Study protocol with statistical analysis plan

Official Title: Pharm-MD; an Open-Label, Randomized Controlled Phase II Study to Evaluate the Efficacy of a Pharmacist Managed Diabetes Clinic in High-Risk Diabetes patients (Pharma MD)

NCT Number: 03377127

Document Date: February 20, 2020

Protocol Information
Study number 2017-494
NCT 03377127

Title: Pharm-MD; an Open-Label, Randomized Controlled Phase II Study to Evaluate the Efficacy of a Pharmacist Managed Diabetes Clinic in High-Risk Diabetes patients (Pharma MD)

Version 1.14, (2/20/2020)

Beaumont Health System – Department of Internal Medicine
Principal Investigator: Halalau, Alexandra I, MD

Additional Investigators:
Bushman, Jordan S
El Masri, Dana
Gierer, Jacqueline L, DO
Kaur, Madhupreet
Keeney, Scott, DO
Shelden, Daniel Thomas, D.O.
Sonmez Ince, Melda
Uddin, Ahsan

Bradley, Kathleen M, CRC I / CRA
Schumacher, Nicole M, CRC I / CRA
Tessmar, Coleen M, Research Nurse Clinician
Kopper, Gloria, RN, MSA, Clinical Research Nurse Manager
Lewis, Bobbie L, RN, BSN, CCRC, Clinical Research Nurse Manager

Study Information

Phase of study: N/A
Sponsor: Beaumont Health
Funding: Herb and Betty Fisher Seed Grant

Locations of Study:
Beaumont Hospital- Royal Oak
3601 W. 13 Mile Rd., Royal Oak, MI 48073

Beaumont Internal Medicine Center-Southfield
29355 Northwestern Hwy #210, Southfield, MI 48034

Norton, Klein, Hug, Sabin & Maddens, MD, PC
3290 West Big Beaver Road, Suite 420, Troy, MI 48084

Beaumont Internal Medicine
1949 12 Mile Road, Berkley, MI 48072

IRB review:
Expedited review by the Beaumont IRB was conducted under the following categories:

- Study does not involve greater than minimal risk
- Information on living individuals is included, and data collection will be via prospective collection of data from chart review or research activities, as well as prospective questionnaire or survey
- Category 4: Study involves collection of data through non-invasive procedures routinely employed in clinical practice, excluding procedures involving x-rays of microwaves
- Category 5: Study involves materials (data, documents, records, or specimens) which have been collected or will be collected solely for non-research purposes
- Use of an information sheet for informed consent with a waiver of consent documentation

Study Overview/Inclusion/Exclusion Criteria

Background and Significance:
Type 2 diabetes mellitus (DM) is a chronic medical condition resulting in the inability to properly respond to insulin, a hormone responsible for the body's use of sugar. This leads to abnormally elevated sugar levels in the bloodstream. Diabetes can affect any of the body's organs, with long term effects including an increase in the risk of heart attack, stroke, kidney disease, eye disease, and nerve disease. According to the Centers for Disease Control (CDC), DM affected 29.1 million Americans in 2014, with approximately 8 million additional undiagnosed cases in 2012. DM was the 7th leading cause of death in 2013 in the US. Additionally, diabetes imposes a large disease burden on society, with an estimated total cost of $245 billion in 2012.

The main goal of diabetes treatment is to lower the blood sugar. A standard blood test called the hemoglobin A1c (HbA1c) is a numerical value (a percentage) that is a reflection of blood sugar control over the prior 2-3 months. The higher the number, the worse the blood sugar control. Therefore,

reduction of the HbA1c is the primary target for measuring disease control. Previous studies have demonstrated that for each 1% reduction in the HbA1c, there was a corresponding 14% reduction the in risk of heart attack, 12% reduction in the risk of stroke, and a 37% reduction of other problems such as nerve, kidney, and eye damage. The Royal Oak Beaumont Hospital resident clinic cares for 908 diabetic patients, of which 214 are considered "high risk" because their hemoglobin A1c is greater than or equal to 9%, which represents poor control of the disease.

In 2016, the Association of American Medical Colleges estimated that the shortage of physicians in the United States would be between 61,700 and 94,700 by 2025. As a means of addressing this shortage, the role of "physician extenders" such as nurse practitioners and physician assistants has increased. Their role in the treatment of diabetes is well established, but our data from a previous study as well as data from our review of the literature suggests that pharmacists are an underutilized resource. In an effort to improve the quality of care delivered to our patients, a Pharmacist Managed Diabetes Clinic (PMDC) was created. The uniqueness of our PMDC, which differentiates it from those in prior studies, is the focus of educational visits on patient-identified goals and barriers to attaining better diabetes management.

