Comparing health outcomes and primary care physician utilization among low-income adults with type 2 diabetes and/or hypertension receiving either standard or intensive care management

By

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ABSTRACT

Comparing health outcomes and primary care physician utilization among low-income adults with type 2 diabetes and/or hypertension receiving either standard or intensive care management

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Background: Care management programs aim to improve individual health outcomes by using care managers to assist with the integration of heterogeneous health care and social service components. Project Access of Durham County (PADC) and Local Access to Coordinated Healthcare (LATCH) administer a care management program to an uninsured and racially diverse population in Durham, North Carolina. This population experiences substantial disparities in type 2 diabetes and hypertension prevalence and secondary complications. PADC-LATCH administers this program through standard (SCM) and intensive (ICM) protocols. The intensive protocol consists of more frequent and comprehensive individual encounters and is reserved for individuals meeting specific criteria with respect to chronic disease diagnoses and/or uncontrolled chronic disease. This evaluation investigates baseline patient characteristics among the protocols, if each is being implemented appropriately, and the effect on clinical outcomes.

Methods: Individuals having a recorded diagnosis of type 2 diabetes and/or hypertension and who were enrolled and receiving care management under the SCM (n=123) or ICM (n=23) protocols between January 1, 2015 and June 30, 2015 were considered in the final evaluation. Individual data were abstracted from care management notes and medical records. Data analysis was performed to investigate outcome changes within and across each group.

Results: Mean age (ICM: 51.9 years ± 8.63, SCM: 51.2 years ± 10.4, P=0.78), baseline systolic (P=0.69), and diastolic blood pressure (P=0.078) were similar for both groups while baseline hemoglobin A1c differed significantly (P<0.05). Those enrolled in ICM experienced a reduction in HbA1c from 10.6 to 9.51% (P=0.1), an 8.76% decrease, compared to individuals in SCM who had a small increase in HbA1c from 6.73 to 6.78% (*P*=0.92), a 2.03% increase. The difference in percent change in HbA1c across groups was not statistically significant (*P*=0.09). Both groups saw non-significant reductions in both systolic (ICM: 141.6 ± 19.1 to 137.2 ± 18.6, *P*=0.17 and SCM: 143.5 ± 21.2 to 140.6 ± 18.9, *P*=0.19) and diastolic blood pressure values (ICM: 81.5 ± 11.2 to 79.8 ± 12.1, *P*=0.60 and SCM: 85.8 ± 10.8 to 84.5 ± 10.6, *P*=0.23). There was no statistically significant difference in percent change in systolic (*P*=0.46) and diastolic blood pressure values (*P*=0.99) across groups. Those receiving SCM had a statistically significant reduction in the proportion of PCP visits with a decrease of 16.7% (*P*<0.05) compared to a decrease of 0.8% (*P*=0.25) among individuals receiving ICM, with no significant difference between groups (*P*=0.39). Lastly, only 57.1% of ICM individuals achieved their care management goals compared to 78.2% of those enrolled in SCM (*P*<0.05).

Conclusions: SCM and ICM protocols have varying results on outcomes of interest. Those enrolled in SCM saw a unexpected decrease in PCP utilization and achieved care management goals at a higher rate than counterparts receiving ICM. Individuals enrolled in the ICM protocol saw a decrease in HbA1c. Effects on blood pressure values were equivocal. This evaluation suggests that each protocol achieves desired results to varying degrees. As such, there should be considerations of modifying both protocols to improve their effects on clinical outcomes and PCP utilization.

OVERVIEW

Chronic disease is highly prevalent among racial minorities in the United States and those living in poverty. This paper aims to evaluate the effects of the standard and intensive components of a care management program among a low-income, racially diverse population with diagnoses of type 2 diabetes mellitus (type 2 DM), hypertension, or both. The effects on health outcomes and primary care physician (PCP) utilization will be the focus, with attention given to additional secondary outcomes. The care management program is administered by Project Access of Durham County (PADC) and Local Access to Coordinated Healthcare (LATCH). This evaluation of the care management program was solicited by PADC program directors and supported by PADC evaluation staff. The evaluation was conducted by a medical student evaluator.

In the next section of this paper I will discuss the prevalence of type 2 DM and hypertension in the general U.S. population, racial minorities, and the poor. I will then discuss care management theory along with various chronic disease care management approaches that have emerged over the last two decades, focusing on care management approaches that most closely resemble the PADC-LATCH care management program. Then I will present the methods used in this analysis of care management program data along with the results of the analysis and a discussion of those results. The appendices at the end of this paper that reflect data presented in this paper. It was my hypothesis that this analysis of the PADC-LATCH care management programs would show no effect on patient health outcomes or patient utilization of their PCPs.

BACKGROUND

Type 2 DM and hypertension prevalence

It is well-established that type 2 DM and hypertension are health problems in both the United States and North Carolina. Recent statistics show a continued year-over-year increase in diabetes prevalence for the past several decades, and intermittent periods of growth and stagnation with overall increased prevalence for hypertension, as shown in Table 1 (Appendix A).[1,2] In 2014, Type 2 DM had a prevalence of 12.3% and prediabetes prevalence was at 37% among all adults in the United States.[3] Prevalence of diabetes has nearly doubled from a 6.2% prevalence during the period between 1988 and 1994.[4] The prevalence of hypertension for adults in the United States was 29.0%, over a 3-year interval (2011-2014). Of those adults with hypertension, 47.0% had uncontrolled hypertension.[5] However, since 1999, there has been a stagnation (range 28.4%-29.9%) in hypertension prevalence with a gradual increase in the proportion of adults having controlled hypertension, increasing from 31.5% in 1999 to 54.0% in 2014.[5]

The burden of these diseases is similar in North Carolina to that of the country overall. In 2014 statewide prevalence was 35.5% for hypertension and 10.8% for diabetes.[6]

High prevalence of these diseases coupled with their high burden of morbidity and mortality make these diseases urgent matters.[3,7] Advanced type 2 DM is associated with micro- and macrovascular complications that are manifested as retinopathy, nephropathy, neuropathy, cerebrovascular accidents, and myocardial infarction.[3] Advanced hypertension places patients at risk for cerebrovascular accidents, myocardial infarction, and congestive heart failure. Death is also a possible complication of both diseases. The attributable death rate for hypertension rose 13.2% from 2001 to 2011 to 18.9/100,000 deaths, while the death rate attributable to type 2 DM stood at 21.7/100000 deaths in 2011.[1]

Disproportionate burden of disease among racial and ethnic minorities

As shown in the Table in Appendix A, there is a differing prevalence of these diseases among racial and ethnic groups in the U.S. Over a 3-year interval (2010-2012), the prevalence of diabetes was shown to be disparate across race and ethnicity with a prevalence of 13.2% in non-Hispanic black adults and 12.8% in Hispanic adults compared to 7.6% among white adults.[3]

Hypertension statistics reveal a similar disparity across racial/ethnic lines with a prevalence of 41.2% among non-Hispanic black adults compared to 28.0% among non-Hispanic white adults, but only 25.9% among Hispanic adults. The lower prevalence of hypertension among Hispanic adults differs from the expected prevalence based on ethnicity. However, non-Hispanic black adults *and* Hispanic adults had a higher prevalence of uncontrolled hypertension compared to their white counterparts.[5]

The disparities across race and ethnicity are also present in the rates of complications from these diseases, with black adults regularly suffering complications at higher rates. The incidence of end-stage renal disease associated with diabetes is sharply higher for black adults (461.7/100 000 people) than either Hispanic and white adults.[8] Visual complications among adults with diabetes is higher in black adults (20.7%) and white adults (17.1%) than Hispanic adults.[9] Only with cardiovascular disease complications do white adults (33.9%) have a slightly higher rate of complications than their black (33.0%) and Hispanic (24.5%) counterparts.[10]

These racial disparities are also reflected in higher mortality rates. Mortality rates among diabetics were highest among black males (44.9/100 000 deaths) and black females (35.8/100 000 deaths) compared to white males (24.3/100 000 deaths).[1] As with type 2 DM mortality rates, the mortality rates associated with hypertension are disproportionate across race with rates at 47.1/100 000 deaths for black males compared to 17.6/100 000 deaths for white males.[1]

Poverty

A disproportionate disease burden also exists among those who are poor. Individuals with family income below the poverty level were found to have 2 times the risk of mortality from diabetes compared to individuals from families with higher incomes.[11] In regards to hypertension, poorer individuals had only a modest increase in their risk of developing the disease compared to wealthier individuals. However, poorer individuals were 2 to 3 times more likely to have a myocardial infarction or stroke.[12]

Ethnic minorities are more likely than white Americans to be poor. A 2014 U.S. Census report found that 26.2% of black adults and 23.6% of Hispanic adults live below the poverty line compared to 10.6% of non-Hispanic whites.[13] Ethnic minorities then face a greater burden of both chronic disease and poverty in the U.S. compared to their counterparts. The reasons behind this racial and income-based increased risk in disease are multifactorial and spans social, cultural, and genetic disciplines.

Some factors behind this increased burden are poverty, daily stressors, language barriers, and neighborhood environment. A lack of sufficient income precludes many minority populations from regular access to healthcare and when there is access there is a persistent lag in quality.[14,15] Inadequate self-management behaviors and spotty access to appropriate medications cause further issues with disease control.[14] Stress has also been associated with a higher prevalence of both type 2 diabetes and hypertension along with a higher risk of morbidity in Hispanics.[16] Low English proficiency among low-income Hispanics increased the likelihood of poor diabetes self-management.[17] Lastly, as mentioned earlier, both Hispanic and African Americans more likely than whites to be poor and as such are more likely to live in poorer neighborhoods. A higher prevalence of diabetes and hypertension has been found among people living in neighborhoods with low socioeconomic levels.[18] This combination of factors leads to a large disease burden placed upon the racial minority communities of the U.S.

