

UNIVERSITY OF WISCONSIN-LA CROSSE

Graduate Studies

EFFECTS OF TWELVE WEEKS OF DIABETES PREVENTION PROGRAM ON  
CARDIOVASCULAR RISK FACTORS

A Manuscript Style Thesis Submitted in Partial Fulfillment of the Requirements for the  
Degree of Clinical Exercise Physiology

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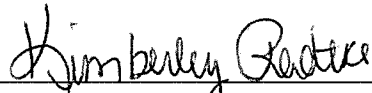
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By Blaire Thielen

We recommend acceptance of this thesis in partial fulfillment of the candidate's requirements for the degree of Clinical Exercise Physiology.

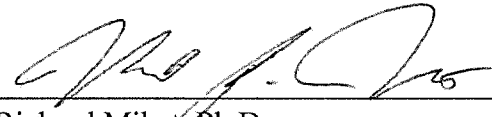
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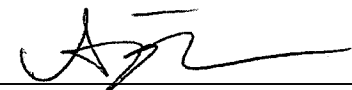
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## ABSTRACT

Thielen, B. Effects of twelve weeks of diabetes prevention program on cardiovascular risk factors. MS in Clinical Exercise Physiology, December 2019, 45pp. (K., Radtke)

The purpose of this study was to generate hypotheses and measure the effectiveness of 12 weeks of Diabetes Prevention Program (DPP). The DPP, focused on increased physical activity, eating healthy, and portion control, was conducted looking specifically at how it affects cardiovascular disease risk factors. Participants from local exercise programs (n=34) ( $\geq 60$  years of age), exercising a minimum of two days per week, meeting one of the following: BMI  $\geq 25$ ; fasting glucose of 100 to 125 mg/dl; hemoglobin A1c (HbA1c) of 5.7-6.4 mmol/L;  $\geq 9$ -point score on DPP questionnaire or a positive screening for prediabetes were included. Body weight, HbA1c, total cholesterol, LDL, HDL, triglycerides, BMI, FFM, body fat, SBP and DBP, PP, and waist circumference were measured pre and post completion of education sessions. Paired samples T test was used to determine statistical significance ( $p < .05$ ). There was a significant decrease in HDL, weight, triglycerides, DBP, waist circumference, FFM and total cholesterol ( $P < 0.05$ ). No significant difference was found in LDL, systolic blood pressure, BF, BMI, PP, or HbA1c.

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I would also like to thank the UW- La Crosse Foundation for allowing me to become a certified lifestyle coach in order to help this group of people be successful. I would also like to thank the RSEL grant foundation at UWL for giving us a grant in order to make this research possible.

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## INTRODUCTION

According to the Center for Disease Control and Prevention (CDC), approximately 30.2 million people (95% CI 27.9-32.7) were diagnosed with diabetes in 2015. Twenty-three million (95% CI 21.1-25.1) were diagnosed and 7.2 million (95% CI 6.0-8.6) were undiagnosed (Centers for Disease Control and Prevention). In 2017, the prevalence of diabetes in adults between the ages of 18-99 years of age was 8.4% and this number is projected to increase to 9.9% by the year 2045. (Cho et al., 2017) An estimated 30 million adults have been diagnosed with diabetes and 84.1 million adults have been diagnosed with pre-diabetes (Diabetes Statistics | NIDDK, n.d.). The Diabetes Prevention Program (DPP) evolved as a means to delay the progression of pre-diabetes to diabetes.

Patients diagnosed with diabetes are also at a higher risk for cardiovascular disease death, stroke, and myocardial infarction death. Approximately seven out of ten diabetics are likely to die from some form of heart disease (Diabetes, Heart Disease, and You.) Individuals with diabetes have a higher likelihood of developing independent cardiovascular risk factors such as elevated blood sugar, body mass index (BMI), cholesterol, hypertension, and a sedentary lifestyle (Riebe, D., Ehrman, J. K., Liguori, G., & Magal, M., 2018). Many of these variables, including elevated blood sugar levels, are also risk factors for developing diabetes.

