**Needs Statement**

In 2012, 1.5% (146,281) of the people living in North Carolina (9,752,073) were Native Americans and Alaskan Natives. Of these, ~36% (52,843) were Native Americans and Alaskan Natives living in Robeson County.1 American Indians in North Carolina (NC) face many health issues, and are less likely to have health insurance, see a medical professional (e.g. MD, PA, nutritionist, pharmacist), live above poverty level, and get the recommended amount of daily activity.2 The leading causes of death in American Indians in NC, of which there is a huge disparity between American Indians and whites, are heart disease, cancer, stroke, and diabetes mellitus (DM). Additionally, the DM prevalence in American Indians is greater than that of African Americans and whites.2

DM is one of the leading causes of death in Native Americans, and Robeson County is one of ten NC counties with the highest DM death rates.2 As of February 2013, the age-adjusted DM death rate per 100,000 residents in Robeson County (48.8) was more than twice that of the state of NC (22.0).3 Complications of DM include lower extremity (LE) amputations and end stage renal disease, both of which are three and six times higher than the rate in the US, respectively.2 Other complications include neuropathy, osteoporosis, and eye damage, which can lead to increased risk of falls.4 Risk factors for DM include physical inactivity, obesity, family history of DM, hypertension (HTN), and low high density lipoprotein (HDL) levels. Familial backgrounds/ethnicities represented in Robeson County include Native American, African American, Hispanic/Latino, Alaska Native, Asian American or Pacific Islander.5 While it is the intention of the Multi-Disciplinary Clinic of Robeson County (MDCRC) to educate in the prevention and management of DM in the Native American population of Robeson County, the aforementioned ethnicities will not be excluded in the effort to diminish the impact that DM is having on this county.

Self-prevention and management of DM has been shown to have positive effects on physiological outcomes on Type 2 DM. Two studies demonstrated that participants with dynamic self-management schedules and procedures were statistically significantly able to lower their HbA1c and cholesterol levels through diet (p<.030), medication (p<.009), and education (p<.001).6, 7 Another study involving nutritional education through internet-delivered menu plans among adults with type 2 DM determined that this program could potentially lead to clinically important weight reductions in greater than 25% of those who adhere to the program, with corresponding improvements in blood pressure (BP).8 Furthermore, a systematic review determined that the standard treatment of DM includes diet, nutrition, drug therapy, and DM education.9 The review supported that long-term education is beneficial for improving diabetic patient self-care management in terms of glycemic control.9 These studies demonstrate the benefits of and need for using DM education in prevention and self-management of DM.

The Health Department of Robeson County currently offers a DM class which is designed for maternity patients diagnosed with gestational diabetes. A registered nurse and dietician provide patient education to help control blood sugar during and after pregnancy.10 Currently the only DM management treatment center for others at risk or with DM other than maternity patients is located in Durham, NC.11 Given the high prevalence of Native Americans, Alaska Natives, and other minorities, the increased risk for DM, and the healthcare disparities as outlined above, Robeson County would benefit from a diabetes prevention and management education program, the first of its kind benefitting middle aged and older adults.

**Background**

Evidence supports DM prevention and treatment through a patient-centered approach focusing on physical activity (PA), proper nutrition, and education. PA plays a major role in the management and prevention of DM and will be a major focus in this program. Duclos et al suggest that 150 to 300 minutes a week of moderate intensity cardiovascular PA, and two non-consecutive sessions a week of resistance activity are linked to the prevention and management of DM.12 In a 2002 Behavior Risk Factor Surveillance System (BRFSS) survey of Robeson County, only 71 of 252 respondents (29.4%) aged 45 years and over reported engaging in moderate PA, which represented the lowest of twelve counties reported in NC.13

Physical therapy interventions will include cardiovascular, strengthening, and balance components. The cardiovascular and strengthening components will promote increasing PA for treatment and self-management in DM participants and to decrease risk of DM in pre-diabetic participants. Balance components will address complications that DM participants experience such as peripheral neuropathy, which affects more than 30% of these patients.14 Peripheral neuropathy can lead to decreased LE strength, sensation, proprioception, and reflexes, which lead to balance deficits.14 A systematic review evaluated the effectiveness of interventions used to decrease balance deficits in patients with diabetic peripheral neuropathy (DPN), and found few studies that supported the clinical recommendation for LE strengthening interventions to treat balance deficits in patients with DPN.14 However, the study was unable to find sufficient support for the effectiveness of balance intervention in DPN patients in general.14 Although evidence is insufficient in this area, balance deficits are linked to falls risk. Therefore, in theory, interventions to increase balance in participants with DPN may result in a decreased falls risk.