Chronic disease care management theory

Care management programs (CMPs) are an approach to potentially improving health outcomes in patients with chronic disease.[19] It is believed that chronic disease care management programs have their origins in the contingency theory of Lawrence and Lorsch. The theory stresses the need for integration and collaboration of many parts of a system in response to the needs of the environment.[20] Walter Leutz applied this theory to health care and noted the need to integrate health care systems and social service systems to improve health outcomes.[21]Responses to varying environments and needs result in heterogeneous programs with differing components.[20] However, CMPs regularly coordinate health and social services for individual patients and are carried out by interdisciplinary teams consisting of a blend from among physicians, pharmacists, nurses, health educators, and community health workers.[22,23]

Approaches to chronic disease care management

Care management programs have taken on many forms within the U.S. and abroad. One study highlighted a case management program in which nurses followed management algorithms under the supervision of physicians within a health maintenance organization.[24] Another study investigated the effect of country-wide, voluntary type 2 DM disease management programs within the German health care system.[25] A nurse-led care management program focused on reducing cardiovascular morbidity in patients with hypertension through an e-mail reminder program [26], while another nurse-led care management intervention focused on motivational interviewing.[27] Lastly, there are some examples of pharmacist-based hypertension care management programs in the literature.[28]

Care management protocols

Because of the variety of CMP models, we will focus our discussion of previous research on models that are most similar to the care management program under study here. The care management program in question is based out of Durham, North Carolina and is affiliated with a local academic hospital. Durham County, North Carolina has a population of 294,000.[29] The program is coordinated and administered by the Project Access of Durham County (PADC) and Local Access to Coordinated Health Care (LATCH) in Durham, North Carolina. Eligible patients are placed in either the standard care management (SCM) or the intensive care management (ICM) protocol depending on the reason they are referred to the program.

The program protocol is initiated with the referral of patients needing specialty care to the PADC program. Primary care providers at Lincoln Community Health Center in Durham, North Carolina, a local Federally Qualified Health Center, or one of its satellite clinics issues these referrals. The referrals are evaluated for eligibility by PADC staff. Eligible patients must be Durham county residents, uninsured, and have household income less than 200% FPL. Eligible patients who enroll have access to specialty care services for one year.

All PADC patients are then enrolled in LATCH. Patients who are designated as needing a specialty care appointment but not meeting any of the criteria listed for ICM, are placed in SCM. Patients meeting any of the following criteria will be enrolled in the ICM protocol: 1.) needing to consult with a specialist for their chronic disease, 2.) out-of-control chronic disease being a barrier to treatment, or 3.) significant psychosocial issues creating barriers to treatment. The following chronic diseases are targeted by the ICM protocol: type 1 or 2 DM, hypertension, hyperlipidemia, asthma and/or chronic obstructive pulmonary disease, and/or congestive heart failure.

Standard care management

Each protocol contains unique components. SCM is visualized in Figure 1 (Appendix B). For SCM, either a nurse care manager (NCM) or a health education specialist (HES) helps patients needing specialty care in two phases pertaining to the specialty care appointment.

Pre-appointment preparation includes either a telephone encounter or home visit, at least 2 weeks in advance of specialty care appointment to: coordinate appointments, discuss and navigate appointment logistics (e.g. pre-appointment labs or procedures), arrange transportation through PADC, provide interpretation services at specialty care appointments, address barriers to accessing care or managing their treatment plan.

SCM post-specialty appointment contact will be made by either telephone encounter or home visit one week after the appointment. This encounter will include: addressing patient concerns, checking on patient's status, referring patient to PCP for any follow-up questions or medication needs, provide medication management as appropriate, assist with medication, assist with durable medical equipment (DME), provide appropriate psychosocial support resources, provide translation of treatment plan, provide assistance with follow-through of treatment plan, and follow-up on patients who miss appointments.

Intensive care management

The ICM protocol is shown in Figure 2 (Appendix B). As with SCM, patients enrolled in ICM are managed by either an HES or NCM. Initial telephone contact by the care managers is made between 5-10 days after the date of referral. This initial contact serves as an assessment of the complexity of the patient's situation, knowledge of disease, and current self-management strategies. Home visits are completed as determined by the NCM or HES. Each home visit consists of: patient education, review of medications and any barriers, setting self-management goals (with a follow-up of 30 days), referral to PCP, assessment of additional barriers to care, and referral to appropriate psychosocial and community resources.

Each patient is contacted or visited prior to each medical appointment, after each appointment, every 2 weeks for 6 weeks after initial referral date, and 3 months after initial referral date. The number of encounters therefore varies, but at minimum will be three, except in cases in which the patient is lost to contact. The nature of each encounter is tailored based on the patient's needs, but generally includes the activities listed above.

Literature review *(refer to Figures 3-5 and Tables 2-6 in Appendix C)*

There is a relative abundance of literature that addresses the effectiveness of care management programs on clinical outcomes. However, a review of the available literature shows there are few articles that reflect the nature of the LATCH-PADC care management program and the population it serves. The programs in the literature are implemented by personnel other than nurses or health educators, do not focus on a largely uninsured and low-income population, and/or do not investigate clinical outcomes. This review, requested by the PADC evaluation team, covers the articles most relevant to the LATCH-PADC care management program.

Kim *et al*. (2014) investigated a nurse-led community-based case management (CBCM) program for patients with hypertension via a prospective cohort study. The intervention consisted of a needs assessment for the patient followed by a prioritization of problems followed by case management to address the prioritized issues. Case management was administered through 6 phone encounters and 2 home visits over a duration of 2-8 months, based on each patient's blood pressure control. The patient population was a specifically low-income population and largely older (85% older than 65 years of age). It was found that both pre/post systolic and diastolic blood pressure levels decreased significantly after enrollment in the CBCM program, along with increased hypertension knowledge and hypertension self-management ability. Despite the results supporting the use of care management programs, this study had a limited external validity due to its uneven patient characteristics (86.4% were older than 65; 77.3% were female) and additional potential sources of bias from the lack of blinding of patients and personnel, its small sample size, and the lack of a control group (other than the patients themselves).[30]

A retrospective study by Sekhobo *et al.* (2008) investigated the effects of a case manager-led chronic disease case management program for patients diagnosed with type 2 DM receiving care at community health centers. Case managers were responsible for delivering diabetes education and self-management approaches along with connecting patients with appropriate resources and ensuring continuity of care. The frequency of case manager encounters was not explicitly stated, but each patient had care management for at least one year. It was found that both systolic and diastolic blood pressure levels decreased significantly after enrollment in the CBCM program, along with hypertension knowledge and hypertension self-management ability.

Results showed improvement in HbA1c control by patients entering the program with intermediate or poor baseline glycemic control. The largest improvements in HbA1c were made by patients with the poorest glycemic control at baseline. Another analysis showed that there was a statistically significant difference in glycemic control for patients enrolled in case management compared to those not receiving case management. This study maintained a low risk of bias, but the small control group sample size and the lack of outcome assessor blinding created some concern for overestimation of program effect. However, the low magnitude of these shortcomings paired with the remaining study characteristics reduced the potential for bias. [31]

The California Medi-Cal Type 2 Diabetes Study Group (2004) produced a randomized controlled study on a team-based intensive diabetes case management program for low-income patients with type 2 DM. Case management consisted of four components: 1.) following evidence-based guidelines in diabetes medication, 2.) identifying and creating plans to overcome barriers to care, 3.) education on proper glucometer use, and 4.) education on diabetes self-management including diet and exercise education. The program was administered on an "as needed" basis with no guidelines noted for case management administration nor for the duration of the intervention.

There was statistically and clinically significant improvement in HbA1c at all points of follow-up in the intervention group compared to the control group. Although the control group still experienced improved HbA1c levels, it was not by the same magnitude experienced by the intervention group. The intervention group also experienced a decrease in systolic blood pressure, whereas the control group stayed stagnant, and a significant decrease in diastolic blood pressure. As a randomized, controlled study, there was an overall low risk of bias, however there was no blinding of participants, personnel, and outcome assessors creating a high potential for both performance and detection bias, and overestimation of the effect of the intervention. However, the remaining characteristics of the study lowered the overall risk of bias for the study.[32]

Hebert *et al.* (2012) investigated a nurse management intervention on patients with hypertension living in Harlem, New York. The article describes a randomized, controlled study that took place at 5 sites across Harlem, including one Federally Qualified Health Center. The patients in this study were not explicitly low-income or uninsured, but eligibility criteria required that patients were either Hispanic or black. The study setting, clinical sites, and ethnic and racial makeup of the recruited patient sample indicate that the patient were more likely to be of a low-income background. This intervention consisted of multiple components, including: 1.) in-person self-management counseling, 2.) smoking and alcohol reduction counseling, 3.) regular telephonic follow-up, and 4.) frequent nurse-physician communication and adaptation on patient treatment plans. There was no clearly stated guide to the number of encounters expected to be administered to each patient, but telephonic care management was delivered for a duration of 9 months.

This study showed that patients enrolled in the nurse management arm of the study had statistically significant decrease in systolic blood pressure at 9-month follow-up and a continued, but non-significant decrease at the 18-month follow-up. Results also showed that patients in the other two groups, the home BP monitor and usual care groups, had non-significant decreases in systolic and diastolic blood pressure at both follow-up time points. Despite the fact that this study was a randomized, controlled study, there was a high risk of bias due to the unorthodox recruitment strategy that was used. The study had begun with 2 study arms, but was increased to 3 study arms after additional funding was secured. This created issues with matching study groups demographically and although the issue was discussed and controls were matched contemporaneously, there is concern that patients recruited earlier in the study were able to be randomized to the home BP monitor group, leading to a potential for selection bias. [33]

Philis-Tsimakas *et al.* (2004) is the last study that was reviewed. This was a prospective cohort study that investigated the effects of a nurse-led care management program paired with a peer education component on HbA1c in patients with diagnosed type 2 DM. This study explicitly recruited patients belonging to one of three low-income payer groups: Medi-Cal, Medically Indigent Adult (MIA) health services program, or uninsured and income under the appropriate federal poverty level. The intervention duration was over 2 years and consisted of a minimum of 4 visits in a calendar year, with an initial 2-hour assessment visit with subsequent clinic visits being used to review treatment guidelines, medication changes, self-management techniques, and care management goals.

The intervention group showed statistically significant decreases in HbA1c and diastolic blood pressure and a non-significant decrease in systolic blood pressure. The control group also exhibited a decrease in HbA1c, but to a lesser degree compared to the intervention group. Overall, this study had too many sources of potential bias stemming from a lack of randomization, high attrition rate, and no blinding of patients, personnel, or outcome assessors. Despite the high potential for an overestimation of the effect of the intervention due to potential biases, the results still reflect decreases in HbA1c and blood pressure. [34]

These studies most closely reflected the program being evaluated in this paper. The results are positive in showing an overall improvement in HbA1c and blood pressure for patients with diabetes and/or hypertension enrolled in various nurse and/or care manager-led care management programs. There was no apparent relationship between the amount of care encounters received and effects on health outcomes. Only 2 of the 5 included studies (Kim *et al*. (2014) and Philis-Tsimakas *et al.* (2004)) had a prescribed minimum number of encounters and the remaining studies were administered as-needed and each had a significant reduction in their respective clinical outcomes.

