Anderson, Funnell, Fitzgerald, & Marrero, 2000; Fitzgerald et al., 1996). Three researchers jointly reviewed each instrument and identified items that matched the study's conceptual framework. The researchers included a nurse, pharmacist, and clinical endocrinologist who provided content validity for the identified items. A total of 79 items were selected from the Diabetes Care Profile, 13 items from the Diabetes Attitude Scale, and 13 items from the Diabetes Empowerment Scale. An additional 2 items were added from a previously unpublished instrument measuring disease and medication knowledge, and 20 new items were developed to fill in concept gaps. This process resulted in a 127-item survey. Twenty-four items measured modifying factors; 32 items measured diabetes knowledge; 44 items measured self-efficacy; and the remaining 27 items addressing various self-care behaviors, access to care, and demographics.

Medical record abstraction. A medical record abstraction sheet was developed to manually collect the following information from participants' medical records: reason for the clinic visit; gender; age; year of diabetes diagnosis; weight; height; body mass index; most recent HbA1c value; most recent blood pressure; most recent blood glucose reading; most recent low-density lipoprotein, high-density lipoprotein, and triglyceride readings; most recent serum creatinine level; presence of diabetes-related complications (retinopathy, nephropathy, chronic renal failure, neuropathy, hypoglycemia

unawareness); list of current medical conditions; list of current medications; presence of diagnosed depression; date of last foot examination; date of last eye examination; date of last influenza vaccine; date of last pneumococcal vaccine; smoking status; alcohol consumption; and any other notes relevant to the participant's diabetes care.

Though the study will only analyze differences in HbA1c and blood glucose, collecting all of the clinical measures provides data for sub-analyses that will be necessary to build a more robust overall model for PHR use behavior that can be used in future studies. In addition, all of this data is collected as a standard of care for patients with diabetes.

Interview protocol. An interview protocol was developed to explore use of the PHR by participants in the intervention group (Creswell, 2013). The central question guiding the interview was, *"How have you used the PHR to manage your diabetes-related health information?"* Questions were designed to gain a deeper understanding of the following topics: what the PHR was used for; how it fit into the participant's life; the most useful aspects of the PHR; barriers to PHR use and strategies employed to overcome these barriers; how PHR use has changed diabetes self-care; how PHR use has changed the relationship with their diabetes care provider; and how PHR use has changed the way they track and manage their health information. The interview protocol was pilot-tested with five individuals, all of whom had either diabetes or another chronic condition. Changes were made to the protocol to clarify confusing phrasing and allow the interviewee to share additional information not explicitly solicited by the interviewer.

Data Collection Process

Baseline. All participants completed the Diabetes Care Survey and had data abstracted from their medical record once their diabetes care provider completed entering the care note for the patient's visit in the clinic's EHR.

Participants in the intervention group received hands-on training for using the PHR. A step-by-step instruction manual was created to guide the PHR training and was provided to participants for personal use. It included screenshots from the PHR with accompanying written instructions guiding users through the process of signing up for the PHR and using it to maintain diabetes-related health information. During training, the participant controlled a laptop computer while a researcher or research assistant provided instruction on using the PHR. Participants were required to demonstrate the ability to enter the following information: birthdate, height, weight, medical condition(s), medication(s), blood glucose, blood pressure, HbA1c, low-density lipoprotein (LDL) cholesterol, and dates of last eye and foot exams. During the PHR training, field notes were recorded about difficulties participants experienced or comments that provided insight into their perspective and behaviors towards diabetes self-care. Participants were not directed to use the PHR in any specific way, but were given instructions to use it as needed to help manage their diabetes-related health information.

Follow-up. Follow-up visits were conducted 3-6 months after the baseline visit, corresponding to typical intervals for diabetes care visits (American Diabetes Association, 2013). All participants again completed the Diabetes Care Survey and had data abstracted from their medical record once their diabetes care provider completed entering the care note for the patient's visit in the clinic's EHR.

All participants in the intervention group completed interviews, guided by the interview protocol. This purposeful sampling procedure was used to ensure that the number of interviews conducted would greatly exceed the typical number needed to reach data saturation across qualitative designs (Patton, 2001; Sandelowski, 1995). If a participant was not available immediately after their visit, the researcher or a research assistant conducted the interview over the telephone at a time mutually convenient to both the participant and the researcher.