A common method for assessing elevated blood sugar levels is a measurement known as glycosylated hemoglobin (HbA1c). HbA1c measures the amount of hemoglobin in the blood that is coated with glucose. The more hemoglobin that are coated, the more uncontrolled the levels of glucose are. This is a measurement that looks at chronic glycemia, due to the 120-day lifespan of the red blood cell. HbA1c is also a convenient measurement because patients are not required to fast and it is a simple blood sample (Florkowski, C., 2013). Previous research has linked dysfunction in glucose regulation with an increased risk for acute coronary syndrome in diabetic populations. Data collection from a clinical trial also found that for every kilogram of weight lost, HbA1c decreased by 0.1%, making weight loss a primary focus in preventing diabetes in obese patients (Gummesson, A., Nyman, E., Knutsson, M., & Karpefors, M., 2017).

Obesity has become a major health concern and a primary comorbidity among diabetics and pre diabetics, making weight loss of 5-7%, with the goal of reducing the risk for the development of diabetes as the focus for the DPP. During the original DPP study, the lifestyle intervention group reduced the onset of diabetes among pre-diabetics by 58% due to the adhering to the 5-7% weight loss (Diabetes Prevention Program (DPP) | NIDDK, n.d.). BMI is a common measurement used for overweight and obese patients in the general population. Evidence has shown that BMI has limitations in determining lean mass versus fat mass leading to a misdiagnosis of obesity in certain individuals (Okorodudu, D. O., et al., 2010). Accurate classification of obesity is essential because research has shown that excess body fat is a major risk factor for the development of insulin resistance (Gómez-Ambrosi, J., et al. 2011). When considering weight loss for obese patients, the weight loss should come from fat mass, preferably visceral, rather than



lean mass. A systematic review assessed whether diet alone or a combination of diet and exercise were better at decreasing fat mass while maintaining or increasing lean mass. The results of this review were inconclusive (Miller, C. T., Fraser, S. F., Straznicky, N. E., Dixon, J. B., Selig, S. E., & Levinger, I., 2013) raising the question of how will the DPP change body composition and effect cardiovascular risk factors.

Cardiovascular disease and diabetes have both been associated with a higher incidence of hypertension and hyperlipidemia (Buse, J. B., & ACCORD Study Group., 2007). Hyperlipidemia increases cardiovascular disease risk and is commonly found among diabetics (Kansal & Kamble, 2016). Research suggests that increased levels of glucose in the blood negatively affect lipid profiles (American Diabetes Association, 2005). This may contribute to plaque buildup in the arteries increasing the incidence of cardiovascular disease. (Kansal & Kamble, 2016).

Elevated blood pressure has also been identified as a factor that is associated with both cardiovascular disease and diabetes. Approximately 80% of people with diabetes also have been diagnosed with hypertension and when these two comorbidities are combined an increased risk of morbidity was found (Lewington et.al). The Framingham study has been collecting data on the relationship of cardiovascular disease and diabetes since 1948. This study found that diabetes doubles the risk for men and triples the risk for women to develop cardiovascular disease (Kannel, W. B., & McGee, D. L., 1979).

More research is needed to identify how the approved DPP curriculum affects the risk for cardiovascular disease. Specifically, it is important to understand the initial effects of the most intensive portion of the DPP. Therefore, the purpose of this study was to evaluate if 12 weeks of the DPP curriculum significantly affected cardiovascular risk

factors. More specifically, this study was a hypotheses generating study to assess changes in dependent variables such as HbA1c, body weight, BMI, changes in fat and lean mass, lipid profile and blood pressure components.

## **METHODS**

### **Subjects**

Thirty-four subjects were recruited from the La Crosse Exercise and Health Program (LEHP) and Strong Seniors Program ( $\geq 60$  years of age). All subjects were assumed to have been participating in facilitated exercise class 2-3 days per week prior to participating in the study. The first 34 volunteers who meet the study requirements were included. Inclusion criteria included: BMI  $\geq 25$ ; fasting glucose of 100 to 125 mg/dl; HbA1c of 5.7-6.4 mmol/mol; greater than a nine-point score on the DPP questionnaire, or a positive screening for prediabetes. Exclusion criteria included smoking and diabetic.

### **Procedures**

Eligible participants were screened at baseline to determine eligibility and placed in the treatment group. Approval from the Institutional Review Board for the Protection of Human Subjects at the University of Wisconsin-La Crosse was obtained before testing. Verbal and written explanations of study protocols were provided for all subjects with the opportunity to ask questions before signing the informed consent form. Subjects were informed that participation was voluntary and they could withdraw at any time.