METHODS

Study overview

A secondary data analysis was conducted to evaluate the ability of the PADC-LATCH intensive care management program to improve HbA1c, blood pressure, and other secondary outcomes in their designated patient population. This analysis was approved by the institutional review board of the Duke University Health System. Research questions for the evaluation included:

i.) ***What do the data indicate about how well the protocol is being implemented? Specifically, do patients designated for ICM show greater clinical need than those designated for SCM?***

ii.) ***Are patients designated for ICM in actuality receiving a greater volume of care than those designated for SCM?***

iii.) How did clinical outcomes and PCP utilization change for each care management group?

iv.) How often did participants meet their behavioral goals?

v.) Was there a difference in outcomes for those receiving standard versus intensive care management?

Study sample

Patients eligible for inclusion in the analysis were 1.) active in the PADC-LATCH care management program (either standard or intensive program) between January 1, 2015 and June 30, 2015, 2.) had a clinical diagnosis of type 2 diabetes, hypertension, or both, confirmed by inclusion in the patient's problem list or being listed as a diagnosis in a clinical progress note created between January 1, 2015 and June 30, 2015, 3.) an age of 18 years or older at time of participation in the program. Patients were excluded if they did not meet the eligibility criteria listed above or if they were missing data in all three key variables of HbA1c, blood pressure, and PCP visits.

A total of 425 patients were initially eligible based on activity in the program during the active dates. This population was reduced as filters were applied to the electronic health record (EHR) data gathering interface to include patients with valid diagnoses. A total of 168 patients who were listed on the hospital's internal Chronic Disease Registry for type 2 diabetes, hypertension, or both remained eligible for participation. After chart review was completed for each patient, 1 patient was excluded for being underage, 1 for insufficient data, 4 for having no record in the care management database, and 16 for having no confirmed diagnosis in their records. There were 146 patients included in the final analysis, as shown in Figure 6 (Appendix D).

Data sources

Data for this analysis were obtained from PADC, LATCH, and the affiliated academic center electronic health record system. PADC and LATCH provided care management encounter data. The EHR provided clinical data. The local Federally Qualified Health Center pharmacy provided data on patient medication adherence.

Variables

Patient characteristics

Patient characteristics were collected from medical records and these data were grouped based on the care management protocol each patient received.

Care management encounters

Care management encounters were included in this analysis if they were classified in one of the following categories in the COACH database: Phone [Patient], Home Visit [Patient], Community Encounter [Patient], or Practice Encounter [Patient]. Encounters were separated as phone encounters, home encounters, or community/practice encounters. Only encounters occurring after within 4 months after each PADC's program participants start date were recorded. Four months was the chosen duration of time given that the ICM protocol lasts for 3 months and it takes 1-15 days for an NCM or HES to make initial contact with a patient.

Hemoglobin A1c

Baseline HbA1c was defined as any HbA1c value calculated from a specimen collected between 7/1/13-12/31/14. If an A1c value was not available for this time period, an A1c value between 1/1/15-6/30/15 was recorded. This allowed for sufficient data to be gathered given that this analysis is retrospective and could not influence when data was gathered. Follow-up HbA1c was defined as any value calculated from a specimen collected between 7/1/15-5/30/16. If an A1c value was not available for this time period, an A1c value between 1/1/15-6/30/15 was recorded. For any individual, baseline and follow-up A1c values were separated by at least 3 months.

Systolic and diastolic blood pressure

Baseline systolic and diastolic blood pressures were defined as the average of 3 readings calculated from consecutive blood pressure readings taken between 7/1/13-12/31/14. If a sufficient number of readings were not available for this time period, readings between 1/1/15-6/30/15 were used in calculating the 3-value average. Follow-up systolic and diastolic blood pressures were defined as the average of at 3 readings calculated from blood pressure readings taken between 7/1/15-5/30/16. If a sufficient number of readings were not available for this time period, readings between 1/1/15-6/30/15 were used in calculating the 3-value average. In instances where there was more than 1 reading in a given visit (e.g. hospital admission, repeat

BP measurement at same office visit), the pair of values with the highest systolic value was recorded to have the estimate lean towards the null hypothesis.

For an individual, any baseline and follow-up blood pressure readings used in calculating the 3-value average were separated by at least 1 month. Patients were included in the analysis if they had at least one reading in either category.

Primary care physician utilization

Baseline quantity of PCP encounters was determined by number of encounters within the 6-month period immediately preceding each participants' program start date. Follow-up quantity of PCP encounters was determined by the number of encounters within the 6-month period with the first day of this period commencing 4 months after each participants' program start date. For example, if patient X's start program start date is 1/1/15, then the baseline period runs from 7/1/14-12/31/15 and the follow-up period runs between 5/1/15-11/1/15. Data were presented as the median number of PCP encounters.

PCP encounters were classified as office visits with a primary care physician. Nurse only visits, lab visits, telephone calls, emergency department visits, urgent care visits, or specialists were not included in the PCP encounter count.

Care management goal achievement

Care management goals, if established, were classified as either achieved (100% completed) or not achieved (<100% completed) based on qualitative encounter data.

Difference in dependent variables among SCM and ICM groups

Statistical comparisons were made between the group means for HbA1c, blood pressure, PCP utilization, and goal achievement.

Statistical Analysis

All analyses were performed using Stata SE v.14 (College Station, TX). The outcome assessor was not masked to patient diagnoses or care management grouping. The normality of all data was assessed using the Shapiro-Wilk test in conjunction with visual representations of the data. An alpha level of 0.05 was used as the metric for statistical significance.

Patient characteristics

Patient characteristics were calculated for each care management group. Means and standard deviations were obtained for continuous variables. Proportions were obtained for each categorical variable. T-tests and chi-squared tests were performed to compare the characteristics of the SCM and ICM groups.

Care management encounters

Care encounter counts were obtained via chart reviews. Due to non-normality, medians and interquartile ranges were obtained for each type of care encounter. Group medians were compared using the Wilcoxon rank-sum test.

Diabetes control, hypertension control, PCP utilization, and care management goals

HbA1c served as a surrogate for type 2 DM control, while systolic and diastolic blood pressure were used to reflect hypertension control. Pre- and post-intervention HbA1c, systolic pressure, diastolic pressure, and PCP visits were analyzed within each group using paired t-tests (which produced a t-statistic) or nonparametric Wilcoxon signed-rank test (which produced a z-statistic), according to the normality of the data.

Repeated measures one-way analysis of variance (ANOVA) (which produced an F-statistic) was used to determine within-subject effects on HbA1c, blood pressure values, and PCP utilization. To fulfill the assumptions associated with the repeated measures one-way ANOVA, outliers were removed, normality was confirmed, and either sphericity was maintained or the Box correction factor was used in reporting statistical output.

I constructed a multivariable ANCOVA model to assess the relationship between the type of care management received (classified as either standard or intensive care management) and, separately, mean change in HbA1c, systolic blood pressure, diastolic blood pressure, and PCP visits. Variables assessed for potential confounding included: age, gender, race/ethnicity, and marital status. All variables were included in the fully adjusted model. Only variables that changed the coefficient of the independent variable within the fully adjusted model by more than 10% were included within the reduced model for each separate relationship assessed. The frequencies of goal achievement from ICM and SCM were compared using a chi-squared test.

RESULTS *(tables in Appendix E)*

Patient Characteristics

Table 7 (Appendix E) summarizes the characteristics of the 146 patients included in the analysis. Patients are counted and described within two groupings contingent on the care management program received (ICM or SCM). Ages were similar with 51.9 and 51.2 years being the mean age for the ICM and SCM groupings, respectively (*P*=0.78). Females patients were predominant in both groups with no significant association found between gender and care management grouping (*P*=0.62).

Overall, patients within the care management groups were most dissimilar by race/ethnicity, marital status, and chronic disease diagnosis. The groups had some racial dissimilarities with 43.5% of ICM patients identifying as Hispanic, while only 24.4% in the SCM did so. The proportion of black patients in each group was similar with 43.5% identifying as black in the ICM group and 50.4% in the SCM group. Despite these characteristics, there was no significant association indicated between race/ethnicity and care management grouping (*P*=0.19). Single persons accounted for 56.9% of the SCM and only 34.8% of the ICM group and married persons made up 21.1% of the SCM group compared to 34.8% of the ICM group (*P*=0.07). With respect to chronic disease diagnoses, 82.6% of the ICM group and only 32.5% of the SCM group had type 2 diabetes (*P*<0.05), 78.3% of ICM and 89.4% of SCM had hypertension (*P*=0.14), and 60.9% of the ICM and 22.0% of the SCM group had both diagnoses (*P*<0.05).

ICM and SCM patients also differed in baseline HbA1c, PCP utilization, and diastolic blood pressure values, but were similar in systolic blood pressure values. The ICM group had a significantly higher baseline HbA1c at 10.6 ± 2.44 compared to 6.73 ± 1.48 (*P*>0.05) within the

SCM group. With respect to PCP visits during the baseline period, 91.3% of ICM versus 95.9% of SCM patients had a PCP visit (*P*=0.34). The median quantity of of PCP visits for each group was at 2 (IQR=2, *P*=0.20). Mean diastolic BP values for ICM patients were lower than those in SCM, with values of 81.5 ± 11.2 and 85.8 ± 10.8 (*P*=0.078), respectively. However, the ICM group had a similar mean systolic BP value of 141.6 ± 19.1 to that of the SCM group, 143.5 ± 21.2 (*P*=0.69).

Care management encounters

There was a significant difference (*P*<0.05) in the number of phone encounters made with ICM patients (median=7; IQR=8) and SCM patients (median=2; IQR=3), as seen in Table 8 (Appendix E). Home and community encounter counts were too low to register a median above 0 (IQR=0). However, the proportion of patients receiving any in-home encounter was 17.4% among ICM patients and 2.44% among SCM patients (*P*=0.002), while the proportion of those receiving any community/practice encounters was 13.0% and 7.32% among ICM and SCM groups, respectively (*P*=0.36).

Diabetes control

Table 9 (Appendix E) shows the change in HbA1c pre- and post-care management participation. ICM patients showed a large, but non-significant decrease in HbA1c from 10.6 ± 2.44 to 9.51 ± 2.80 (t=1.73, *P=0.10*). The repeated measure ANOVA showed a non-significant difference in group pre- and post-intervention means (F=3.0, *P*=0.10). The SCM group showed almost no change in HbA1c (6.73 ± 1.48 to 6.78 ± 1.31, *P*=0.92) and no change in pre-post means (F=2.01, *P=0.166*).