Data Analysis

Quantitative data analysis. Quantitative data was analyzed using descriptive statistics for demographics, clinical outcomes, and social cognitive outcomes (both independent samples and paired t-tests to compare continuous variables and chi-square to compare categorical variables). Due to the relatively small sample size, some demographic variables were dichotomized to allow for direct statistical comparison between both groups. Each of the social cognitive factors was scored by summing participants' responses to the corresponding items for the factor. Higher scores indicated more positive characteristics. The highest possible scores for each of the factors were: 108 for modifying factors, 160 for diabetes knowledge, and 220 for self-efficacy. Additionally, participants in the intervention group were categorized as either "PHR users" or "PHR non-users". PHR use logs were examined, and any patient using the PHR at least once after baseline was classified as a PHR user. A sub-analysis of PHR users and PHR non-users was also conducted to examine differences in clinical and social cognitive outcomes.

A linear regression was also run to determine the relationship between each of the different social cognitive factors, PHR use, and HbA1c using the following model: Effectiveness of care (HbA1c) = PHR use + modifying factors + diabetes knowledge + self-efficacy.

Qualitative data analysis. Two of the study researchers participated in coding and analysis of the qualitative data. The transcripts were analyzed using an iterative approach to data analysis, starting with multiple readings through each transcript to immerse the researcher in the data and gain an overarching perspective of participants' responses (Hsieh & Shannon, 2005). This data immersion also allowed the researchers to engage in reflexivity; reflecting on their own backgrounds and beliefs that could potentially bias their interpretation of participant interviews, and to gain awareness of these biases during the data analysis and interpretation (Creswell, 2013). This was followed by individual coding of each transcript to identify key concepts. Memoing and *in vivo* coding procedures were used to maintain the integrity of the participants' own words and experiences (Miles, Huberman, & Saldana, 2014). During this coding process each researcher referred to field notes from both the PHR training and the interview for each participant to gain additional context beyond the information available solely in the transcripts. Researchers' thoughts and insights were captured in notes made in the transcript margins next to each code. These notes were used for further refinement. Once coding was complete, codes capturing similar ideas were grouped together to develop categories centered on patients' use of the PHR to manage their diabetes-related health information. The two researchers performing the data analysis met to compare categories and resolve differences in interpretation of coding leading to category

formation. The researchers examined and discussed the relationships between the different categories using the central research question as a guiding framework for discussion. Overarching themes emerged from examination of the relationships between categories. Data saturation was achieved, and meaningful quotes were identified that were representative of each theme.

Mixed methods data analysis. Mixing in this study occurred during the data interpretation phase. Qualitative data from patients about their use of the PHR and self-reported behaviors were used to explain the quantitative findings (change in HbA1c).

Chapter 3: Results

A total of 117 participants completed the study, 61 members of the control group and 56 members of the intervention group. The 23 participants who did not complete the study either asked to be removed from the study or did not return for a follow-up diabetes care visit within the study timeframe. A total of 23 participants were classified as PHR users, and 33 participants were classified as PHR non-users.

Quantitative Findings

Demographics. Table 1 displays the demographic characteristics for the overall sample, with no statistically significant demographic differences between the control and intervention groups.

Clinical outcomes for all participants. At baseline, participants' average HbA1c level was 7.69% with the control group having an average HbA1c level of 7.53% and the intervention group having an average HbA1c level of 7.86%. There was no statistically significant difference between groups at baseline for HbA1c level ($p = .301$). At follow-up, participants' average HbA1c level was 7.86% ($\Delta = +0.17\%$), with the

Table 3.1. *Sample Demographics*

Demographic Characteristic	**Overall (N=117)**	**Control Group (n=61)**	**Intervention Group (n=56)**	**P-value**
Age, years	59	59	59	
Years since diagnosis, years	12	11	13.5	.133
Gender, n (%)				
Male	53 (45.3)	32 (52.5)	21 (37.5)	.104
Female	64 (54.7)	29 (47.5)	35 (62.5)	
Race, n (%)				
White	89 (76.1)	47 (77.0)	42 (75.0)	.795
African American or Hispanic	28 (23.9)	14 (23.0)	14 (25.0)	
Marital status, n (%)				
Married	69 (59)	36 (59.0)	33 (58.9)	.992
Single	49 (41)	25 (41.0)	23 (41.1)	
Level of education, n (%)				
Less than college graduate	73 (62.4)	39 (63.9)	34 (60.7)	.719
College graduate	44 (37.6)	22 (36.1)	22 (39.3)	
Income, n (%)				
Less than $70,000	76 (68.5)	40 (69.0)	36 (67.9)	.906
$70,000 or greater	35 (31.5)	18 (31.0)	17 (32.1)	
Employment status, n (%)				
Not currently working	62 (53)	33 (54.1)	29 (51.8)	.802
Currently working	55 (47)	28 (45.9)	27 (48.2)	