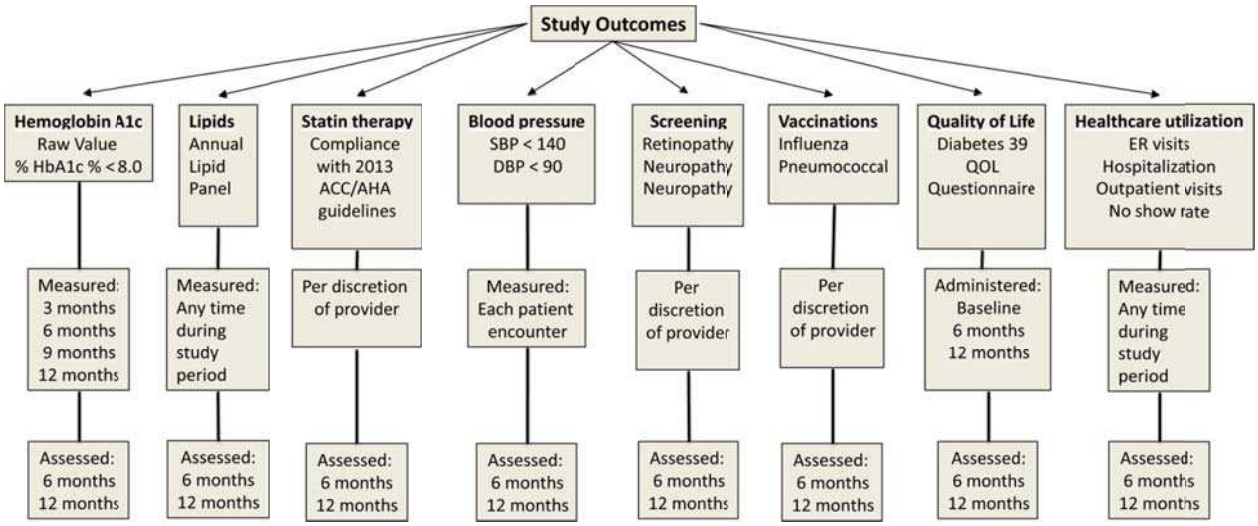
The impact of our PMDC on the quality of care for high risk diabetes patients was evaluated in a study looking back at the electronic health record from our clinic. The results at three and six months revealed a significant decrease in the HbA1c in the patients who go to the PMDC versus the patients who did not. The data from this study is very impressive, but there are limitations to studies that look back in time versus forward in time. Therefore, we aim to conduct a randomized controlled trial (RCT) in which patients would be randomly assigned to attend the PMDC or to continue with regular physician visits. Our hypothesis is that the PMDC, which is focused on patient-identified diabetes management gaps and goals, would result in a higher quality of care at a lower price. A RCT would provide further clarity on the impact on patient outcomes and important evidence with regard to how we can deliver the best care for this high-risk population.

Outcomes:
The primary outcome for this study is the hemoglobin A1c (HbA1c), measured at baseline, at 6 months and at 12 months after randomization.

Secondary outcomes for this study are related to the impact of the PMDC on all diabetes core measures, patient quality of life, and harms and cost effectiveness related to the intervention. Secondary outcomes for this study include the following:

- Percentage of patients achieving a hemoglobin A1c measurement of less than 8.0% at the end of the trial period.
- Achievement of annual lipid panel testing.
- Compliance with statin therapy per the 2013 American College of Cardiology / American Heart Association guidelines.
- Blood pressure goal of less than 140/90 at the end of the trial period.
- Compliance with recommended diabetic screening: annual retinopathy examination via dilated retinal examination, annual nephropathy evaluation with urine microalbumin testing, and annual neuropathy evaluation with lower extremity monofilament testing.
- Compliance with recommended vaccinations including annual influenza vaccination and pneumococcal vaccination.

- Quality of life assessment via the Diabetes 39 questionnaire administered at baseline and at the conclusion of the trial period (6 months).
- Number of Emergency Center visits related to hyperglycemia or hypoglycemia. 6 and 12, all ED visits
- The overall quantity of total inpatient and outpatient visits.
- The "no-show" rate.



Study setting:

The study will be conducted in the outpatient internal medicine clinic at Beaumont Hospital, Royal Oak, Michigan. The outpatient clinic is a resident (physicians in training under the supervision of a teaching physician) clinic that delivers medical care to over 920 patients with diabetes mellitus. The patients are assigned to 60 internal medicine residents and 16 internal medicine-pediatrics residents. Potential subjects with "high-risk" diabetes mellitus (patients with a hemoglobin A1c > 9.0%, which indicates poor control of the disease) will be identified through weekly reports and from the daily schedule and will be recruited from this pool of patients exclusively. The patients will be enrolled over a 6-month period and will be randomly assigned to the control group (standard care - SOC) and the intervention group (standard of care plus the Pharmacist Managed Diabetes Clinic (PMDC),(SOC + PMDC) a pharmacist-led clinic that has been fully functioning in our clinic since January 2015 and is an available resource).

The intervention group patients will be managed by their assigned primary care physicians (PCPs) per the standard of care and will have six extra scheduled face-to-face visits with the pharmacists in the PMDC for the 6 month duration of the intervention. The PMDC visits will be scheduled more frequently in the first 2 months of the intervention to ensure patient engagement and provide enough opportunities and time to address all of the patient goals and concerns. The PMDC visit encounters will focus on patient-identified goals for the management of their diabetes. The initial visit in the PMDC will be 60-90 minutes with follow up visits lasting 30-45 minutes. Patients will be asked to describe their own gaps in knowledge and to identify their own management goals. Identification of knowledge gaps will allow targeted patient education to close those gaps. Other potential educational opportunities will be discussion of the understanding of the disease process, blood sugar control goals, management of high and low blood sugars, review of medications, and counseling regarding diet and exercise. The control group patients will be managed by their assigned PCPs, per the standard of care. Management per the standard of care includes medications, referrals, diabetic education, laboratory studies, and

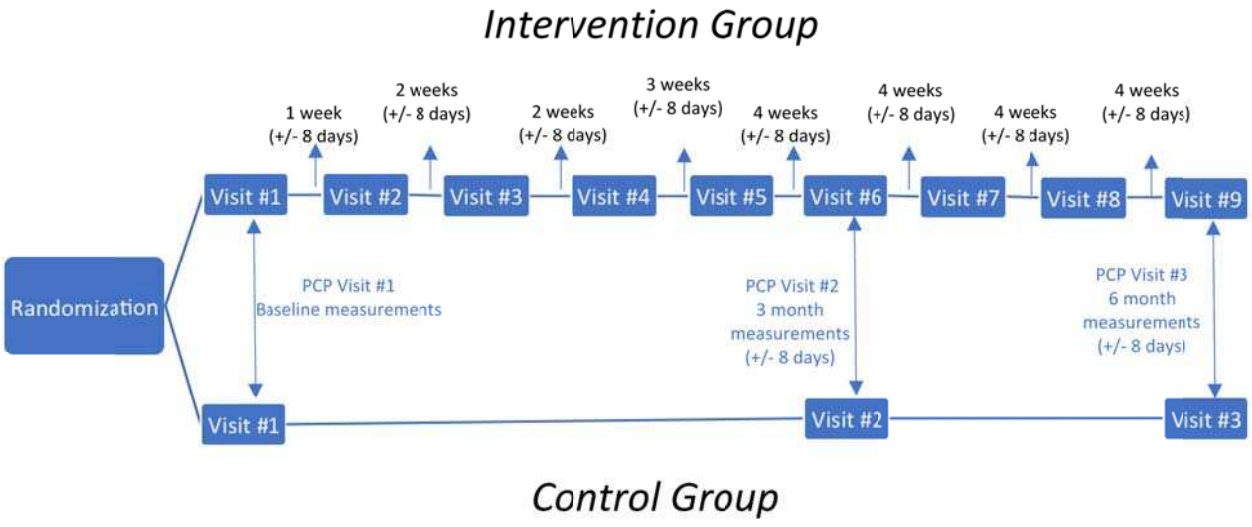
vaccinations and will be ordered or performed at the discretion of each patient's PCP.