Hypertension control

Systolic blood pressure decreased among those receiving ICM from 141.6 ± 19.1 to 137.2 ± 18.6 (t=1.43, *P=0.168*; F=0.204, *P=0.168*) as seen in Table 11 (Appendix E), but the decrease was non-significant. There was a similar non-significant decrease in systolic blood pressure among the SCM group (t=1.73, *P=0.086*; F=1.76, *P=0.188*).

There were also non-significant decreases in the pre-post diastolic values for the ICM (t=0.536, *P=0.598*; F=0.29, *P=0.598*) and SCM (t=1.44, *P=0.153*; F=1.49; *P=0.225*) groups (Table 13, Appendix E).

Primary care physician utilization

Patients receiving SCM showed a statistically significant decrease in number of PCP visits (z=4.012, *P<0.05*) as shown in Table 15 (Appendix E). While number of PCP visits in patients receiving ICM showed no significant change with a median of 2 (IQR=2) for both pre and post-intervention visits (*P*=0.25). Overall, the proportion of ICM patients having any PCP visits in the period before and the period after receiving care management decreased from 91.3% to 82.6%, while it decreased even further from 95.9% to 72.4% among those receiving SCM.

Difference in dependent variables among SCM and ICM groups

Diabetes control

Across groups, the unadjusted average decrease in HbA1c was 1.12 % (-1.96, -0.26; 95% CI) among ICM patients and a 0.02% (-0.56, 0.60: 95% CI) increase in HbA1c among SCM patients did not show a significant difference (*P*=0.11), as depicted in Table 10 (Appendix E). When adjusted for marital status (the only confounder in the reduced model), ICM patients showed an average 0.90% (-1.73, -0.08: 95% CI) decrease in HbA1c while those in SCM showed a smaller HbA1c decrease of 0.078% (-0.63, 0.48; 95% CI). The comparison of these mean changes remained statistically non-significant (*P*=0.11).

Hypertension control

Table 12 (Appendix E) shows the unadjusted mean change in systolic BP was a 5.55 (-13.1, 2.0; 95% CI) point decrease among those in ICM and a 2.89 (-6.16, 0.38; 95% CI) point decrease among those in SCM, the difference between these mean changes was non-significant (*P*=0.53). When adjusted for race and marital status, the mean change in systolic BP among ICM patients was reduced to 4.81 (-12.35, 2.75; 95% CI) points and increased to 3.03 (-6.29, 0.23; 95% CI) points for those in SCM. The difference in mean systolic BP change in the adjusted model remained non-significant (*P*=0.67).

The model showing the unadjusted mean change in diastolic BP found a 1.68 (-6.17, 2.79; 95% CI) point decrease among ICM patients and a 1.30 (-3.24, 0.64; 95% CI) decrease among those in SCM, as seen in Table 14 (Appendix E). The unadjusted mean changes showed non-significant differences (*P*=0.88). Within the fully adjusted model—in this case, accounting for age, race, gender, and marital status—the mean change in diastolic BP for ICM showed a slight change with a 1.70 (-6.15, 2.75; 95% CI) mean decrease and no change for those in SCM with a 1.30 (-3.22, 0.62; 95% CI) decrease. The adjusted model continued to show a non-significant difference between mean changes in diastolic BP among the groups (*P*=0.87).

Primary care physician utilization

Across groups, there was a non-significant difference in mean change in number of PCP in both the unadjusted (*P*=0.98) and the fully adjusted models (*P*=0.98) (Table 16, Appendix E).

Care management goal achievement

Among the SCM group, 78.2% of patients achieved their care management goals compared to 57.1% of ICM patients (Table 17, Appendix E).

DISCUSSION

This evaluation of the PADC-LATCH care management program on the basis of health outcomes and PCP utilization shows overall mixed results. The hypothesis was that there would be no change in clinical outcomes or PCP utilization. These results only partially refuted that hypothesis since results were largely statistically non-significant, but clinically relevant. A review of patient characteristics reveals that individuals with the highest baseline HbA1c values were enrolled in ICM, indicating that diabetic patients most in need of an intensive care program were more likely to be receiving ICM. The opposite was true with respect to BP values, however. Patients enrolled in SCM had the highest mean systolic and diastolic BP values. This is not the expected result since the ICM protocol seeks to enroll very ill patients with diabetes and/or hypertension. There is an expectation that patients receiving ICM would have worse clinical statuses. This could be due to patients with complicated diabetes having more severe and immediate reasons to access to ICM compared to a stable patient with asymptomatic uncontrolled hypertension.

Care management encounter data shows that ICM patients received significantly more phone encounters compared to their SCM counterparts. This is in addition to a greater proportion of ICM patients receiving home and community/practice encounters. These data are consistent with the expectation that ICM patients receive at least 3 care management encounters over the 3-month protocol period and that SCM patients receive less care than ICM. This is evidence that the protocols are being properly administered to ICM and SCM patients.

There was a substantial HbA1c reduction from to pre- to post-care management participation among those receiving ICM which is clinically relevant given that this group has a worse clinical status at baseline. The ICM group had an acceptable baseline HbA1c and even with the small increase in HbA1c, the group mean remained within an acceptable range. When controlled for marital status, there was no significant difference in HbA1c change between groups. The hypothesized result was that of no change in HbA1c, especially considering the small sample size of the ICM group and the difficulty of effecting changes in poor clinical statuses. Despite a lack of statistical significance (possibly due to small sample size), the reduction in HbA1c among ICM patients is a positive effect of this program.

With respect to blood pressure, patients receiving ICM and SCM showed non-significant decreases in systolic and diastolic blood pressure. In both unadjusted and reduced models adjusted for race and marital status, there was no significant difference between groups for both systolic and diastolic blood pressure.. The ICM group had lower baseline BP values, but also had the largest mean reduction in both BP values among the groups (almost double the mean reduction in systolic BP and only a slightly greater reduction in diastolic BP), however, the ability to find statistical significance was limited by the small sample size in this group. These results show that the higher frequency of care management encounters had by ICM patients may lead to greater reductions in BP compared to SCM. These results are encouraging in showing a slight positive effect on patient health outcomes.

An increase in PCP visits paired with a decrease in emergency department and/or or urgent care use was the expected medical use pattern for both groups, since they have high medical need. However, there is also a possibility that a reduction in PCP utilization could be desired for those who are accessing care too frequently without a valid medical need. In this analysis, PCP utilization decreased to a significant degree only in the SCM group, with an overall mean reduction in number of PCP visits in both groups. There was no significant difference between groups even when adjusted for all potential confounders. Similar high proportions of ICM and SCM patients visited a PCP before receiving care management and both post-care management proportions of patients visiting a PCP decreased. However, the SCM group had the largest reduction in patients seeing a PCP post-care management at all.

The reduction of PCP visits among both groups may attributed in part to the following reasons. Most uninsured patients in this evaluation access care at an FHQC. PCPs at this particular FHQC could be accessed free-of-charge until the fall of 2014, when a minimum payment system was installed. Either some or most of the decrease in the PCP utilization may be explained by this since all patients being served by these programs are low-income and may have found it more difficult to access primary care once it had a monetary cost attached. The decrease in PCP utilization could also be secondary to patients continuing to access the health care systems through avenues other than their PCP, i.e. emergency departments or urgent care centers. The larger decrease in the proportion of patients accessing a PCP post-care management in the SCM group may be explained by the reasons noted above and because SCM patients may have less medical problems and less severe disease complications that do not require as much PCP follow-up as a more ill and medically complex ICM patient may otherwise need.

Care management goals were achieved at a significantly higher rate by SCM individuals. The desired result would be that of having ICM patients achieve care management goals with same frequency as SCM. However, there is the possibility of ICM patients having more appointments to keep, more disease control goals, and more significant psychosocial barriers that make care management goals more difficult to achieve when compared to their less medically and psychosocially complex counterparts. Since ICM patients are receiving more care encounters than those in SCM and still achieving care management goals at a lower rate, this suggests that ICM patients may require more care encounters to achieve goals at the same rate.

The intended effect of PADC-LATCH care management programs is to improve patient efficacy and self-management skills to improve health outcomes and appropriate utilization of the healthcare system. The results of this evaluation of these care management programs indicate that both ICM and SCM programs are appropriately providing care management as seen through the most ill patients being enrolled in ICM and receiving more care encounters than SCM patients. Supporting goal achievement and improving clinical status as measured through decreased HbA1c and decreased BP values. However, goal achievement was lower in the ICM group suggesting that ICM patients require even more care management to achieve goals at the same rate. PCP utilization decreased for both groups and may have been most affected by external factors and not by the care management received. Given the collection of results, there is evidence that both programs are producing positive and clinically relevant, albeit not statistically significant, results. As such, there is an indication for the care management programs to be modified and improved so that clinical status, goal achievement, and PCP usage are able to improve to greater degrees.

Comparison to other studies

The results of this analysis are somewhat similar to the results from similar studies. Kim *et al*. (2014) and Hebert *et al.* (2011) showed statistically significant improvements in pre-post blood pressure values for patients enrolled in nurse-led care management interventions. The Sekhobo, *et al.* (2008), Jovanovich *et al.* (2004), and Philis-Tsimakas *et al.*(2004) investigations all found reductions in pre- and post-care management HbA1c values, similar to the reductions found in this analysis. However, these 5 studies all found some degree of statistical significance in their health outcome improvements, whereas this evaluation did not yield any statistically significant improvement in HbA1c or blood pressure values.

Limitations

There were some limitations to this evaluation. The retrospective design of this data analysis creates selection bias since patients were not randomized and the baseline patient characteristics were dissimilar. There was a relatively small sample that participated in the ICM component, which means that the results from the sample may have limited generalizability and limited power. Lastly, the large time period allotted for adequate collection of HbA1c and blood pressure values may bias the results away from the null. It would be difficult to separate what effects on health outcomes were a result of the care management or a result of other factors, including time.

Conclusions

Despite the potential for biases in this evaluation, it shows weakly positive, but clinically relevant results. Both groups have their merits in improving in a few categories: patients in the ICM group showed large reductions in HbA1c and systolic BP, while patients in SCM showed modest reductions in BP values and a rate of goal achievement. However, larger reductions in HbA1c and BP values paired with higher goal achievement and improved PCP utilization are goals for each program. As such, a recommendation to modify the care management protocol for each group to address deficiencies in improving HbA1c, BP values, goal achievement, and individually appropriate PCP usage is the most prudent step forward.