control group having an average HbA1c level of 7.75% (Δ = +0.22%) and the intervention group having an average HbA1c level of 7.98% (Δ = +0.12%). There was no statistically significant difference between groups at follow-up for HbA1c level (p = .455). A paired samples t-test revealed no statistically significant change in HbA1c from baseline to follow-up for either the control group (p = .252) or the intervention group (p = .535).

Blood glucose, a more transient measure of diabetes control was also assessed. At baseline, participants' average blood glucose level was 174.9 mg/dL with the control group having an average blood glucose level of 173.7 mg/dL and the intervention group having an average blood glucose of 176.4 mg/dL. There was no statistically significant difference between groups at baseline for blood glucose level ($p = .864$). At follow-up, participants' average blood glucose level was 177.4 mg/dL ($\Delta = +2.5$ mg/dL) with the control group having an average blood glucose of 168.9 mg/dL ($\Delta = -4.8$ mg/dL) and the intervention group having an average blood glucose of 186.9 mg/dL ($\Delta = +10.5$ mg/dL). There was no statistically significant difference between groups at follow-up for blood glucose level ($p = .233$). A paired samples t-test revealed no statistically significant change in blood glucose level from baseline to follow-up for either the control group ($p = .901$) or the intervention group ($p = .397$).

Clinical outcomes for the intervention group. At baseline, participants' average HbA1c level was 7.86% with the PHR users having an average HbA1c level of 7.46% and the PHR non-users having an average HbA1c level of 8.14%. There was no statistically significant difference between groups at baseline for HbA1c level ($p = .204$). At follow-up, participants' average HbA1c level was 7.98% ($\Delta = +0.12\%$), with the PHR users having an average HbA1c level of 7.78% ($\Delta = +0.32\%$) and the PHR non-users having an average HbA1c level of 8.12% ($\Delta = -0.02\%$). There was no statistically significant difference between groups at follow-up for HbA1c level ($p = .546$). A paired samples t-test revealed no statistically significant change in HbA1c from baseline to follow-up for either the PHR users ($p = .338$) or the PHR non-users ($p = .901$).

Blood glucose was also assessed in PHR users and non-users. At baseline, participants' average blood glucose level was 176.3 mg/dL with the PHR users having an average blood glucose level of 151.1 mg/dL and the PHR non-users having an average blood glucose of 193.7 mg/dL. There was no statistically significant difference between groups at baseline for blood glucose level ($p = .072$). At follow-up, participants' average blood glucose level was 170.2 mg/dL ($\Delta = -6.1$ mg/dL) with the PHR users having an average blood glucose of 156.5 mg/dL ($\Delta = +5.0$ mg/dL) and the PHR non-users having an average blood glucose of 208.2 mg/dL ($\Delta = -14.5$ mg/dL). There was a statistically significant difference between groups at follow-up for blood glucose level ($p = .022$). However, a paired samples t-test revealed no statistically significant change in blood glucose level from baseline to follow-up for either the PHR users ($p = .507$) or the PHR non-users ($p = .525$).

Social cognitive outcomes for all participants. At baseline, participants' average score for modifying factors was 79.2 (out of a possible 108) with the control group having an average score of 81.8 and the intervention group having an average score of 76.4. There was no statistically significant difference between groups at baseline for modifying factors ($p = .334$). At follow-up, participants' average score for modifying factors was 81.7 ($\Delta = +2.5$) with the control group having an average score of 80.3 ($\Delta = -1.5$) and the intervention group having an average score of 83.3 ($\Delta = +6.9$). There was no statistically significant difference between groups at follow-up for modifying factors score ($p = .138$). A paired samples t-test revealed no statistically significant change in modifying factors score from baseline to follow-up for either the control group ($p = .274$) or the intervention group ($p = .238$).