Participant timeline:

Once enrolled in the study, the patients in both groups will complete the Diabetes 39 survey, a quality of life assessment survey at initial PCP visit (baseline) and again at 6 month PCP visit with a window of plus / minus 1 month to allow patients to reschedule if they are not able to complete their scheduled visit. If the patient can not or does not reschedule their 6 month PCP visit we will mail out the 6 month survey with a prepaid return envelope for the patient to complete within the 1 month timeframe.

They will be scheduled to start seeing the PMDC in 1 week and return for a visit with their PCP in three months. After completion of the first PMDC visit, the patients will be scheduled to return in two weeks to the PMDC. The next two PMDC visits will be two and three weeks apart. In four weeks after the PMDC visit the patients will have their 3 month visit with their PCP. After this PCP visit, the patients will complete another 2 visits with the PMDC and at 6 month from starting the intervention, the patients will have the last visit with their own PCP. Of note, additional PCP visits in either group can occur at the discretion of the PCP at any other time during the study period. Each visit follow up will have a window of plus / minus 8 days to allow patients to reschedule if unforeseen problems would prevent them from completing the initially scheduled follow up visit. At the time of the enrollment, each patient will receive an appointment card with their follow up visits for the rest of the study as follows: the SOC group will get their two scheduled physician visits and the SOC + PMDC group will get their first pharmacy visit scheduled along with their two physician visits. At the time of the first pharmacy visit, the patients in the SOC+PMDC group will get the appointment card with the next 5 follow up visits with the pharmacy clinic. The patients will be contacted by the study personnel throughout the study by mail or by phone.

Study Timeline:



Recruitment:
The recruitment is planned to take place over 6 months.

The patients will be identified via the diabetic registry through business office software and through the daily clinic schedule from the EPIC electronic medical record. Currently enrolled patients in the PMDC and the patients that had a PMDC visit within the last 3 months will be excluded. The patients with

hemoglobin A1c greater than 9% and overdue for their primary care physician follow up diabetes visit, identified through the diabetes registry, will be called to schedule an appointment with their primary care physician (PCP) and will be approached at the time of the clinic visit.

The patients will also be identified from the daily schedule through electronic reports from the EPIC electronic medical record. Daily reports will be run for the next day to identify the patients with diabetes and hemoglobin A1c greater or equal to 9, that have an appointment with our clinic. Manual chart review will be performed to confirm the eligibility criteria based on hemoglobin A1c higher than 9.

Recruitment letters will be mailed to all the patients found eligible to be enrolled in the study based on their hemoglobin A1c level and being overdue (over 3 months) for their primary care visit. The patients will be directed to call the research assistant and they will be helped to schedule a PCP appointment if they are overdue. We considered overdue appointment for patients with hemoglobin A1c greater or equal than 9 if they haven't seen their PCP in over 3 months. If the patients had a recent PCP appointment and therefore are not overdue, but are interested to be enrolled in the study, the research assistant will help them schedule their next PCP visit and will advise them that they will be enrolled at that visit. The research assistant will keep record of these patients and their follow up PCP appointment date and time.

A brochure with information about the PHARMA MD study is to be displayed in exam rooms, pharmacist offices where they meet with patients and waiting rooms of the Royal Oak Medical Office Building outpatient clinics for patients that might be interested in joining the study.

Consent procedure:
Research assistant will provide an Information sheet to the patients and enroll them. Full consent will not be needed as this study does not involve more than minimal risk. Sandra Baker CRA II, Kathleen Bradley CRA II, Coleen Tessmar (senior research nurse clinician) and Janna Fett (PharmD) will provide the information sheet to the patients and will get an information sheet receipt.

Methods:
Allocation (patient group assignment): Subjects will be allocated to the PMDC or the standard of care in a 1 to 1 fashion, meaning the groups will have equal numbers of patients. The randomization scheme and the study envelopes with each protocol, based on the randomization scheme, will be prepared by a biostatistician that will not be involved in the study. The envelopes with each assigned protocol will be closed and opaque and will be given to the research assistant. The opaque envelopes that will contain the group allocation will be kept in a locked boxed in the clinic and the research assistant will be the only person with access to the box. The envelopes will be opaque in order to maintain the concealment of the allocation, which minimizes study bias. Once the eligible patients present to their PCP visit, the research assistant will consent the patients and enroll them into the study and provide the next available envelope with the assigned group protocol (intervention or control group). The research assistant will be under the supervision of a medically trained principal investigator.

As this is an open-label study, the patients and the physicians will be aware of group allocation. However, individuals who collect and analyze the data, the biostatistician, and individuals who assess the outcomes of the study will be unaware of which group the patients are in. Only the research assistant will be aware of the real allocation after the patients are assigned to a group randomly. The research assistant will enter the enrolled patients in a spreadsheet within a secured, shareable online database and assign each patient a number (0 or 1) based on the group assignment. The group number

assigned will not be revealed to any study personnel until the final statistical analysis will be completed.

The majority of the data will be collected at the baseline (beginning) of the study and at 6 and 12 months after starting the intervention. Hemoglobin A1c will be collected at 6 months (+/- 3 months) and at 12 months (+/- 3 months) to be able to capture any value done in between the 6-12 months mark. This will include the hemoglobin A1c value and "goal of < 8%", lipid panel, blood pressure management (goal of < 140/90 mmHg), compliance with recommended DM screening (checking the eyes, kidneys, and nerves for diabetic-related damage), immunizations (influenza and pneumonia vaccines), quality of life (Diabetes 39, description below), number of emergency center visits for high or low blood sugar, overall numbers of hospital and clinic visits, and the 'no-show' rate (the rate at which the patients do not attend scheduled appointments).