The transtheoretical model (TTM) assesses an individual's readiness to embrace a healthier behavior, and provides strategies of change to guide the individual through the stages of change.15 Research indicates the TTM has the potential of positively impacting the health of broad populations of individuals with DM,16 therefore utilizing this model will pave the way for maintained change in participants’ lifestyles. Initially the TTM will be utilized at each participant point of entry into the program, to determine which of the six stages of change the participant currently fits: 1) pre-contemplation, 2) contemplation, 3) preparation, 4) action, 5) maintenance, or 6) termination. Based on the participant’s evaluation and goals, the therapist and participant will create a tailored exercise program founded on the participant’s stage of change as described above. The health belief model (HBM) will also be incorporated with each participant’s plan of care to identify the stage at which the participant’s perceptions play a role in their self-efficacy. A recent randomized control trial (RCT) demonstrated that utilization of the HBM, peer education, and a walking training program developed for diabetic patients and its implementation by the participants in order to control blood sugar was useful and effective.17 Patients’ utilization of both models will optimize their ability to achieve and maintain success with DM management and healthier lifestyles. Lastly, Burke et al concluded that daily exercise tracking may improve self-monitoring adherence, as this was greater in the patients with the greatest weight change observed than the non-monitoring group.18

**Program Objectives**

 The primary goal of the MDCRC is to educate the middle aged and older adult Native American population of Robeson County on the management and prevention of DM. Specific aims utilizing a patient-centered approach to improve health literacy include:

* To increase understanding of the benefits of regular skin integrity assessments.
* To increase understanding of the benefits of regular PA including strength, endurance, and balance.
* To develop a tailored exercise program to include strength, endurance, and balance, based on the participant’s individual interests.
* To demonstrate a lifestyle behavior change in PA participation levels.
* To demonstrate improved quality of life (QoL) for all participants in the program.

**Proposed Intervention**

 A monthly pro bono interdisciplinary health clinic will focus on providing health care services to prevent and manage DM in a predominately Native American underserved rural area in Robeson County, NC. Participant demographics include but are not limited to middle aged (40+ years) and older adults who are residents of Robeson County. Physical therapists and other disciplines (e.g. MD, PA, Nutritionist, and Pharmacist) will use a patient-centered approach to design health and wellness programs that will aid in the treatment and self-management of DM in previously diagnosed participants, and help to decrease risks of DM in pre-diabetic participants.

Participants attending the MDCRC will receive a full evaluation that will determine their functional limitations and develop an individualized plan of care based on the participant’s goals and willingness to adopt behavioral change. The MDCRC will have three phases including initial screening, PA program implementation, and assessment of outcomes. The PA program implementation will consist of monthly appointments and meetings and will take place over the course of one year.

**Site Parameters**

 The proposed site for the program is the local First Health clinic and gym, located in Lumberton, NC. The county offers a public transportation system, South East Area Transit System, for those who have no other means of transportation.19 The multi-disciplinary team will use clinic evaluation rooms and gym equipment on interdisciplinary health clinic days.