At baseline, participants' average score for diabetes knowledge was 133.1 (out of a possible 160) with the control group having an average score of 133.6 and the intervention group having an average score of 132.6. There was no statistically significant difference between groups at baseline for diabetes knowledge ($p = .638$). At follow-up, participants' average score for diabetes knowledge was 134.6 ($\Delta = +1.5$) with the control group having an average score of 134.1 ($\Delta = +0.5$) and the intervention group having an average score of 135.2 ($\Delta = +2.6$). There was no statistically significant difference between groups at follow-up for diabetes knowledge score ($p = .595$). A paired samples t-test revealed no statistically significant change in diabetes knowledge score from baseline to follow-up for either the control group ($p = .695$) or the intervention group ($p = .098$).

At baseline, participants' average score for self-efficacy was 166.9 (out of a possible 220) with the control group having an average score of 165.9 and the intervention group having an average score of 167.9. There was no statistically significant difference between groups at baseline ($p = .497$). At follow-up, participants' average score for self-efficacy was 167.9 ($\Delta = +1.0$) with the control group having an average score of 167.4 ($\Delta = +1.5$) and the intervention group having an average score of 169.0 ($\Delta = -1.1$). There was no statistically significant difference between groups at follow-up for self-efficacy score ($p = .627$). A paired samples t-test revealed no statistically significant change in self-efficacy score from baseline to follow-up for either the control group ($p = .367$) or the intervention group ($p = .701$).

Social cognitive outcomes for the intervention group. At baseline, participants' average score for modifying factors was 76.4 (out of a possible 108) with

the PHR users having an average score of 83.4 and the PHR non-users group having an average score of 71.5. There was no statistically significant difference between groups at baseline for modifying factors ($p = .298$). At follow-up, participants' average score for modifying factors was 83.2 ($\Delta = +6.8$) with the PHR users having an average score of 85.6 ($\Delta = +2.2$) and the PHR non-users group having an average score of 81.6 ($\Delta = +10.1$). There was no statistically significant difference between groups at follow-up for modifying factors score ($p = .151$). A paired samples t-test revealed no statistically significant change in modifying factors score from baseline to follow-up for either the PHR users ($p = .136$) or the PHR non-users ($p = .306$).

At baseline, participants' average score for diabetes knowledge was 132.6 (out of a possible 160) with the PHR users having an average score of 134.0 and the PHR non-users having an average score of 131.7. There was no statistically significant difference between groups at baseline for diabetes knowledge ($p = .490$). At follow-up, participants' average score for diabetes knowledge was 135.2 ($\Delta = +2.6$) with the PHR users having an average score of 135.7 ($\Delta = +1.7$) and the PHR non-users having an average score of 134.8 ($\Delta = +3.1$). There was no statistically significant difference between groups at follow-up for diabetes knowledge score ($p = .770$). A paired samples t-test revealed no statistically significant change in diabetes knowledge score from baseline to follow-up for either the PHR users ($p = .575$) or PHR non-users ($p = .063$).

At baseline, participants' average score for self-efficacy was 167.9 (out of a possible 220) with the PHR users having an average score of 170.8 and the PHR non-users having an average score of 165.9. There was no statistically significant difference between groups at baseline ($p = .245$). At follow-up, participants' average score for self-

efficacy was 169.0 (Δ = +1.1) with the PHR users having an average score of 174.8 (Δ = +4.0) and the PHR non-users having an average score of 164.9 (Δ = -1.0). There was a statistically significant difference between groups at follow-up for self-efficacy score (p = .027). However, a paired samples t-test revealed no statistically significant change in self-efficacy score from baseline to follow-up for either the PHR users (p = .083) or the PHR non-users (p = .359).

Linear regression model. A linear regression was conducted to model the relationship between the social cognitive factors, PHR use, and the primary outcome variable of HbA1c. This analysis resulted in the following regression equation:

$$\text{HbA1c'} = 10.813 + (.224)\text{PHR use} + (.007)\text{Modifying factors} + (-.027)\text{Diabetes knowledge} + (-.002)\text{Self-efficacy}$$

R^2 = .035, and none of the social cognitive factors or the use of the PHR was a significant contributor to predicted HbA1c. Regression data for the model is presented in Table 2.