Personnel will include investigators, a research assistant, and a research nurse manager. They will be trained in the standardized measurement of blood pressure and administering immunizations as well as eliciting information and collecting questionnaires from patients in a uniform manner. To assess patient quality of life at the start and conclusion of the study period, the Diabetes-39 questionnaire will be utilized. This questionnaire is appropriate for use in a diverse diabetic patient population and is an excellent query of a broad conceptualization of diabetes specific quality of life [Watkins]. There are 5 domains assessed in the questionnaire: energy and mobility, diabetes control, anxiety and worry, social/peer burden, and sexual functioning. The questionnaire is comprised of 39 total questions and is scored via a visual analogue scale, with higher scores reflecting a poorer quality of life [Boyer]. The diabetes-39 questionnaire has good reliability (Cronbach's alpha ranging from 0.81 to 0.93) and internal and external validity [Garratt].

All the pharmacy visits from the patients in the intervention group will be analyzed and data will be pulled accordingly to the data collection sheet. There will be no patient contact or communication.

Dr. Halalau has entered the study into the CinicalTrails.gov website and will update as needed.

Inclusion Criteria:

The target population will be comprised of high risk diabetes mellitus type 2 patients (hemoglobin A1c equal to or greater than 9%) that are not currently enrolled in PMDC. In order for the patient to be eligible for enrollment, they will have to be established with a primary care resident internal medicine or medicine-pediatrics resident. The patient will have to carry a diagnosis of diabetes mellitus type 2. The patient's will be screened based on the diabetic registry in the electronic medical record. If the patient is diagnosed with diabetes mellitus type 2, has a hemoglobin A1c equal to or greater than 9%, and is under the care of a primary care resident they will be eligible for enrollment.

Exclusion criteria:

Patients will be excluded if they have been seen by the PMDC within the past 3 months. This time period was chosen to mitigate the risk for the potential confounder of a PMDC visit directly affecting the hemoglobin A1c. By selecting this time period, we aim to maintain a larger pool of patients to select from than we would otherwise if we completely excluded patients who had previously been seen in the PMDC.

Patients will be excluded if they are under 18 years of age. Patients will also be excluded if they are documented as having type 1 diabetes.

Patients older than 75 years of age will be excluded because their hemoglobin A1c goal might be different than the general population given all the concurent comorbidities.

A Screening/Eligibility Checklist will be used to ensure only the intended populations are enrolled.
Other - Describe tool or method to assure that participants meet inclusion/exclusion criteria

Statistical Data Analysis:

Sample size calculation:
Assuming an allocation of 1:1 that will result in equal sample sizes and a mean difference of hemoglobin A1c of 1.0 between the two groups and SD of 1.5 for both groups, the sample size was calculated at 36 per arm or a total of 72 with 80% power at a $p<0.05$ significance. Adding 20% for attrition, the final sample size was calculated at 86 patients. We considered a hemoglobin A1c difference of 1% as being clinically significant in long term reduction of stroke, myocardial infarction and microvascular complications. (2)

Data analysis plan:
Continuous variables will be reported as means or medians with standard deviation or range, based on the normality of the sample distribution. Categorical variables will be reported as percentages. Parametric or non-parametric statistics will be used for inferential statistics. A p-value of <0.05 is considered statistical significant.

Data from the pharmacy visits will be qualitatively and quantitatively analysed by the Beaumont biostatistician with the help from the OU biostatistician for the qualitative part.

Research Participant Enrollment and Participation

Duration of participation for individual participant is 12 months.
Target participant enrollment: 100
Expected number of participants to be screened to meet enrollment goal: 1000

Participant population by age and gender:
Gender: Male and Female
Age range: 18-75

Screening for potential study participants will include the use of medical records, computer databases and recruitment letters.
Participants/specimens/charts will be recruited or identified via:

- Direct person to person solicitation
- Medical record / One Chart Review / Computer databases
- Advertisement/ Notice / Flyer
- Recruitment letters

A recruitment letter will be mailed to the patients.

A brochure with information about the PHARMA MD study will be displayed in exam rooms, pharmacist offices where they meet with patients and waiting rooms of the Royal Oak Medical Office Building outpatient clinic for patients that might be interested in joining the study.

Vulnerable Participant Populations:
Children (< 18 years of age) are excluded from study
Patients younger than 18 years of age are likely having diabetes mellitus type 1 and these patients are excluded from the study population.

Pregnant Women, Fetuses & Neonates may be incidentally included

Economically or Educationally Disadvantaged individuals may be incidentally included
Any incentives offered for study participation will be within the guidelines set forth by the HIC.

Students/Trainees/Staff may be incidentally included
Students, trainees or staff will not be recruited or consented by a supervisor or individual who may have influence over their decision to participate.

Cognitively Impaired or Mentally Disabled individuals may be incidentally included

Risks of Research:
The main risk of this research is breach of confidentiality
In order to protect the rights and welfare of the research participants, data will be stored on a secure SharePointe site, or in a secured/locked department office.

Data Collection & Storage, Research Records, Confidentiality and Privacy:

Research participants/specimens/documents will be identified in research documents by:

- Name
- Medical record number
- Unique code/study ID

Direct participant identifiers will not be shared outside of Beaumont study key personnel, The Institutional Review Board, Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Office of Civil Rights (OCR) and/or the study sponsor has the authority to access study data.

Electronic data will be stored to minimize risk, preserve confidentiality of the research information collected and protect the privacy of participants on Beaumont SharePointe sites.

Hard copy data (i.e. source document, consent form, checklists, data collection forms) will be stored to minimize risk, preserve confidentiality of the research information collected and protect the privacy of participants locked in the research assistant office area.