Preceding screening day, subjects were informed to come to scheduled appointment fasting for at least 12 hours (no food, alcohol or caffeine). No morning medication were allowed prior to screening, but subjects were advised to bring medications that could taken immediately after testing. On screening day, each subject completed paperwork, which included an informed consent and the DPP questionnaire. Next, subjects

completed anthropometric measurements. Height was measured using a stadiometer, measuring to the nearest 0.5 centimeters. Body weight was measured to the nearest tenth of a kilogram using a calibrated Rice Lake Weighing Systems Healthweigh scale. These measurements were used to calculate BMI ( $\text{kg}/\text{m}^2$ ). Waist and hip circumference were obtained following the American College of Sports Medicine guideline recommendation for measurements. Waist circumference was taken at the narrowest part of the torso, between the last rib and the iliac crest, using a cloth tape measuring to the nearest 0.5cm. Hip circumference was measured to the nearest 0.5cm with the subject standing with feet together at the largest part of hips at largest protuberance of the gluteus (Riebe, D., Ehrman, J. K., Liguori, G., & Magal, M., 2018).

Following a 12-hour fast, two blood samples were taken using a Unistik 2 Normal lancet. Lithium Heparin Capillary tubes (40 $\mu\text{L}$ ), by Alere, were used to collect blood samples. Blood was entered into an Afinion HbA1c test cartridge and a Cholestech LDX TC·GLU cartridge. Both samples were tested using Alere Afinion<sup>TM</sup> AS100 Analyzer made by Abbott Laboratories to obtain fasting measurements of glucose, HbA1c, HDL, LDL, total cholesterol, triglycerides, and the risk ratio (total cholesterol/ HDL).

Resting brachial blood pressure measurement was performed on the bare right arm with a SphygmoCorXCEL PWA & PWV by AtCor Medical Pty Ltd. Subjects rested in a supine position for five minute prior to testing, with eyes covered wearing noise cancelling headphones. Bioelectrical impedance analysis was completed using the RJL Systems Quantum IV BIA Analyzer. This system was used to identify fat-free mass (FFM) using one of the following gender-specific formulas: Male FFM (kg) =  $-10.678 + 0.262 \text{ mass} + 0.652 \text{ height}^2 / \text{R} + 0.015 \text{ R}$ ; Female FFM (kg) =  $-9.529 + 0.168 \text{ w} + 0.696$

$\text{height}^2 / R + 0.016 R$  where ht = height in cm, mass in kg, R = resistance (Li, Y., 2012). The estimation of FFM was subtracted from total mass to determine fat mass (FM). Body fat percent will be calculated by taking FM X 100 and divide by total body mass.

Subjects in the treatment group were tested at baseline and 12 weeks. The same order and protocol were used for each subject. The treatment group attended weekly education classes from the CDC-approved curriculum that included dietary modifications and increased physical activity (at least 150 minutes of moderate intensity physical activity). Body weight in pounds was obtained at weekly meetings using a calibrated Rice Lake Weighing Systems Healthweigh scale. Total physical activity minutes for the previous week were recorded.