Qualitative Findings

Qualitative data analysis yielded nine themes that reflect the mixed experiences of participants in the intervention group with PHR use. The positive themes were: complete and accessible record; and increased awareness. The negative themes were: double tracking; PHR design issues; out of sight, out of mind; economic, infrastructure, and computer literacy barriers; I would have used it if I were sicker; lack of patient-provider engagement; and security and privacy concerns.

Theme 1: Complete and accessible record. Participants valued the PHR as a self-maintained, self-controlled complete and accessible record of their health information. Participants described the PHR as their *"personal data vault,"* and

Table 3.2 *Linear Regression Model for PHR Use, Social Cognitive Factors and HbA1c*

	B	**SE**	**P-value**
Constant	10.813	1.988	.000
PHR use	.244	.307	.429
Modifying factors	.007	.018	.706
Diabetes knowledge	-.027	.019	.168
Self-efficacy	-.002	.014	.890

"general overall record of my health." The PHR was helpful for participants who were not previously tracking their health information, or for those who only used their memory to remember their health information. Participants also described targeted use of the PHR to track less frequent labs (e.g. lipids), while using their glucometer for daily blood glucose readings. Other participants saw value in having all of their health information in one location accessible anywhere with Internet connectivity, illustrated by a participant recognizing the benefit in emergency situations stating, *"if something happens and I needed medical records, now they can get it."*

Theme 2: Increased awareness. PHR use increased participants' awareness of fluctuations in their diabetes care, primarily through the ability to graph blood glucose readings within the PHR. This function made it easier for participants to see long-term cause-and-effect compared to on paper or a glucometer, illustrated by one participant sharing, *"I like that I can track my glucose level and I can see what I've been doing and if food is what was causing me to have highs or lows."* This longitudinal look at their diabetes progress was helpful for participants *"to see where I was going and where I had been."* PHR use highlighted potential areas for self-care improvement, which led some

participants to make behavioral changes. One participant shared that, *"it allowed me to adjust my insulin because if it [blood glucose levels] was too low then I wouldn't take as much so it really did help me to manage that."* Using the PHR led several participants to exercise more and lose weight, led one participant to begin monitoring her blood pressure, and another to share that using the PHR, *"makes me check my sugars more like I'm supposed to."*

Theme 3: Double tracking. Participants still used other mechanisms for tracking their health information, including their memory, print-outs, handwritten records, Microsoft Excel, and their glucometer. Participants expressed a comfort level with their existing mechanisms, so what was typical for the patient did not change with the introduction of the PHR. An example was a patient who used the PHR but maintained use of his Excel file because, *"being able to average and get my blood sugars in Excel is what I am used to."* Participants noted that using the PHR takes an *"additional step"* (i.e. logging in) to record information compared to other mechanisms. This contrast was viewed negatively, illustrated by a participant who stated, *"just give me a piece of paper and I can write it down."* Another participant described how she *"put in a few things in the beginning, but I usually just keep it on paper. It's easier for me to just write it on paper where I test my blood sugar."*

Theme 4: PHR design issues. There were multiple design-related issues that made the PHR difficult to use. First, the PHR was difficult to navigate, even for simply locating the log-in page from the website homepage. It was also demanding with its data entry requirements, forcing patients to assign unit labels for laboratory test results in order to enter information into the PHR (e.g. mg/dL for blood glucose or % for HbA1c).

As one participant noted, *"I think it requires a lot of clicking to put in your history."* Participants did not perceive the PHR as a value add for their existing self-care behaviors.

Theme 5: Out of sight, out of mind. Participants shared a wide range of issues that limited opportunities to engage with the PHR, including personal illness, family and work responsibilities, temporary residential displacement, and traveling. These issues proved to be major barriers to PHR use, resulting in participants forgetting their usernames or passwords and leading to non-use. It is clear that the PHR was not viewed as a crucial tool in participants' daily self-management of diabetes. As one participant expressed, *"I never got into the habit of doing it. It was out of sight, out of mind."*