Research records, for approved human participants' protocols, in accordance with all federal and

institutional requirements, including but not limited to the HIPPA Privacy Rule, the Food and Drug Act and Medicare policy will be stored in a secure, protected manner in an off-site storage facility as designated by Beaumont Health System for a minimum of 11 years per HIPAA regulations

Funding:
Funding was received from the Herb and Betty Fisher Seed Grant

Participant Reimbursement/compensation:
Research participants will receive patient stipends of

- $15 per visit X 9 visits for 43 patients in the intervention arm
- $5,805; $15 per visit X 3 visits for 43 patients in the control arm

Total dispersed:

- $1,935. The patient stipends were calculated based on the sample size and 20% possible attrition.

An individual participant may receive up to $135 in stipends.
The compensation will be dispensed after each visit that is designated to receive a stipend.

Research Waiver of Authorization:
This study meets the HIPAA Requirements to Review Patient Data without Patient Consent

- The identifiers will be protected from improper use and disclosure via storage in a secured/locked department office and electronic data on a secure SharePointe site.
- Only study key personnel on the study roster will have access to patient identifiers
- Identifiers will be destroyed at the earliest opportunity, by shredding of paper documents and deletion of electronic data
- The list of identifiers will be destroyed
    - Upon manuscript acceptance
    - When deemed ineligible
    - Upon declining participation

Appendix:

1. Patient Recruitment Brochure
2. Patient reminder letter
3. Control participant refrigerator reminder sheet
4. Intervention participant refrigerator reminder sheet
5. Intervention participant refrigerator sheet pharm 1 visit
6. Intervention participant refrigerator sheet pharm 2-6 visits
7. Baseline Characteristics data collection tool
8. Outcomes data collection tool
9. Diabetes 39 QOL data collection tool
10. WHO BREF QOL questionnaire

IRB NUMBER: 2017-494
IRB APPROVAL DATE: 01/23/2019

Dear _____

Thank you for your participation in the Beaumont study entitled: Pharm-MD; an Open-Label Randomized Controlled Phase II Study to Evaluate the Efficacy of a Pharmacist Managed Diabetes Clinic in High-Risk Diabetes Patients.

As part of the study you enrolled in, there was a follow-up survey to be completed at your 6-month Primary Care Physician appointment. If you could please take the time to fill out the enclosed survey and return it in the prepaid envelope it would be greatly appreciated.

As a reminder the surveys are voluntary and if you feel uncomfortable answering any questions you may skip it and go on to the next question. We hope you will complete all the questions in the survey and return it to us as it will give us important information for the study.

Thank you for your participation in this study. If you have any questions, please do not hesitate to call Kathleen Bradley, CRA II at (248) 964-8529.

Thank you,

Alexandra Halalau, M.D., F.A.C.P.
Principle Investigator
Beaumont Hospital
3601 West 13 Mile Road
Royal Oak, MI 48073

PHARMACIST MANAGED DIABETES TRIAL

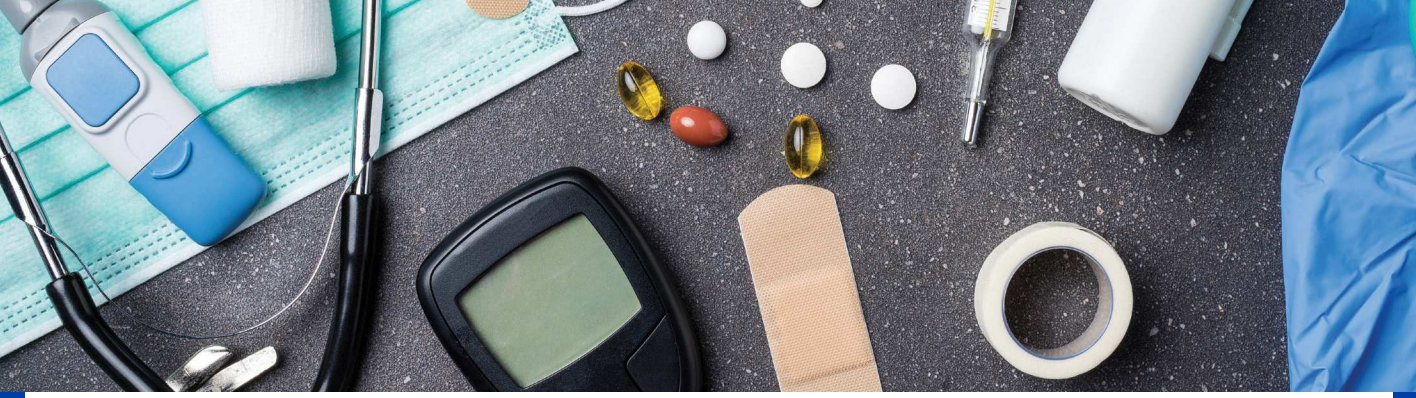
Beaumont Hospital, Royal Oak
Medical Office Building
3535 West 13 Mile Road
Royal Oak, MI 48073

Beaumont

beaumont.org

P19334d1_20867_021119

Beaumont



ABOUT THE STUDY

- The purpose is to investigate the impact of a pharmacist managed diabetes clinic in helping to control your diabetes and improve your quality of life.
- You will be assigned to one of two groups and appointments will be scheduled with your primary care resident and/or the pharmacy clinic.
- Group 1 will be scheduled with a primary care resident at three months and six months.
- Group 2 will be scheduled with a primary care resident at three months and six months plus an additional six visits with the pharmacy clinic over the six month period.
- You will be compensated for your time and travel.
- This study will be conducted in the outpatient clinic at Beaumont Hospital, Royal Oak.
- The study will last approximately six months.

YOU MAY BE ELIGIBLE TO PARTICIPATE IN THIS STUDY IF:

- you are between the ages of 18 and 75
- you have a diagnosis of Type 2 diabetes mellitus with a hemoglobin A1c equal to or greater than 9 percent
- are an established patient with a primary care resident at Beaumont, Royal Oak

TYPE 2 DIABETES MELLITUS

Millions of Americans are currently living with diabetes. Approximately 1.5 million cases are being diagnosed each year, causing diabetes to be the seventh leading cause of death in the United States.