### **Statistical Analysis**

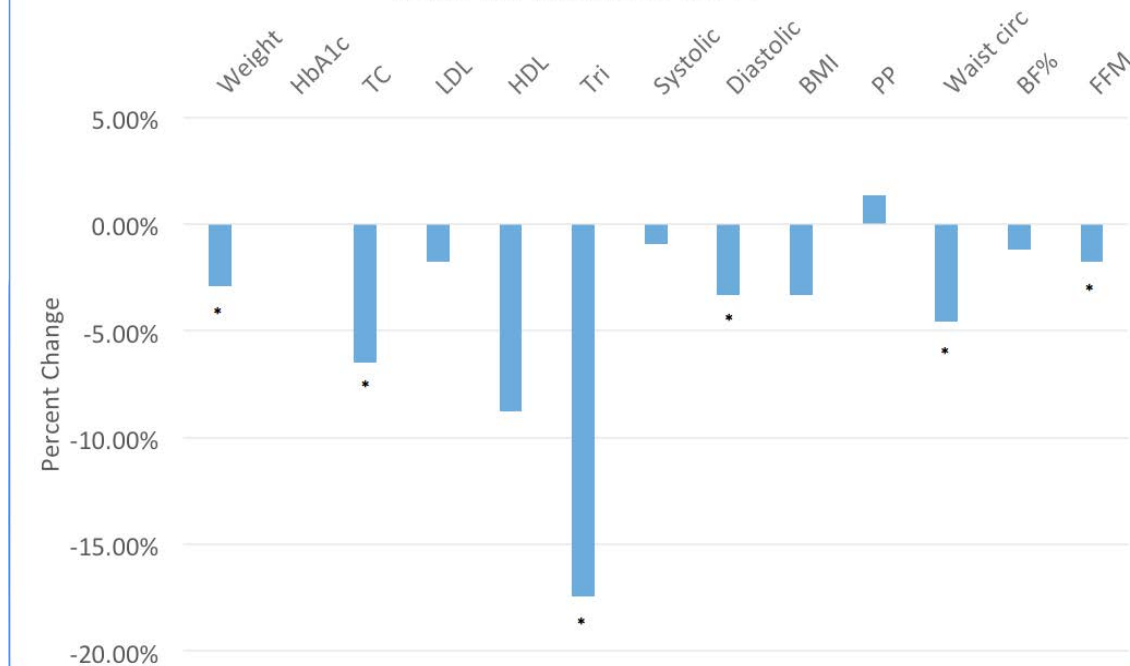
The SPSS statistical analysis program was used to analyze the data. A one- tailed paired t-test was used to determine if significant changes between groups occurred over the course of the 12-week study. The alpha level was set at 0.05 to achieve statistical significance for this hypotheses generating study. An estimation of an appropriate sample size was conducted using previous research investigating the effects of DPP vs. usual care in older adults (Xiao et al. 2013 Nutrition and Diabetes). With an effect size of 0.73, 8 prediabetic subjects per group would enable us to observe a significant difference (5%) in weight between treatments (DPP vs. control) with a power of 80%. We chose weight as our primary variable to investigate the effects of a predicted outcome of DPP on our target cardiometabolic markers. Data was screened for accuracy, completeness and normality. For tests where normality failed, a Wilcoxon test was used to determine p

values. Differences in HbA1c, body weight, BMI, fat mass, lean mass, total cholesterol, LDL, HDL, triglycerides, resting pre and post systolic and diastolic blood pressures were analyzed using a one tailed paired samples t-test. To avoid Type 1 error, the results are to be viewed as hypotheses generating data for future studies.

## **RESULTS**

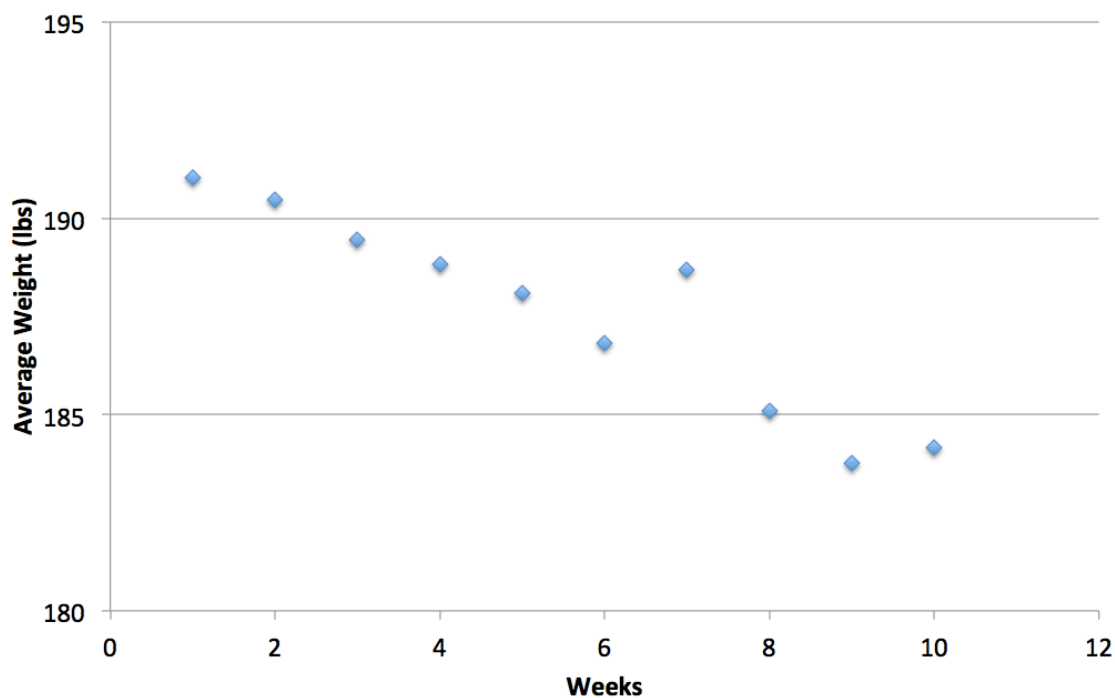
The intervention group significantly decreased weight, BMI, waist circumference and fat free mass from the start of the study to the end of the 12 week data collection ( $p < .05$ ), but the intervention group did not significantly change body fat percentage ( $p > .05$ ). The lipid profile also changed significantly ( $p < .05$ ). Total cholesterol and triglycerides significantly decreased ( $p < .05$ ). However, LDL and HDL did not significantly change from pre to post measurements ( $p > .05$ ). Diastolic blood pressure was significantly reduced ( $p < .05$ ) but systolic blood pressure and pulse pressure were not significantly different ( $p > .05$ ). A graph representing all of the variables from pre to post using the DPP intervention are represented in Figure 1.