Theme 6: Economic, infrastructure, and computer literacy barriers. Economic barriers including cost of Internet access and computer hardware problems inhibited PHR use. One participant shared that he *"got rid of my computer service [Internet access] because I couldn't afford it."* Other participants had their computer break down and did not have the financial resources to fix or replace it. Participants also lacked alternate means of computer access if their primary access was unavailable (e.g. if their home computer broke, they could not use a work computer for personal use). Even for participants with consistent access to a working computer, unstable Internet connectivity or slow speeds were barriers to PHR use. One participant faced unreliable Internet connections at the public library, while another participant lived in a rural area with only a dial-up connection. Finally, despite asking participants to self-identify being comfortable using a computer, issues related to computer literacy were expressed, exemplified by the comment, *"I'm not a computer person so for me to get on to it, it took a while."*

Theme 7: I would have used it if I were sicker. Some participants who were adequately managing their diabetes care believed the PHR was not needed because of their positive health status. As one person shared, *"my A1c has been steady. So I didn't feel like I really needed to use it as often…that wasn't particularly useful for me."* Another participant believed he would have used the PHR if he was uncontrolled and/or needed to check his blood sugars more frequently, *"I could see if I was trying to see trend lines, like if I did glucose daily or multiple times during the day."*

Theme 8: Lack of patient-provider engagement with the PHR. Most participants did not share the PHR with their physician. Participants perceived that the *"doctor already has all my information."* Additionally, although all clinic providers were informed of their patients' participation in the study, no participant discussed their provider asking to see the PHR or wanting to view it when asked by the participant.

Theme 9: Privacy and security concerns. Few participants voiced concerns about the privacy and security of information maintained in the PHR. For those that did, concerns ranged from personal fears to technical questions. One participant shared, *"I'm a private person and dislike my entire life being recorded on some electronic device."* Another participant wondered if the PHR *"is adequately secure enough, because it's in the cloud and I'm always a little worried. Are the insurance companies watching or how secure is it? Those are part of my concerns."*

Chapter 5. Discussion

The quantitative findings did not indicate a statistically significant difference between either the control and intervention group or the PHR users and PHR non-users

from baseline to follow-up. This lack of quantitative evidence of improvement is likely due to the identified barriers that emerged in the qualitative themes.

There were a number of barriers that inhibit sustained and effective PHR use. These barriers must be addressed before the PHR can become a useful health technology. A few of these barriers, such as those described in the theme, *Out of sight, out of mind*, cannot be easily addressed or alleviated (e.g. personal illness or temporary residential displacement). Nor can infrastructure or economic issues such as slow public Internet speeds, lack of high-speed Internet access in rural areas, or costs related to purchasing Internet access or repairing a broken computer. Instead, focus should be placed on addressing those barriers that can be overcome.

Barriers associated with PHR design can be addressed by incorporating the viewpoints and needs of patients. This is particularly important given earlier research indicating that most standalone PHRs fail to meet even half of patient-identified desires (Fuji et al., 2012). Poor usability also has a secondary "time cost" associated with it; if the PHR takes too much time to use, patients will be less likely to use it (illustrated by participants who negatively contrasted using the PHR with perceived easier record-keeping tools such as written records) (Wynia & Dunn, 2010). PHR usability can be enhanced by accounting for issues of health literacy, evidenced by participants' difficulty with placing unit labels for laboratory test results (Detmer, Bloomrosen, Raymond, & Tang, 2008; Tang et al., 2006). PHR designers should consider pre-populating unit labels and having the normal limits for each laboratory test indicated within the PHR. PHR designers could also develop mobile platforms for PHRs, allowing individuals who are busy, traveling, or have limited time to sit down at a computer to engage with the PHR

on-the-go (Tom, Mangione-Smith, Solomon, & Grossman, 2012). PHRs are not a "one-size-fits-all" technology, and should possess functionalities that would bring value to patients with varying levels of engagement and need. For example, providing tailored advice such as identification of potential drug-drug interactions could provide additional value and stimulate adoption among individuals who did not use the PHR because they perceived that they were already taking adequate care of their condition (Fuji et al., 2012; Tenforde et al., 2012; Tom et al., 2012).

Security and privacy concerns were rarely discussed by participants despite being identified in the literature as a potentially large barrier to PHR use (Kaelber et al., 2008; Kahn et al., 2009; Wynia & Dunn, 2010). Although unlikely due to participants' high educational levels, participants in this study may not have expressed concern due to a lack of knowledge about potential negative consequences that could result from security and privacy issues with a PHR. Alternatively, participants may simply be willing to accept security and privacy risks for the potential positive gains resulting from PHR use. Further exploration is needed to better understand what prompts security and privacy concerns by patients and what measures can be taken to address these concerns.