**Intervention Phase I – Initial Screening**

The initial screening will consist of questionnaires, vitals, sensation and skin integrity check, and outcome measures (OM’s). At least two physical therapists will perform the screening, as well as other PTA’s and PT/PTA students from local PT programs. Two questionnaires will be given to each participant in the lobby. The SF-36 questionnaire will be used to assess participant perceived health related QoL, and the Health Knowledge, Attitudes, and Practices Questionnaire (HKAPQ) will be used to measure current knowledge of the benefits of PA, proper nutrition, and QoL. Participants will then be directed to the private vitals station room to measure heart rate, BP, height, weight, BMI calculation, skin integrity check, and questionnaire review. OM assessments will be performed in the gym and will be divided into 3 stations to assess balance, endurance and strength. At the balance station, participants will perform the items of the Berg Balance Scale (BBS) to assess static balance and falls risk. Participants will perform at the endurance station the 6 Minute Walk Test (6MWT) to measure exercise tolerance and assess ambulation. Participants will perform at the strength station the Five Times Sit To Stand (5xSTS) to measure functional LE muscle strength.

The last portion of the initial screening will include a brief consultation with a physical therapist. The consultation will allow the therapist to perform a skin sensation assessment and visual inspection to check for skin breakdown, pressure sores or other peripheral neuropathy complications. The participant will also schedule their follow up appointment at this time. After the initial screening the participant will see the MD or PA to be cleared to begin an exercise program. Participants will also have the opportunity to meet with a nutritionist and pharmacist to review their daily nutrition and discuss healthy alternatives, and to review and discuss their medication regimen.

**Rationale for Selected Outcome Measures**

The SF-36 questionnaire is used to assess health-related QoL and consists of 36 items divided into 8 subscales, which evaluate self-perceived body function, activity, and participation.20 It is considered a useful and appropriate tool for assessing QoL in more than 200 diseases/conditions and has been used in publications of more than 50 diseases/conditions including DM.21 The HKAPQ is utilized for patients with DM and addresses health-related knowledge, barriers to healthy behaviors, dietary intake, exercise behaviors, and communication with medical personnel regarding preventive health habits.22

The BBS is a 15-20 minute assessment of balance and falls risk with 14 items of varying difficulties including static and dynamic activities. It has been used in several balance assessment studies in patients with DM including an RCT that evaluated the efficacy of stability training in improving balance.23 The 6MWT measures the distance an individual can safely walk with or without their assistive device in 6 minutes.24, 25 Two studies support the use of the 6MWT as an OM when evaluating efficacy of exercise interventions in patients with DM.26, 27 The 5xSTS is a measure of functional LE muscle strength and may be useful in quantifying functional change of transitional movements.28 One postural control and functional strength study concluded that patients with Type 2 DM, with or without diabetic neuropathy, showed deficits in postural control and functional strength compared with healthy individuals of the same age group,29 further justifying the 5xSTS as an appropriate outcome measure.

**Intervention Phase II – Physical Activity Program Implementation**

The first follow up appointment will be scheduled two weeks after the initial screening, and will be used to develop a tailored home exercise program (HEP) based on the participant’s stage of change according to the TTM.30 The HEP will include cardiovascular, strengthening, and balance exercises and will be performed as specified by the physical therapist. Frequency and duration will be determined based on the needs and barriers of each participant but will follow the recommendations by Duclos et al, which suggest cardiovascular exercise for 150-300 minutes and 2 non-consecutive days of resistance activity per week. Participants will be given a 12-month, daily exercise log to track their progress and to improve adherence, which will be an effective tool both for the physical therapist and the participant. After the first follow up appointment, participants will be seen on a monthly basis for 12 months to review the exercise log, vitals and skin integrity check, performance of exercises to progress or modify their HEP, and refer to other disciplines as needed.

**Intervention Phase III – Assessment of Outcomes**

The third phase of the intervention will include assessment of outcomes. While the primary goal of MDCRC is to educate the middle aged and older adult Native American population on the management and prevention of DM, positive outcomes in addition to improved strength, balance, and endurance may include reduction in heart rate, BP and BMI. Vitals, SF-36, BBS, 6MWT, and 5xSTS will all be administered at baseline, quarterly through 12 months, and 6 months post program completion. The HKAPQ will be administered at baseline, 12 months, and 6 months post program completion. The physical therapist will review the results with the participants to evaluate progress and reassess goals at each assessment in an attempt to ensure individual success.