Figure 1. Percent change of cardiovascular risk factors after 12 weeks of DPP.



\*Significant difference pre to post ( $p < .05$ ).

Figure 2. Average weight through 12 weeks of DPP





**Table 1. Difference from pre to post in various cardiovascular risk factor after 12 week DPP intervention.**

Variable	Pre Mean±SD	Post Mean±SD	P value
HbA1c (mmol/mol)	5.5±0.31	5.5±0.26	0.108
Weight (kg)	85.8±18.55	83.3±18.54	<.001*
BMI (kg/m <sup>2</sup> )	29.5±5.10	28.52±5.12	<.001* <sup>#</sup>
Body Fat%	34.1±6.91	33.7±6.46	0.365 <sup>#</sup>
Fat Free Mass (kg)	55.8±14.69	54.8±13.89	0.014*
Waist Circ. (cm)	100.7±16.48	96.1±15.04	0.002* <sup>#</sup>
TC (mmol/L)	187.1±39.82	175.0±37.40	0.006* <sup>#</sup>
LDL (mmol/L)	103.2±30.29	101.4±38.08	0.084 <sup>#</sup>
Triglyceride (mmol/L)	131.2±66.79	108.3±38.28	0.039* <sup>#</sup>
HDL (mmol/L)	60.4±23.64	55.1±21.14	0.969 <sup>#</sup>
Systolic (mmHg)	140.1±16.57	138.8±15.15	0.146
Diastolic (mmHg)	80.5±9.87	77.8±10.28	0.024* <sup>#</sup>
PP (mmHg)	60.3±11.97	61.1±13.21	0.656

\*Significantly different than pre (p<.05).

<sup>#</sup> Wilcoxon test used to determine p value.

## **DISCUSSION**

The purpose of this study was to generate hypotheses for future studies by observing the effects of 12 weeks of the DPP curriculum on cardiovascular risk factors. The intervention group was successful at significantly decreasing weight, BMI total cholesterol, HDL, triglycerides, diastolic blood pressure, waist circumference and fat free mass. Although not significant, systolic blood pressure was trending toward significance in the intervention group.

Weight loss was significantly reduced from pre to post testing in turn causing BMI to decrease due to weight being the variable to change in the equation. There was also a significant decrease in waist circumference, which is associated with a reduction in visceral adiposity (Bigaard, J., et al., 2005). Waist circumference and BMI have been implemented into clinical practice because the two together are more accurate at predicting mortality. An individual with a high BMI and a large waist circumference is at an increased cardiovascular risk compared to someone with a high BMI and a small waist circumference. Bigaard et al, (2005), found that a 10% higher waist circumference corresponded to a 1.48 times increased mortality. Therefore the decrease in waist circumference and BMI in the present research corresponds to a decreased risk in mortality for these subjects.