The qualitative themes also identified a lack of shared patient-provider engagement with the PHR. It is clear that the PHR has not engaged providers to a great degree. For the PHR to add value to care delivery and lead to clinical improvements, providers must become more educated about the PHR, promote its use as an important tool in patients' diabetes care, and identify ways to use information in the PHR to enhance clinical decision-making. It has been shown that a strong patient-provider relationship is associated with PHR adoption, and provider support may also help patients

identify how to integrate PHR use into their self-care routine (Agarwal, Anderson, Zarate, & Ward, 2013). However, prior research has revealed that 25% of physicians did not know about PHRs, and 60% did not know if their patients used a PHR (Fuji, Galt, & Serocca, 2008). Patients in this study indicated that their providers did not show interest in or ask to see the PHR despite all providers being aware their patients were using a PHR. This is consistent with prior research where only 42% of physicians indicated a willingness to use a PHR in their practice (Wynia, Torres, & Lemieux, 2011).

The qualitative themes also revealed that despite a lack of quantitative evidence of improvement, the PHR can still provide benefits to patients, namely, developing a complete and accessible record that was helpful for the patient, and enhancing awareness of their diabetes management. Enhanced awareness led some participants to make modest behavioral changes, achieving some of the promise inherent in PHR use. The PHR also helped patients at different levels of self-care engagement, from those who previously had not tracked their health information to patients who did so regularly. The PHR did not replace existing health information record-keeping tools, as some participants either double-tracked their information or used the PHR as a supplementary record (e.g. to track yearly laboratory values while using other mechanisms to track daily blood glucose levels). Thus, the PHR did not need to replace other mechanisms for it to be a useful health information management tool.

It is important for all stakeholders to understand how patients and providers can benefit from a comprehensive, accurate PHR. Patients have the potential to achieve the positive outcomes in this study (maintaining a complete record and enhanced awareness leading to behavioral change), while providers have a more complete picture of the

patient to fully inform medical decision-making (Smith et al., 2005; Witry, Doucette, Daly, Levy, & Chrischilles, 2010). This is particularly important given the fact that not all electronic health record systems are interoperable, meaning that providers still possess an incomplete picture of the patient; information gaps that the PHR can help fill (Tang & Lansky, 2005).

Limitations

The length of time between baseline and follow-up (3-6 months) may not have been sufficient for patients to establish the use of the PHR in their normal self-care management and routines, and then have the benefits of PHR use manifest in quantitatively measureable outcomes. Future studies should utilize a similar mixed methods approach over at least a one year study period to better understand PHR use and allow sufficient time to observe quantitative changes.

The researchers were not able to obtain detailed information about PHR use (e.g. number of log-ins, number of times viewing a particular section within the PHR, etc.). Thus, the simple measure of whether or not a patient used the PHR even once after baseline was used to differentiate between PHR users and PHR non-users. This simple measure may not have adequately captured the meaningful differences in PHR use that could lead to measureable changes in clinical and social cognitive outcomes.

This was a pilot study with a relatively small sample size that was only powered to detect changes in HbA1c. Thus, it may have been underpowered to detect a potentially small effect size relative to the impact of the PHR on social cognitive factors.

The inclusion criteria of HbA1c $\geq$6.0 meant that there was potentially less opportunity to detect meaningful changes in clinical outcomes (i.e. it is easier to

demonstrate clinical change from "poor to good" rather than "good to excellent"). In order to address this potential limitation, a sub-analysis of participants with a HbA1c > 7.0 was conducted. It resulted in the identification of 64 participants (34 in the control group and 30 in the intervention group), and revealed no statistically significant difference between baseline and follow-up for HbA1c in either the control group (8.48% to 8.25%, $p = .405$) or the intervention group (9.10% to 8.87%, $p = .375$).

Future Research Needs

Future research should focus on identifying and developing strategies for enhancing the PHR's value and integrating it into a patient's self-care routine. Increased use of a mixed methods approach can help to identify potential predictors of PHR use and identify the key functions and features within a PHR that lead to actual quantitative clinical change. Additionally, the benefits that emerged from PHR use in this study warrant further explanation. In a longer-term study, it would be beneficial to explore if these benefits actually lead to clinical improvement, or if they result in non-tangible outcomes such as increased awareness that may or may not manifest itself through clinical outcomes.