**Anticipated Outcomes:**

After twelve months, anticipated outcomes for the MDCRC program include:

1. Utilizing the HKAPQ, 75% of participants will demonstrate increased knowledge by 50% in exercise behaviors and dietary intake.
2. Utilizing the SF-36, 75% of participants will demonstrate improved QoL as indicated by a 10% improvement from baseline measures.
3. Utilizing the BBS, 75% of participants will demonstrate increased balance as indicated by at least a 4.6 point increase from baseline measures.
4. Utilizing the 6MWT, 75% of participants will demonstrate improved exercise tolerance as indicated by at least a 175 foot increase from baseline measures.
5. Utilizing the 5xSTS, 75% of participants will demonstrate improved functional LE strength as indicated by at least 2.3 second decrease from baseline measures.
6. 75% of participants will demonstrate independence with individualized HEP’s as documented in their exercise log.

At six months post program completion, anticipated outcomes for the MDCRC program include comparison to 12-month OM’s, and retention such that:

1. 80% of participants will demonstrate retained knowledge of DM management and treatment as measured by the HKAPQ.
2. 80% of participants will continue to demonstrate improved QoL as measured by the SF-36.
3. 80% of participants will demonstrate continued adherence with individual HEP as measured by the BBS, 6MWT, 5xSTS, and exercise logs.

**Program Evaluation**

 A comprehensive evaluation of the MDCRC will be utilized to determine the clinic’s success in the education and management of DM in the Native American population of Robeson County. Program design and implementation will be evaluated annually and monitored continuously in an effort to consistently improve over time. The evaluation process will consist of comparison of OM’s pre- and post-program completion, a satisfaction survey, and a survey designed for participants who drop out.

 OM’s data utilizing the SF-36, HKAPQ, BBS, 6MWT, 5xSTS, and participant exercise logs will be statistically analyzed at baseline, program completion, and six months post program completion in an effort to identify positive and negative trends. The perceived success of the program will be evaluated using the satisfaction survey in an effort to address recommended modifications for future MDCRC improvement. The participants who drop out will be contacted via mailed survey and/or telephone in an effort to determine barriers to program completion.

 OM’s and satisfaction surveys will generate quantitative and qualitative data that will be used to address individual and program-wide trends. Quantitative data from OM’s will be used to examine long-term lifestyle changes as a result of program participation. Qualitative data from satisfaction and dropout surveys and exercise logs will include recruitment methods, site accessibility, and perception of program efficacy. Outcomes of participants continuously attending the MDCRC will be compared to dropout participants. Program outcomes will be presented to the funding source for financial purposes to maintain accountability and act as a pilot program and foundation for continued financial support and future programs.

**Potential Program Limitations**

 Potential MDCRC program limitations include the concerted effort of many healthcare professionals and participant adherence to ensure success. Constructive cooperation and communication between disciplines and the First Health clinic and gym is vital to individual participant and hence program success. Maintaining a positive working relationship across disciplines, with the First Health clinic and gym, and with participants may lead to MDCRC success but it is not guaranteed. Furthermore program success is highly dependent on participant adherence. Barriers to full participation include transportation, time, and facility access.

**Program Relevance**

 DM is one of the leading causes of death in the Native American population in Robeson County, NC.2 Physical inactivity, a risk factor for DM,5 can be addressed through DM prevention and management education.6, 7, 8, 9 A 2002 community assessment demonstrated that less than 30% of middle aged and older adults reported engaging in moderate PA.13 The MDCRC will provide middle aged and older adults an opportunity to modify current health behavior in an effort to prevent and manage DM more effectively. The MDCRC’s evidence-based approach to behavioral interventions may lead to a lifestyle behavior change in PA participation levels and improved QoL for program participants. The MDCRC’s comprehensive evaluation process will identify program strengths and weaknesses which can be applied to future programs. Evidence from this pilot program will be reported and can lead to future program implementation in other rural counties experiencing high DM prevalence. Furthermore, the results of the MDCRC program may then be used to address DM prevention and management on a larger level.

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*Tracy Taylor, Joslyn Chavis*