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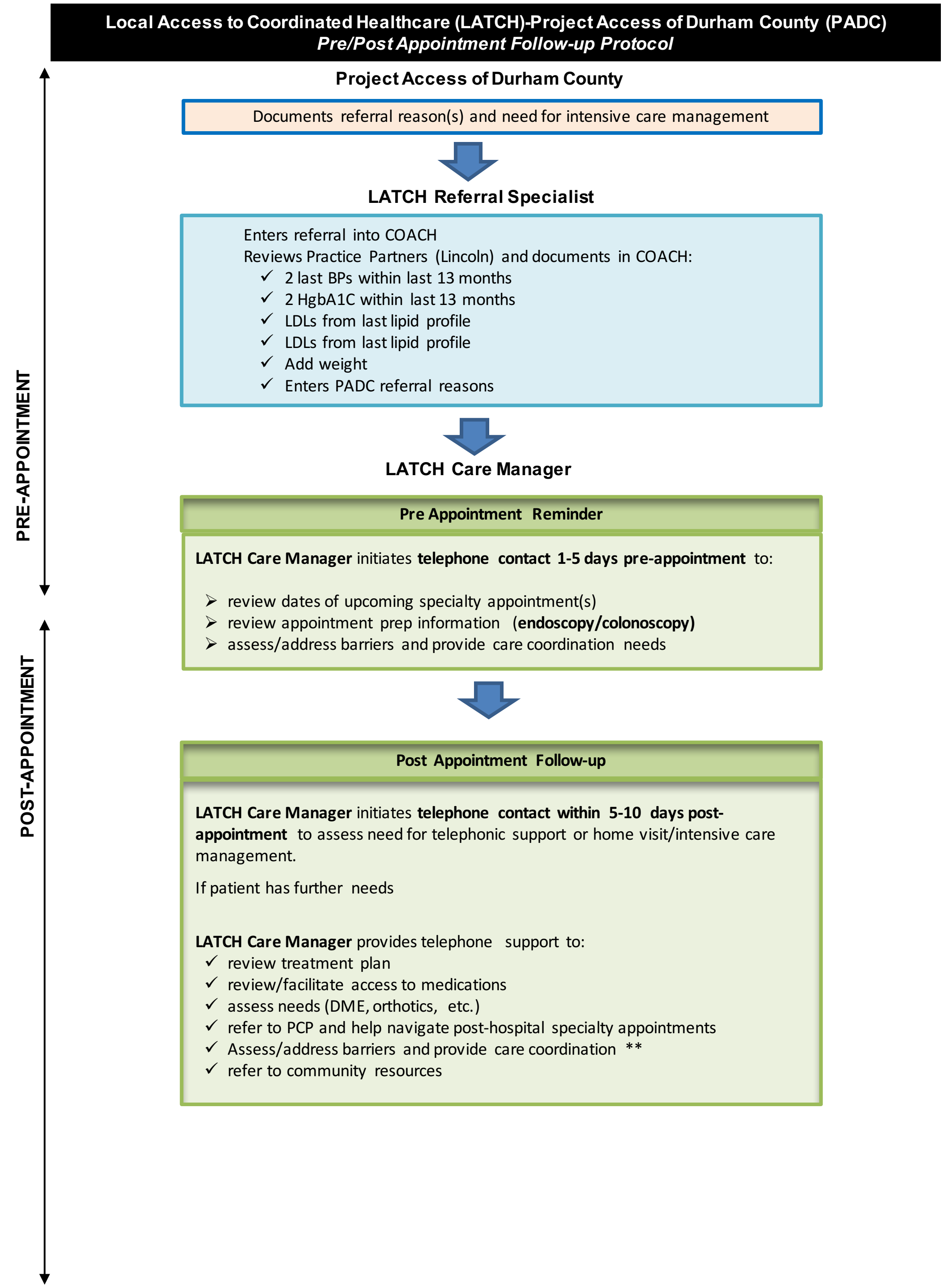
APPENDIX

Appendix A: Table 1-Type 2 DM and hypertension statistics by race and poverty level

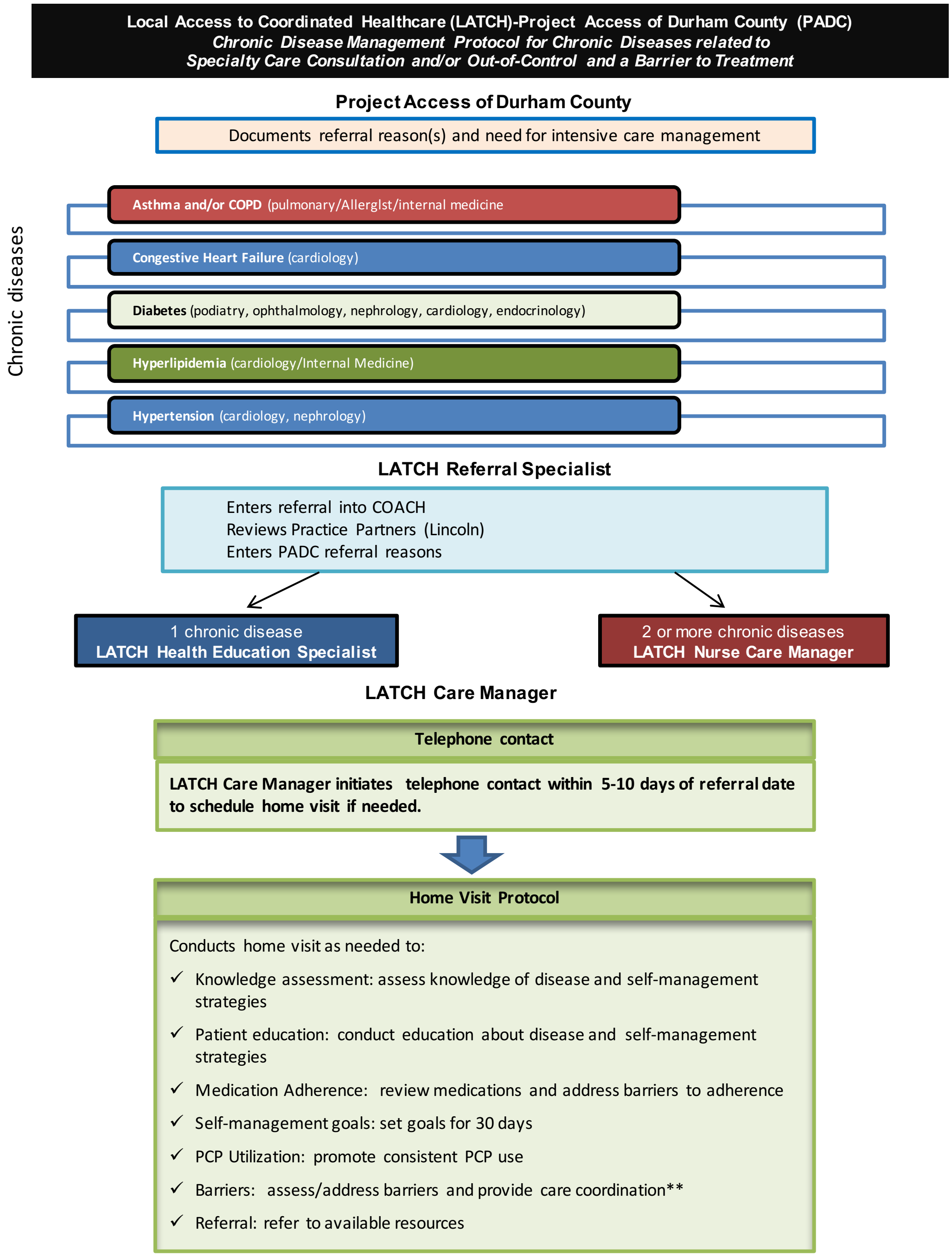
	Race/Ethnicity		
	Black adults	**Hispanic adults**	**Non-Hispanic White adults**
Diabetes prevalence (CDC, 2014) (%)	13.2	12.8	7.6
Mortality rate attributed to type 2 DM (Mozaffarian et al., 2015) (per 100 000 deaths)	male-44.9 female-35.8	N/A	male-24.3 female-16.2
Hypertension prevalence (Yoon et al., 2015) (%)	41.2	25.9	28
Mortality rate attributed to hypertension (Mozaffarian et al., 2015) (per 100 000 deaths)	male-47.1 female-17.6	N/A	male-17.6 female-15.2
Living below the poverty line (DeNavas-Walt & Proctor, 2015) (%)	26.2	23.6	10.6
Incidence of ESRD associated with diabetes (CDC's Division of Diabetes Translation-National Center for Chronic Disease Prevention and Health Promotion, 2013a) (per 100 000 people)	461.7	271.8	170.7
Percentage of adults with diagnosed diabetes reporting visual impairment (CDC's Division of Diabetes Translation-National Center for Chronic Disease Prevention and Health Promotion, 2013b) (%)	20.7	15.6	17.1
Percentage of adults 35 and older with diagnosed diabetes reporting heart disease or stroke (CDC's Division of Diabetes Translation-National Center for Chronic Disease Prevention and Health Promotion, 2014) (%)	33	24.5	33.9

Appendix B: Figure 1-LATCH-PADC Standard care management protocol



Source: Local Access to Coordinated Healthcare, Durham, NC

Appendix B: Figure 2-LATCH-PADC Intensive care management protocol



Source: Local Access to Coordinated Healthcare, Durham, NC

Appendix B, continued: Figure 2-LATCH-PADC Intensive care management protocol, continued

Local Access to Coordinated Healthcare (LATCH)-Project Access of Durham County (PADC)
Chronic Disease Management Protocol for Chronic Diseases related to
Specialty Care Consultation and/or Out-of-Control and a Barrier to Treatment

(continued)

LATCH Care Manager

Follow-ups – 6 weeks

LATCH Care Manager conducts bi-weekly phone/home visit for 6 weeks to assess:

- ✓ follow-through on PCP and other referrals
- ✓ progress on self-management goals
- ✓ barriers to meeting goals and care coordination needs