People with diabetes are twice as likely to have heart disease or stroke compared to those without diabetes. Diabetes is also the leading cause of kidney failure and can lead to permanent visual impairment.

IF YOU'RE INTERESTED IN PARTICIPATING IN THIS STUDY, **CONTACT KATHLEEN BRADLEY AT 248-964-8529.**

IRB NUMBER: 2017-494
IRB APPROVAL DATE: 02/21/2019

IRB NUMBER: 2017-494
IRB APPROVAL DATE: 03/01/2018

Beaumont

PHARM-MD; an Open-Label, Randomized Controlled Phase II Study to Evaluate the Efficacy of a Pharmacist Managed Diabetes Clinic in High-Risk Diabetes Patients

Principal Investigator: Dr. Alexandra Halalau

STANDARD OF CARE (SOC) Schedule

PARTICIPANT ID NUMBER _____

PHYSICIAN VISIT 2 DATE: _____ TIME: _____

PHYSICIAN VISIT 3 DATE: _____ TIME: _____

If you are unable to make your appointment, please call 248-551-3000 so we can reschedule as soon as possible. Being part of a study is very important. The data we collect from you will help us learn how to better care for our diabetic patients.

THANK YOU FOR PARTICIPATING

Beaumont

PHARM-MD; an Open-Label, Randomized Controlled Phase II Study to Evaluate the Efficacy of a Pharmacist Managed Diabetes Clinic in High-Risk Diabetes Patients

Principal Investigator: Dr. Alexandra Halalau

STANDARD OF CARE (SOC) Schedule

PARTICIPANT ID NUMBER _____

PHYSICIAN VISIT 2 DATE: _____ TIME: _____

PHYSICIAN VISIT 3 DATE: _____ TIME: _____

If you are unable to make your appointment, please call 248-551-3000 so we can reschedule as soon as possible. Being part of a study is very important. The data we collect from you will help us learn how to better care for our diabetic patients.

THANK YOU FOR PARTICIPATING

IRB NUMBER: 2017-494
IRB APPROVAL DATE: 03/01/2018

Beaumont

PHARM-MD; an Open-Label, Randomized Controlled Phase II Study to Evaluate the Efficacy of a Pharmacist Managed Diabetes Clinic in High-Risk Diabetes Patients

Principal Investigator: Dr. Alexandra Halalau

STANDARD OF CARE (SOC) Schedule

PARTICIPANT ID NUMBER _____

PHARMACY VISIT 2 DATE: _____ TIME: _____

PHARMACY VISIT 3 DATE: _____ TIME: _____

PHARMACY VISIT 4 DATE: _____ TIME: _____

PHARMACY VISIT 5 DATE: _____ TIME: _____

PHARMACY VISIT 6 DATE: _____ TIME: _____

If you are unable to make your appointment, please call 248-551-3000 so we can reschedule as soon as possible. Being part of a study is very important. The data we collect from you will help us learn how to better care for our diabetic patients.

THANK YOU FOR PARTICIPATING

Beaumont

PHARM-MD; an Open-Label, Randomized Controlled Phase II Study to Evaluate the Efficacy of a Pharmacist Managed Diabetes Clinic in High-Risk Diabetes Patients

Principal Investigator: Dr. Alexandra Halalau

STANDARD OF CARE (SOC) Schedule

PARTICIPANT ID NUMBER _____

PHARMACY VISIT 2 DATE: _____ TIME: _____

PHARMACY VISIT 3 DATE: _____ TIME: _____

PHARMACY VISIT 4 DATE: _____ TIME: _____

PHARMACY VISIT 5 DATE: _____ TIME: _____

PHARMACY VISIT 6 DATE: _____ TIME: _____

If you are unable to make your appointment, please call 248-551-3000 so we can reschedule as soon as possible. Being part of a study is very important. The data we collect from you will help us learn how to better care for our diabetic patients.

IRB NUMBER: 2017-494
IRB APPROVAL DATE: 03/01/2018

Beaumont

PHARM-MD; an Open-Label, Randomized Controlled Phase II Study to Evaluate the Efficacy of a Pharmacist Managed Diabetes Clinic in High-Risk Diabetes Patients

Principal Investigator: Dr. Alexandra Halalau

STANDARD OF CARE PLUS PHARMACY MANAGED DIABETES CLINIC (SOC+PMDC) Schedule

PARTICIPANT ID NUMBER _____

PHARMACY VISIT 1 DATE: _____ TIME: _____

3 Month PHYSICIAN VISIT DATE: _____ TIME: _____

6 Month PHYSICIAN VISIT DATE: _____ TIME: _____

If you are unable to make your appointment, please call 248-551-3000 so we can reschedule as soon as possible. Being part of a study is very important. The data we collect from you will help us learn how to better care for our diabetic patients.

THANK YOU FOR PARTICIPATING

Beaumont

PHARM-MD; an Open-Label, Randomized Controlled Phase II Study to Evaluate the Efficacy of a Pharmacist Managed Diabetes Clinic in High-Risk Diabetes Patients

Principal Investigator: Dr. Alexandra Halalau

STANDARD OF CARE PLUS PHARMACY MANAGED DIABETES CLINIC (SOC+PMDC) Schedule

PARTICIPANT ID NUMBER _____

PHARMACY VISIT 1 DATE: _____ TIME: _____

3 Month PHYSICIAN VISIT DATE: _____ TIME: _____

6 Month PHYSICIAN VISIT DATE: _____ TIME: _____

If you are unable to make your appointment, please call 248-551-3000 so we can reschedule as soon as possible. Being part of a study is very important. The data we collect from you will help us learn how to better care for our diabetic patients.