Conclusions

Understanding of the potential PHRs have for facilitating patient knowledge gains and engagement in self-care, addressing usability and accessibility issues inherent in technology use, and educating providers about the benefits of PHR use are crucial for enhancing adoption and effective use of PHRs.

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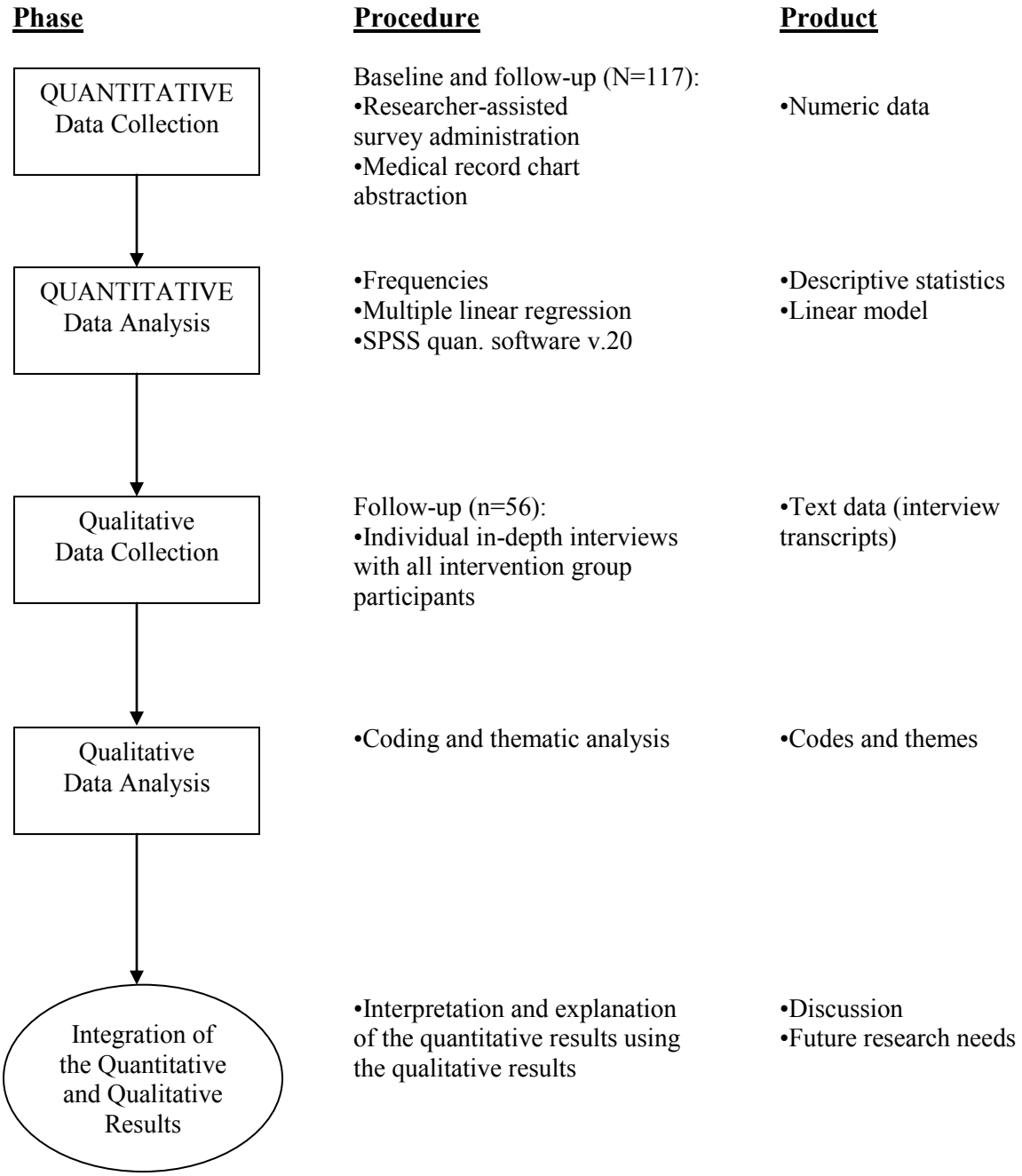

Figure 2.1. *Intervention Mixed Methods Study Design Diagram*