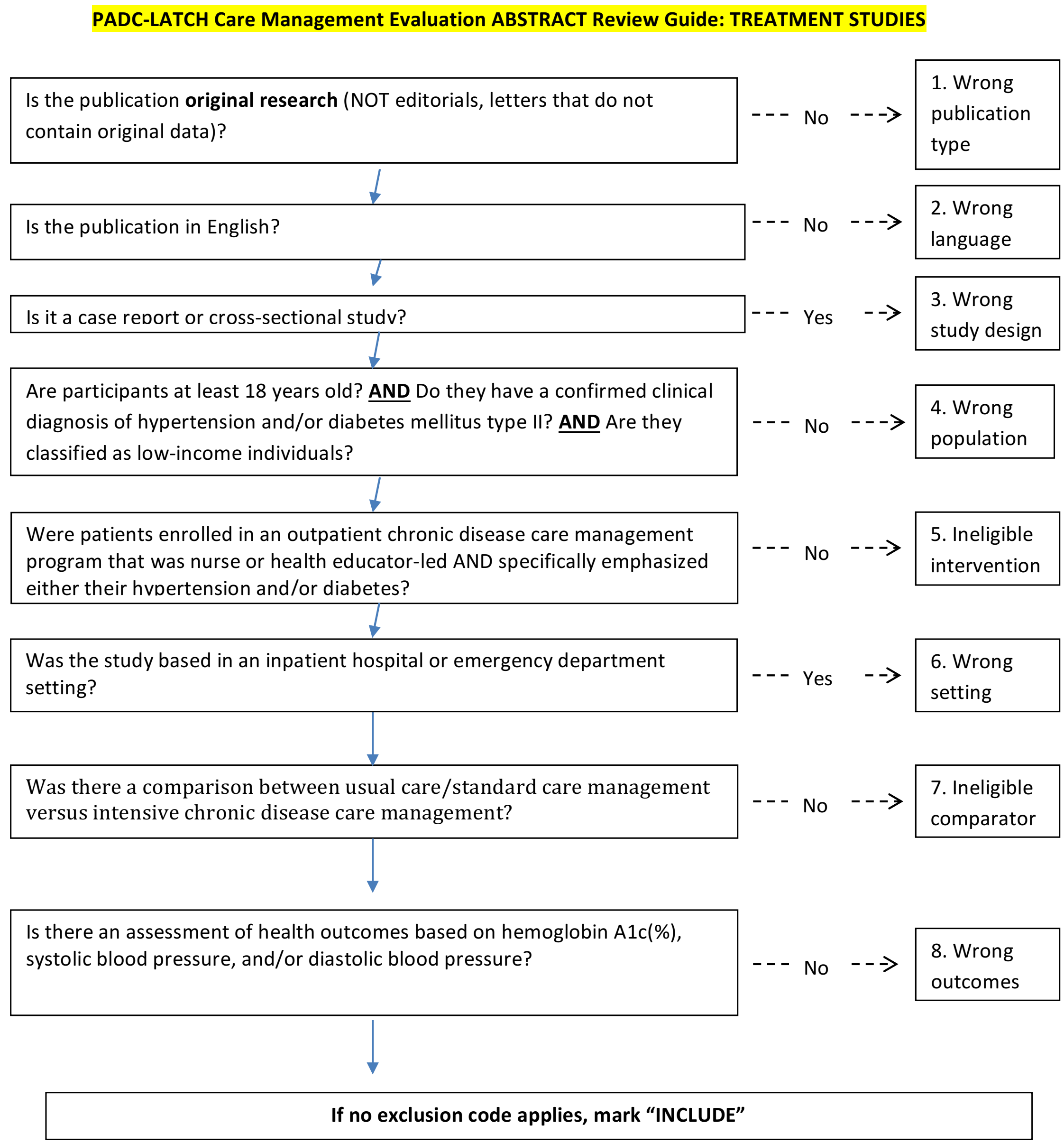
3-Month Follow-up

LATCH Care Manager conducts 3-month telephone contact to assess:

- ✓ follow-through on PCP and other referrals
- ✓ Documented progress on self-management goals, document which goals achieved and identifies barriers
- ✓ barriers to meeting goals

Source: Local Access to Coordinated Healthcare, Durham, NC

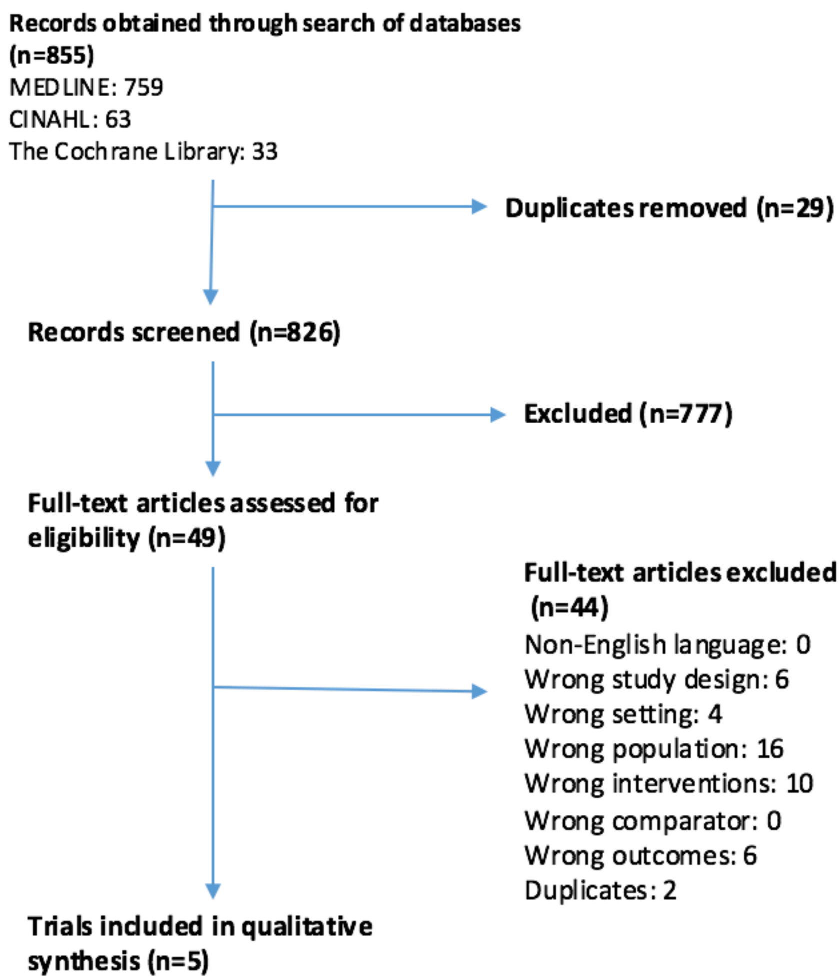
Appendix C: Figure 3-Literature eligibility criteria



Appendix C: Figure 4-PUBMED search strategy

1. "adult" [Mesh] OR "middle aged adults"[tiab] OR "young adults"[tiab] OR "aged"[tiab] OR "elderly"[tiab]
    a. **(Results: 6164023)**
2. "disease management"[Mesh] OR "care management"[tiab] OR "intensive care management"[tiab] or "case management"[tiab]
    a. **(Results: 59508)**
3. "diabetes mellitus, type 2"[Mesh] OR "diabetes type 2"[tiab] OR "type 2 diabetes mellitus"[tiab] OR "adult onset diabetes mellitus"[tiab] OR "non-insulin dependent diabetes mellitus"[tiab]
    a. **(Results: 108069)**
4. "hypertension"[Mesh] OR "high blood pressure"[tiab]
    a. **(Results: 229654)**
5. (("diabetes mellitus, type 2"[Mesh] OR "diabetes type 2"[tiab] OR "type 2 diabetes mellitus"[tiab] OR "adult onset diabetes mellitus"[tiab] OR "non-insulin dependent diabetes mellitus"[tiab]))) OR (("hypertension"[Mesh] OR "high blood pressure"[tiab])
    a. **(Results: 330366)**
6. ((("adult" [Mesh] OR "middle aged adults"[tiab] OR "young adults"[tiab] OR "aged"[tiab] OR "elderly"[tiab]))) AND (("disease management"[Mesh] OR "care management"[tiab] OR "intensive care management"[tiab] or "case management"[tiab]))) AND (((("diabetes mellitus, type 2"[Mesh] OR "diabetes type 2"[tiab] OR "type 2 diabetes mellitus"[tiab] OR "adult onset diabetes mellitus"[tiab] OR "non-insulin dependent diabetes mellitus"[tiab]))) OR (("hypertension"[Mesh] OR "high blood pressure"[tiab]))
    a. **(Results: 759)**

Appendix C: Figure 5-Review article flow



Appendix C: Table 2-Study characteristics

Study	Country	Study design	Care management intervention	Patients with type II diabetes	Patients with hypertension	Low-income/uninsured patients	Age, yr, mean ± SD
Kim et al, 2014	South Korea	Prospective cohort study, "single group pretest-post-test"	Community-based case management	No	Yes	Yes; Family income below 120% of minimum living costs	85% were older than 65 years
Sekhobo et al, 2008	USA	Retrospective cohort study	Chronic disease case management program	Yes	No	Yes; predominantly low-income, minority population receiving care at a multisite community health center	3 groups based on A1c control: Good-62.4 ± 14.4, Intermediate-61.4 ± 12.7, Poor-58.7 ± 11.2
California Medi-Cal Type 2 Diabetes Research Group, 2004	USA	Randomized, controlled study	Intensive diabetes case management	Yes	No	Yes; study conducted at clinical sites serving low-income Medi-Cal populations	Intervention: 57.0 ± 0.9. Control: 56.9 ± 1.0.
Hebert et al., 2012	USA	Randomized controlled effectiveness trial	Nurse management intervention	No	Yes	Yes; patients recruited from highly diverse urban Harlem, New York neighborhood and from a FQHC. However, risk of other patients being included since low income or uninsurance was not an explicit criteria for eligibility.	Nurse group: 60.5 ±11.1. Usual care: 61.2 ±12.0. BP monitor: 61.3 ±11.7. Usual care: 61.0 ±11.8.
Philis-Tsimikas et al., 2004	USA	Prospective cohort study	Nurse-led case management and group peer education	Yes	No	Yes; patients belonged to one of 3 low-income payer groups: Medi-Cal, Medically Indigent Adult (MIA) health services program, or uninsured and income under the appropriate federal poverty level.	Intervention: 51 ± 12.9. Control: 50 ± 12.