THANK YOU FOR PARTICIPATING

IRB NUMBER: 2017-494
IRB APPROVAL DATE: 03/01/2018

Beaumont

PHARM-MD; an Open-Label, Randomized Controlled Phase II Study to Evaluate the Efficacy of a Pharmacist Managed Diabetes Clinic in High-Risk Diabetes Patients

Principal Investigator: Dr. Alexandra Halalau

STANDARD OF CARE PLUS PHARMACY MANAGED DIABETES CLINIC (SOC+PMDC) Schedule

PARTICIPANT ID NUMBER _____

PHARMACY VISIT 2 DATE: _____ TIME: _____

PHARMACY VISIT 3 DATE: _____ TIME: _____

PHARMACY VISIT 4 DATE: _____ TIME: _____

PHARMACY VISIT 5 DATE: _____ TIME: _____

PHARMACY VISIT 6 DATE: _____ TIME: _____

If you are unable to make your appointment, please call 248-551-3000 so we can reschedule as soon as possible. Being part of a study is very important. The data we collect from you will help us learn how to better care for our diabetic patients.

THANK YOU FOR PARTICIPATING

Patient Baseline Characteristics Data Collection Tool	
Patient name	
MRN	
Group allocation (0 or 1)	
HgA1c	
Age	
Gender	
Race	
BMI	
SBP	
DBP	
Creatinine	
eGFR	
Microalbumin	
Total cholesterol	
LDL	
HDL	
Triglicerides	
Tobacco (current, former never)	
Neuropathy	
Retinopathy	
Nephropathy	
Macrovascular complications (MI, stroke)	
Oral agents only	
Insulin combination	

Patient Outcomes Data Collection Tool	
Patient name	
MRN	
Group allocation	
Baseline HgA1c	
HgA1c 6 months	
HgA1c 12 months	
HgA1c<8	
Lipid panel	
SBP at 6 mos	
DBP at 6 mos	
SBP at 12 mos	
DBP at 12 mos	
Retinopathy screening	
Nephropathy screening	
Neuropathy screening	
Influenza	
Pneumonia	
Quality of life baseline	
Quality of life at 6 - 9 months	
Number EC visits for hyper and hypoglycemia	
Number of inpatient visits	
Number of outpatient visits	
Number of no-show visits	

Subject ID:_____
Date: _____

Diabetes-39

Quality of Life Questionnaire – Baseline / 6 Months

IRB# 2017-494 - Study Name_____

A person's quality of life is affected by many things. These things might include health, the opportunity for recreation and holidays, friends and family, work and the hassles and inconveniences of diabetes. This questionnaire is designed to help us learn more about what affects the quality of life of people with diabetes.

How to complete the questionnaire.

- For each of the following questions we want to know how much your quality of life has been affected. Please circle a number which you think best describes how your quality of life has been affected in the past month.
- If you have any questions about how to complete the questionnaire, please ask the research coordinator

During the past month how much was the quality of your life affected by:

1. Your daily medication for your diabetes

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

2. Worries about money matters

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

3. Limited energy levels

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

4. Following your doctor's prescribed treatment plan for diabetes

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

5. Food restrictions to control your diabetes

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

Subject ID:_____
Date: _____

6. Concerns about your future

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

7. Other health problems besides diabetes

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

8. Stress or pressure in your life

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

During the <u>past month</u> how much was the quality of <u>your</u> life affected by:

9. Feelings of weakness

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

10. Restrictions on how far you can walk

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

11. Any daily exercises for your diabetes

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

12. Loss or blurring of vision

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

13. Not being able to do what you want to do

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

Subject ID:_____
Date: _____

14. Having diabetes

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

15. Losing control of your blood sugar levels

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

16. Other illnesses besides diabetes

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

During the <u>past month</u> how much was the quality of <u>your</u> life affected by:

17. Testing your blood sugar levels

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

18. The time required to control your diabetes

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

19. The restrictions your diabetes places on your family and friends

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

20. Being embarrassed because you have diabetes

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

21. Diabetes interfering with your sex life

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

Subject ID:_____
Date: _____

22. Feeling depressed or low

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

23. Problems with sexual functioning

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

24. Getting your diabetes well controlled

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

During the <u>past month</u> how much was the quality of <u>your</u> life affected by:

25. Complications from your diabetes

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

26. Doing things that your family and friends don't do

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

27. Keeping a record of your blood sugar levels

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

28. The need to eat at regular intervals

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

29. Not being able to do housework or other jobs around the house

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

Subject ID:_____
Date: _____

30. A decreased interest in sex

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

31. Having to organize your daily life around diabetes

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

32. Needing to rest often

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

During the <u>past month</u> how much was the quality of <u>your</u> life affected by:

33. Problems in climbing stairs or walking up steps

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

34. Having trouble caring for yourself (dressing, bathing, or using the toilet)

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

35. Restless sleep

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

36. Walking more slowly than others

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

37. Being identified as a diabetic

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

Subject ID:_____
Date: _____

38. Having diabetes interfere with your family life

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

39. Diabetes in general

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

OVERALL RATINGS

1. Please circle below to indicate your overall rating of quality of life

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

2. Please circle below to show how severe you think your diabetes is

Not affected At all	1	2	3	4	5	6	7	Extremely Affected

Disclaimer:
Permission for use of this questionnaire was granted by Dr. Gregory Boyer, PhD

WHOQOL-BREF

June 1997

U.S. Version

University of Washington

Seattle, Washington

United States of America

Emblem...Soul Catcher: a Northwest Coast Indian symbol of physical and mental well-being. Artist: Marvin Oliver

WHOQOL-BREF

About You

Before you begin we would like to ask you to answer a few general questions about yourself by circling the correct answer or by filling in the space provided.

1. What is your gender — Male — Female

2. What is your date of birth? _____ / _____ / _____
   Day Month Year

3. What is the highest education you received?
   None at all
   Elementary School
   High School
   College

4. What is your marital status?
   Single — Separated
   Married — Divorced
   Living as Married — Widowed

5. Are you currently ill? — Yes — No

6. If something is wrong with your health, what do you think it is? _____ illness/problem

Instructions

This questionnaire asks how you feel about your quality of life, health, or other areas of your life. Please answer all the questions. If you are unsure about which response to give to a question, please choose the one that appears most appropriate. This can often be your first response.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life in the last two weeks. For example, thinking about the last two weeks, a question might ask:

For office use		*(Please circle the number)*				
		Not at all	**A little**	**Moderately**	**Mostly**	**Completely**
	Do you get the kind of support from others that you need?	**1**	**2**	**3**	**4**	**5**

You should circle the number that best fits how much support you got from others over the last two weeks. So you would circle the number 4 if you got a great deal of support from others. o

For office use		*(Please circle the number)*				
		Not at all	**A little**	**Moderately**	**Mostly**	**Completely**
	Do you get the kind of support from others that you need?	**1**	**2**	**3**	**④**	**5**

You would circle number 1 if you did not get any of the support that you needed from others in the last two weeks. o

For office use		*(Please circle the number)*				
		Not at all	**A little**	**Moderately**	**Mostly**	**Completely**
	Do you get the kind of support from others that you need?	**①**	**2**	**3**	**4**	**5**

Please read each question, assess your feelings, and circle the number on the scale that gives the best answer for you for each question.

For office use			*(Please circle the number)*				
			Very poor	**Poor**	**Neither poor nor good**	**Good**	**Very Good**
G1 / G1.1	1.	How would you rate your quality of life?	**1**	**2**	**3**	**4**	**5**

For office use			*(Please circle the number)*				
			Very dissatisfied	**Dissatisfied**	**Neither satisfied nor dissatisfied**	**Satisfied**	**Very satisfied**
G4 / G2.3	2.	How satisfied are you with your health?	**1**	**2**	**3**	**4**	**5**

The following questions ask about **how much** you have experienced certain things in the last two weeks.

For office use			*(Please circle the number)*				
			Not at all	**A little**	**A moderate amount**	**Very much**	**An extreme amount**
F1.4 / F1.2.5	3.	To what extent do you feel that physical pain prevents you from doing what you need to do?	**1**	**2**	**3**	**4**	**5**
F11.3 / F13.1.4	4.	How much do you need any medical treatment to function in your daily life?	**1**	**2**	**3**	**4**	**5**
F4.1 / F6.1.2	5.	How much do you enjoy life?	**1**	**2**	**3**	**4**	**5**

For office use			(Please circle the number)				
			Not at all	A little	A moderate amount	Very much	An extreme amount
F24.2 / F29.1.3	6.	To what extent do you feel your life to be meaningful?	**1**	**2**	**3**	**4**	**5**

For office use			(Please circle the number)				
			Not at all	Slightly	A Moderate amount	Very much	Extremely
F5.2 / F7.1.6	7.	How well are you able to concentrate?	**1**	**2**	**3**	**4**	**5**
F16.1 / F20.1.2	8.	How safe do you feel in your daily life?	**1**	**2**	**3**	**4**	**5**
F22.1 / F27.1.2	9.	How healthy is your physical environment?	**1**	**2**	**3**	**4**	**5**

The following questions ask about **how completely** you experience or were able to do certain things in the last two weeks.

For office use			(Please circle the number)				
			Not at all	A little	Moderately	Mostly	Completely
F2.1 / F2.1.1	10.	Do you have enough energy for everyday life?	**1**	**2**	**3**	**4**	**5**
F7.1 / F9.1.2	11.	Are you able to accept your bodily appearance?	**1**	**2**	**3**	**4**	**5**
F18.1 / F23.1.1	12.	Have you enough money to meet your needs?	**1**	**2**	**3**	**4**	**5**

For office use		*(Please circle the number)*				
		Not at all	**A little**	**Moderately**	**Mostly**	**Completely**
F20.1 / F25.1.1	13. How available to you is the information that you need in your day-to-day life?	**1**	**2**	**3**	**4**	**5**
F21.1 / F26.1.2	14. To what extent do you have the opportunity for leisure activities?	**1**	**2**	**3**	**4**	**5**

For office use		*(Please circle the number)*				
		Very poor	**Poor**	**Neither poor nor well**	**Well**	**Very well**
F9.1 / F11.1.1	15. How well are you able to get around?	**1**	**2**	**3**	**4**	**5**

The following questions ask you to say how **good** or **satisfied** you have felt about various aspects of your life over the last two weeks.

For office use		*(Please circle the number)*				
		Very dissatisfied	**Dissatisfied**	**Neither satisfied nor dissatisfied**	**Satisfied**	**Very satisfied**
F3.3 / F4.2.2	16. How satisfied are you with your sleep?	**1**	**2**	**3**	**4**	**5**
F10.3 / F12.2.3	17. How satisfied are you with your ability to perform your daily living activities?	**1**	**2**	**3**	**4**	**5**
F12.4 / F16.2.1	18. How satisfied are you with your capacity for work?	**1**	**2**	**3**	**4**	**5**

For office use		*(Please circle the number)*				
		Very dissatisfied	**Dissatisfied**	**Neither satisfied nor dissatisfied**	**Satisfied**	**Very satisfied**
F6.4 / F8.2.2	19. How satisfied are you with yourself?	**1**	**2**	**3**	**4**	**5**
F13.3 / F17.2.3	20. How satisfied are you with your personal relationships?	**1**	**2**	**3**	**4**	**5**
F15.3 / F3.2.1	21. How satisfied are you with your sex life?	**1**	**2**	**3**	**4**	**5**
F14.4 / F18.2.5	22. How satisfied are you with the support you get from your friends?	**1**	**2**	**3**	**4**	**5**
F17.3 / F21.2.2	23. How satisfied are you with the conditions of your living place?	**1**	**2**	**3**	**4**	**5**
F19.3 / F24.2.1	24. How satisfied are you with your access to health services?	**1**	**2**	**3**	**4**	**5**
F.23.3 / F28.2.2	25. How satisfied are you with your mode of transportation?	**1**	**2**	**3**	**4**	**5**

The follow question refers to **how often** you have felt or experienced certain things in the last two weeks.

For office use		*(Please circle the number)*				
		Never	**Seldom**	**Quite often**	**Very often**	**Always**
F8.1 / F10.1.2	26. How often do you have negative feelings, such as blue mood, despair, anxiety, depression?	**1**	**2**	**3**	**4**	**5**

Did someone help you to fill out this form? *(Please circle Yes or No)* Yes No

How long did it take to fill out this form? _____

THANK YOU FOR YOUR HELP