Appendix C: Table 3-Study characteristics, continued

Study	# of patients	Intervention components	Duration of intervention	Frequency of CM encounter	Eligibility criteria	Exclusion criteria
Kim et al, 2014	22	Community-based case management: 1. Selection of participants, 2. Needs assessment, 3. Prioritization of problems and planning case management, 4. Implement case management service, 5. Evaluate case management service.	2-8 months	6 home visits, 2 telephone contacts	1. 30 years or older, newly diagnosed with hypertension per JNC-7 or taking anti-hypertensive medications, 3. Within lowest 50% of health insurance level, 4. Income below 120% of minimum living standards	None identified; 2 patients excluded due to excessive missing data
Sekhobo et al, 2008	132	Case managers provide diabetes education and self-management support to patients, link patients to important resources to ensure continuity of care	2 years (1/1/2003-12/31/2005)	Unclear	Patients with type 2 diabetes active in 2002, with follow-up visits in the study period.	Patients missing data on key variables were excluded.
California Medi-Cal Type 2 Diabetes Research Group, 2004	362	1. Adherence to EBM practice guidelines for diabetes medication, 2. Identification of barriers to care, and plans to address barriers, 3. Glucometer and education on use, 4. Diet, exercise, and diabetes self-management education. (Interactions were in-home or telephonic encounters, as needed).	4 years (7/1/1195-6/30/1999)	As needed	HbA1c levels greater than 7.5%	Patients missing HbA1c data
Hebert et al., 2012	416	Nurse management-1. Face-to-face counseling to improve self-care behaviors, 2. Counseling on reducing making and alcohol intake, 3. Regular telephone follow-up, 4. Nurse and physician communication about patient treatment plan. Home BP monitor intervention-1. Receive BP monitor, information on use, and no nurse follow-up.	9 months	Unclear	1. 18 years or older, 2. Living within community at time on enrollment, 3. Receiving care for at least 6 months at clinical site, 4. uncontrolled hypertension recorded in their last two visit notes, 5. BP >=150/95 at recruitment.	1. Pregnancy, 2. renal dialysis, 3. terminal illness, 4. blindness, deafness, or cognitive impairment.
Philis-Tsimikas et al., 2004	153	Nurse-led management-1. 2-hour baseline visit, 2. Subsequent clinic visits reviewed self-management, guidelines, and goals along with medication changes. A minimum of 4 clinic visits with nurses was advised. Peer education component-1. Peer educators taught classes on diabetes self-management	2 years (6/1998-6/2000)	Minimum of 4 nurse visits per year advised.	1. Diagnosis with either type 1 or type 2 diabetes, 2. Aged 18-80, 3. Belongs to one of 3 payer groups: Medi-Cal, Medically Indigent Adult (MIA) health services program, or uninsured and income under the appropriate federal poverty level.	1. Diabetes in pregnancy, 2. severe medical conditions precluding consistent attendance to clinic, 3. Anticipated death in less than 2 years, 4. serum creatinine >3.5 mg/dL, 5. Active alcohol or drug abuse, 6. Lack of permanent residency in San Diego County.

Appendix C: Table 4-Study characteristics, continued

Study	Control	Setting	Personnel providing CM	Duration of follow-up	Outcomes measured	Sources of conflict
Kim et al, 2014	None; patients served as controls within pretest-post-test design	Public health center in Seoul serving a population of 400,000.	Nurses	Unclear	1. Hypertension knowledge, 2. hypertension self-management, 3. Blood pressure control	None listed and none identified.
Sekhobo et al, 2008	Control clinic belongs to same network as study clinic but does not have case management	Multisite community health center	Case managers specially trained In chronic disease management	2 years-study period listed	Improvement in HbA1c.	First author employed as research scientist at New York State Dept. of Health, second author was medical director of Open Door Family Clinic. No additional COIs identified.
California Medi-Cal Type 2 Diabetes Research Group, 2004	Control group was randomized at each of the 3 clinical sites	Three clinical sites serving Medi-Cal patients in Santa Barbara, Los Angeles, and San Diego. One was community-based, other 2 were university-based.	Registered nurses, registered dietitians, endocrinologist at each site.	Mean duration of follow-up was 25.3 months	Glycemic control, measured by HbA1c.	None listed. However, the California Medi-Cal Managed Care Division and CDC funded the study, potential for overestimate of care management effect.
Hebert et al., 2012	Usual care-Received BP pamphlet and regular visits with clinician.	Federally Qualified Health Center and four hospitals in Harlem, New York.	Nurses	18 months	Primary outcome-BP at 9 and 18 months. Self-care behaviors and self-reported medication adherence were measured via surveys.	None disclosed, however study was funded, in part, by NIH-National Center for Minority Health and Health Disparities which may lead to an implicit bias that may overestimate effect of nurse management intervention.
Philis-Tsimikas et al., 2004	Usual care	Six clinical sites across San Diego County	Nurse-led team consisting of RN/certified diabetes educator, medical assistant, and dietitian.	1 year	Outcomes in HbA1c, BP, lipids, BMI, patient satisfaction with program, patient knowledge, and patient beliefs regarding diabetes self-management were measured.	Multiple pharmaceutical companies listed as funders or in-kind supporters for the study.

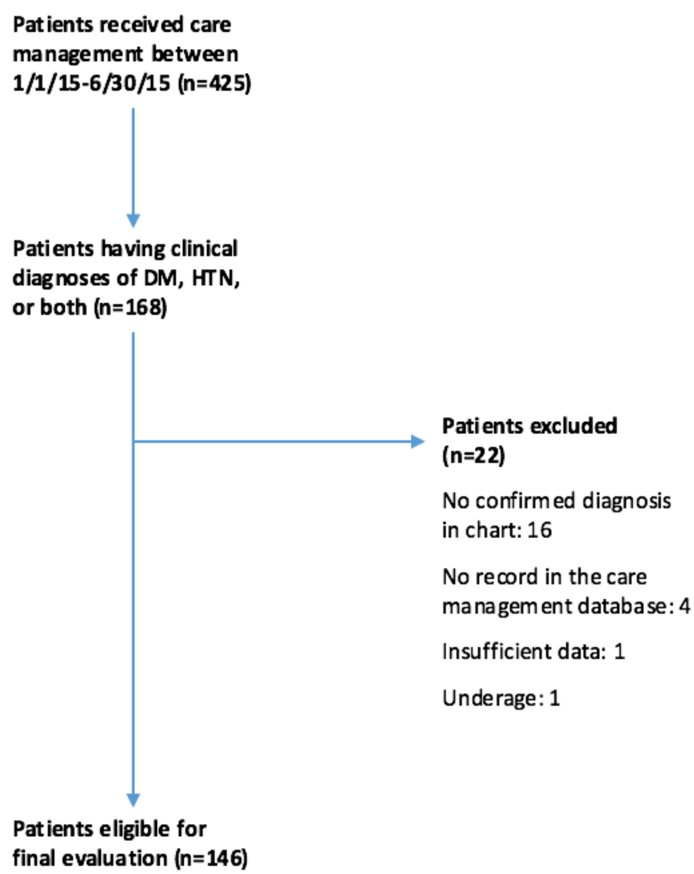
Appendix C: Table 5-Risk of bias for included studies

Study	Study design	Random sequence generation	Allocation concealment	Similar baseline characteristics
Kim et al., 2014	Prospective cohort study, "single group pretest-post-test"	Low risk of bias-No sequence generation, all patients were given the same intervention.	Low risk of bias-Patients were openly informed, consented, and enrolled in the intervention.	High risk of bias-86.4% were older than 65 years, 77.3% were female, and 59% lived alone.
Sekhobo et al., 2008	Retrospective cohort study	Low risk of bias-No sequence generation because of retrospective design and all patients at study clinic were given intervention so no selective enrollment.	Low risk of bias-No random sequence generated, so now concealment needed. All patients at study clinic were given intervention.	High risk of bias-Only 29 subjects in control group compared to 103 in in study group.
California Medi-Cal Type 2 Diabetes Research Group, 2004	Randomized, controlled study	Low risk of bias-Computer-generated time-blocked allocation sequence was used for randomization at each of the 3 clinical sites.	Low risk of bias-Allocation was concealed using sequentially labeled sealed envelopes.	Low risk of bias-Groups were similar at baseline, no exceptional differences exist.
Hebert et al., 2012	Randomized controlled effectiveness trial	Low risk of bias-Computer-generated random-number sequence without blocking or stratification for randomization	Low risk of bias-concealment through sealed opaque envelopes.	Low risk of bias-All 3 groups were similar at baseline. The only exception was a greater proportion of patients with depression in the BP monitor group (25.8%) compared to usual care (14.7%)
Philis-Tsimikas et al., 2004	Prospective cohort study	High risk of bias-The first 310 patients referred to the program were enrolled into the intervention arm. All patients referred thereafter were relegated to the usual care arm.	High risk of bias-No randomization, so no allocation of treatment group.	Low risk of bias-Groups were similar at baseline across gender, age, ethnicity, HbA1c, and lipid outcomes.

Appendix I: Table 6-Risk of bias for included studies, continued

Study	Incomplete outcome data	Blinding of participants and personnel	Blinding of outcome assessors	Selective outcome reporting	Other bias
Kim et al., 2014	Low risk of bias-Only 2 withdrawals due to excessive missing data. Cross-overs were not possible with this study. Adherence issues were not noted.	High risk of bias-Risk of performance bias due to lack of blinding of these two groups and the open knowledge of being involved in a study.	Low risk of bias-No note of this blinding, however since all patients were given the same intervention and there are no groups being compared, there is a low risk of detection bias.	Low risk of bias-this was not discussed by the authors, however all outcomes reported in methods were reported in results	High risk of bias-small sample size, lack of control group.
Sekhobo et al., 2008	Low risk of bias-Only 6 of 138 eligible patients were excluded due to missing data on key variables. No withdrawals due to study design.	Low risk of bias-Not needed since study was not ongoing at time of intervention.	High risk of bias-No note of assessor blinding, this may lead to detection bias since there was a study and control group being compared.	Low risk of bias-not discussed, but all discussed outcomes were reported in results.	Low risk of bias-no other potential for bias identified
California Medi-Cal Type 2 Diabetes Research Group, 2004	Low risk of bias-15 patients were lost to follow-up in the intervention group, and 26 patients were lost to follow-up in the control group. No withdrawals or cross-overs were noted, but analysis was performed with intention-to-treat to minimize bias.	High risk of performance bias-HbA1c values were available to both groups. Blinding of either group was impossible given nature of intervention.	High risk of bias-No mention of blinding of outcome assessors, which leads to potential for bias given that an intervention and control group are being compared.	Low risk of bias-the primary outcome of HbA1c was reported on in addition to numerous secondary outcomes.	Low risk of bias-no other potential for bias identified
Hebert et al., 2012	Low risk of bias-49 of 176 people were lost to follow-up in the usual care arm, 32 of 120 in the BP monitoring group, and 35 of 120 in the nurse management group. However, there was a similar rate of attrition in each group and analysis was done with multiple imputation to account for missing data, so risk of bias is lowered.	High risk of bias-Given the nature of the interventions it is difficult to blind participants and personnel. This leads to potential for performance bias.	Low risk of bias-Study personnel recording BPs were blinded to patient assignment	Low risk of bias-Not mentioned by authors, but primary outcome of BP at 9 months was recorded and examined.	High risk of bias-unorthodox recruitment in which study began as a 2-arm trial (nurse and usual care groups) and once further funding was secured was expanded to 3-arms to included home BP monitoring. Limitation discussed, especially effect on controls, but this may still provide biased results.
Philis-Tsimikas et al., 2004	High risk of bias-Only 153 of the original 310 patients recruited completed the intended study duration. Statistical analysis did not account for this attrition.	High risk of bias-No blinding of either group and both parties knew that a study was ongoing.	High risk of bias-No note of outcome assesssors being blinded, with 2 groups being compared, there is a high risk of detection bias.	Low risk of bias-not discussed, but all intended outcomes were reported.	Low risk of bias-no other potential for bias identified

Appendix D: Figure 6-Patient flow diagram



Appendix E: Table 7-Patient characteristics

	Care Management Received		
	ICM (comparison group)	**SCM (referent group)**	**P**
Sample size (n)(%)	23 (15.8)	123 (84.2)	
Age (years)			
Mean (SD)	51.9 (8.63)	51.2 (10.4)	0.78
Gender			
Male (%)	39.1	44.7	
Female (%)	60.9	55.3	0.62
Race/Ethnicity			
Black (%)	43.5	50.4	
Hispanic (%)	43.5	24.4	
White (%)	13	17.1	
Other (%)	0	8.13	0.19
Marital Status			
Single (%)	34.8	56.9	
Married (%)	34.8	21.1	
Divorced (%)	26.1	11.4	
Other (%)	4.4	10.6	0.07
Type 2 diabetes diagnosis (%)	82.6	32.5	0
Hypertension diagnosis (%)	78.3	89.4	0.14
Type 2 diabetes and hypertension diagnoses (%)	60.9	22.0	0
Baseline Hgb A1c (SD)	10.6 (2.44) (20 obs)	6.73 (1.48) (56 obs)	0
Baseline Systolic BP (SD)	141.6 (19.1) (23 obs)	143.5 (21.2) (122 obs)	0.69
Baseline Diastolic BP (SD)	81.5 (11.2) (23 obs)	85.8 (10.8) (122 obs)	0.078
PCP visits (pre-care management) (IQR)	2 (2)	2 (2)	0.2
Patients having a PCP visit during baseline period (%)	91.3	95.9	0.34

Data compiled by myself. Key: SD, standard deviation; ICM, intensive care management; SCM, standard care management; HbA1c, hemoglobin A1c; CI, confidence interval; BP, blood pressure; PCP, primary care physician. Statistical significance set at *P<0.05*.

Appendix E: Table 8-Care management encounters

	Care Management Received		
	ICM	**SCM**	**P**
Sample size (n)	23	123	
CM phone encounters (IQR)	7 (8)	2 (3)	0
CM In-home encounters (IQR)	0 (0)	0 (0)	0.002
Patients having an in-home encounter (%)	17.4	2.44	0.002
CM community/practice encounter (IQR)	0 (0)	0 (0)	0.36
Patients having a community/practice encounter (%)	13.0	7.32	0.36

Data compiled by myself. Key: ICM, intensive care management; SCM, standard care management; CM, care management; IQR, interquartile range. Statistical significance set at *P<0.05*.

Appendix E: Table 9-Change in hemoglobin A1c

	Care Management Received		
	ICM	**SCM**	**P**
Sample size (n)	23	123	
Baseline HbA1c (SD)	10.6 (2.44) (20 obs)	6.73 (1.48) (56 obs)	0
Follow-up HbA1c (SD)	9.51 (2.80) (20 obs)	6.78 (1.31) (58 obs)	0.004
t-statistic	1.73	-0.096	
P	0.1	0.923	
F-statistic	3	2.01	
df	20	65	
P	0.1	0.166	
Change in HbA1c (SD)	-1.12 (2.81)	0.02 (1.30)	0.11
% change in HbA1c	-8.76	2.03	0.09

Data compiled by myself. Key: SD, standard deviation; ICM, intensive care management; SCM, standard care management; HbA1c, hemoglobin A1c; df, degrees of freedom. Comparisons were made by paired t-test (reported with t-statistic), Wilcoxon signed-rank test (z-statistic), or repeated measures one-way ANOVA (F-statistic). Statistical significance set at *P<0.05*.

Appendix E: Table 10-Change in HbA1c ANCOVA model

Care management group	Unadjusted mean change in HbA1c (95% CI)	P	Fully adjusted mean change in HbA1c[1] (95% CI)	P	Adjusted mean change in HbA1c[2] (95% CI)	P
Standard	0.02 (-0.56, 0.60)	0.04	-0.06 (-0.63, 0.50)	0.1	-0.078 (-0.63, 0.48)	0.11
Intensive	-1.12 (-1.96, -0.26)		-0.94 (-1.78, -0.09)		-0.90 (-1.73, -0.08)	

Data compiled by myself. Key: HbA1c, hemoglobin A1c; CI, confidence interval. 1. Adjusted for age, gender, race, and marital status. 2. Adjusted for marital status. Statistical significance set at *P<0.05*.

Appendix E: Table 11-Change in systolic blood pressure

Care Management Received

	ICM	SCM	P
Sample size (n)	23	123	
Baseline Systolic BP (SD)	141.6 (19.1) (23 obs)	143.5 (21.2) (122 obs)	0.69
Follow-up Systolic BP (SD)	137.2 (18.6) (22 obs)	140.6 (18.9) (118 obs)	0.43
t-statistic	1.43	1.73	
P	0.168	0.086	
F-statistic	2.04	1.76	
df	22	113	
P	0.168	0.188	
Change in Systolic BP (SD)	-5.55 (18.2)	-2.89 (18.0)	0.53
% change in Systolic BP	-3.18	-1.15	0.46

Data compiled by myself. Key: SD, standard deviation; ICM, intensive care management; SCM, standard care management; BP, blood pressure; df, degrees of freedom. Comparisons were made by paired t-test (reported with t-statistic), Wilcoxon signed-rank test (z-statistic), or repeated measures one-way ANOVA (F-statistic). Statistical significance set at *P<0.05*.

Appendix E: Table 12-Change in systolic blood pressure ANCOVA model

Care management group	Unadjusted mean change in systolic BP (95% CI)	P	Adjusted mean change in systolic BP[1] (95% CI)	P	Adjusted mean change in systolic BP[2] (95% CI)	P
Standard	-2.89 (-6.16, 0.38)	0.53	-3.01 (-6.25, 0.24)	0.65	-3.03 (-6.29, 0.23)	0.67
Intensive	-5.55(-13.10, 2.00)		-4.90 (-12.43, 2.62)		-4.81 (-12.35, 2.75)	

Data compiled by myself. Key: BP, blood pressure; CI, confidence interval. 1. Adjusted for age, gender, race, and marital status 2. Adjusted for race and marital status. Statistical significance set at *P<0.05*.

Appendix E: Table 13-Change in diastolic blood pressure

	Care Management Received		
	ICM	**SCM**	**P**
Sample size (n)	23	123	
Baseline Diastolic BP (SD)	81.5 (11.2) (23 obs)	85.8 (10.8) (122 obs)	0.078
Follow-up Diastolic BP (SD)	79.8 (12.1) (22 obs)	84.5 (10.6) (118 obs)	0.1
t-statistic	0.536	1.44	
P	0.598	0.153	
F-statistic	0.29	1.49	
df	22	107	
P	0.598	0.225	
Change in Diastolic BP (SD)	-1.69 (14.8)	-1.31 (9.80)	0.91
% change in Diastolic BP	-0.87	-0.89	0.99

Data compiled by myself. Key: SD, standard deviation; ICM, intensive care management; SCM, standard care management; BP, blood pressure; df, degrees of freedom. Comparisons were made by paired t-test (reported with t-statistic), Wilcoxon signed-rank test (z-statistic), or repeated measures one-way ANOVA (F-statistic). Statistical significance set at *P<0.05*.

Appendix E: Table 14-Change in diastolic blood pressure ANCOVA model

Care management group	**Unadjusted mean change in diastolic BP (95% CI)**	**P**	**Adjusted mean change in diastolic BP[1] (95% CI)**	**P**
Standard	-1.30 (-3.24, 0.64)	0.88	-1.30 (-3.22, 0.62)	0.87
Intensive	-1.68 (-6.17, 2.79)		-1.70 (-6.15, 2.75)	

Data compiled by myself. Key: BP, blood pressure; CI, confidence interval. 1. Adjusted for age, gender, race, and marital status. Statistical significance set at *P<0.05*.

Appendix E: Table 15-Change in primary care physician utilization

	Care Management Received		
	ICM	**SCM**	**P**
Sample size (n)	23	123	
PCP visits (pre-care management) (IQR)	2 (2)	2 (2)	0.2
PCP visits (post-care management) (IQR)	2 (2)	1 (2)	0.052
z-statistic	1.15	4.012	
P	0.25	<0.05	
Change in PCP visits (SD)	-0.65 (2.04)	-0.64 (1.66)	0.98
% change in PCP visits	-0.8	-16.7	0.39
Patients having a PCP visit during baseline period (%)	91.3	95.9	0.34
Patients having a PCP visit during follow-up period (%)	82.6	72.4	0.30

Data compiled by myself. Key: SD, standard deviation; ICM, intensive care management; SCM, standard care management; PCP, primary care physician; IQR, interquartile range. Comparisons were made by paired t-test (reported with t-statistic), Wilcoxon signed-rank test (z-statistic), or repeated measures one-way ANOVA (F-statistic). Statistical significance set at *P<0.05*.

Appendix E: Table 16-Change in PCP utilization ANCOVA model

Care management group	**Unadjusted mean change in PCP utilization (95% CI)**	**P**	**Adjusted mean change in PCP utilization[1] (95% CI)**	**P**
Standard	-0.64 (-0.95, -0.34)	0.98	-0.64 (-0.94, -0.34)	0.98
Intensive	-0.65 (-1.35, 0.05)		-0.65 (-1.35, 0.05)	

Data compiled by myself. Key: BP, blood pressure; CI, confidence interval. 1. Adjusted for age, gender, race, and marital status. Statistical significance set at *P<0.05*.

Appendix E: Table 17-Care management goal achievement

	Care Management Received		
	ICM	**SCM**	**P**
Sample size (n)	23	123	
Achieved goals	57.1	78.2	0.04
Did not achieve goals	42.9	21.8	

Data compiled by myself. Key: ICM, intensive care management; SCM, standard care management. Statistical significance set at *P<0.05*.

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