The goal of the DPP is to lose 5-7% of their body weight in a year. The present study was 12 weeks and the subjects revealed to have decreased their body weight by 2.91%. However, despite the reduction in visceral adiposity, it is important to note there

was a significant reduction in FFM. In the present research, the decrease in FFM indicates that a significant contributor of the weight loss was from lean mass. This loss will reduce their basal metabolic rate and make this loss hard to maintain (Blackburn, G., 1995). Interestingly, when taken together, the reduction in both lean mass and visceral adiposity likely points to diet being a primary contributor to the total decrease in weight. Washburn et al. (2014) found weight loss through diet alone decreased resting and non-resting energy expenditures, oxidation, thyroid hormones and increased cortisol. All of these factors lead to the person regaining the weight, but more specifically gaining fat because these processes are related to elevated energy storage. Physical activity is thought to maintain FFM and decrease BF and increasing FFM can lead to a high resting metabolic rate. Physical activity also interrupts homeostasis which keeps the appetite under control (Washburn R., et al., 2014). The present study did not see a maintenance of FFM and decrease in BF% with diet and exercise. The decrease in FFM as well as the slight decrease in HDL could be due to noncompliance with increased exercise or the weight loss was primarily from dietary modifications. FFM measurement could also be altered if the subject attended testing in a different hydration status. It was assumed subjects followed the same routine before each testing day being BIA is a good measurement of relative but not absolute change in body composition.

A study done by Leenen et al., looked at the effects of weight loss on lipid profiles and found visceral fat loss in women was associated with an increase in HDL. The present research did not find a significant decrease in BF% and saw a decrease in HDL. However, a reduction in waist circumference was noted which is associated with decreases in visceral fat. Research has indicated that assessing visceral fat through

abdominal BIA is more sensitive than the traditional methodology used in the present study (Ryo et al., 2005). Therefore, our methodology of measure body fat may have not been as accurate assessment. The decrease in waist circumference is a clinically important finding as excess visceral fat accumulation in obese and prediabetic patients is related to the development of type 2 diabetes (Iwahashi et al., 2015) Leenen et al. also found weight loss of 12.6 kg for men and 11.7 kg for women resulted in decreased total cholesterol, LDL, and triglycerides and suggested these changes were due to visceral fat loss (Leenen, R., 1993).

In contrast, Orchard et al. and the study conducted by the Diabetes Prevention Program Research group observed an increase in HDL while the present study found a no change, but prior studies had an advantage due to the longer follow up time. Additionally, Orchard et al. found decreases in both systolic and diastolic blood pressure as well as decreases in LDL and triglycerides, but the present study only observed changes in diastolic pressures and decreased triglyceride levels. Systolic blood pressure did decrease slightly in the present study but it was not considered significant. Measurements of blood pressure were taken in a similar fashion as Orchard et al. requiring patients to sit for five minutes before the measurements were taken. For our protocol, patients were lying down whereas in Orchard et al. the patients were seated. Both the present study and Orchard et al. used an enzymatic process to determine lipid profile.

The results of this study disagree with findings of DPP research utilizing similar measurements. Gummesson, Nyman, Knutsson, and Karpefors found a significant decrease in HbA1c in relation to decreased body weight Gummesson, A., Nyman,

E., Knutsson, M., & Karpefors, M., 2017). Additionally, Boniol, Dragomir, Autier and Boyle found a significant correlation between an increase in activity with decreased HbA1c levels (Boniol, M., Dragomir, M., Autier, P., & Boyle, P., 2017). Increased physical activity was part of the intervention and weight loss was the overall goal. Weight loss was considered significant but HbA1c decrease was not considered significant, the previous research did however have longer duration.

The current study was a convenience sample and the following limitations should be noted. It was difficult to obtain a large number of people who met the inclusion criteria and who were willing to fully commit to 12 weeks of participation. Compliance to eating healthy, reducing caloric intake, and obtaining at least 150 minutes of moderate exercise a week was also an issue. The study was 12 weeks in duration and conflicted with some subject's vacation schedules. Two education sessions were lower in attendance due to inclement winter weather conditions. Subjects met for weekly meetings and reported total number of exercise minutes and direct observation of exercise was not regulated. Dietary journals were discussed and encouraged but not required as part of the DPP program. Another limitation of the study included the measurement of FFM and BF%. These measurements were obtained through BIA, which has been found to have high variability based on hydration status. The subjects were instructed to come in for screenings in a fasting state, possibly affecting hydration status, making reliability of body composition results questionable. HDL was another variable that was questioned. Many of our subjects had above average HDL readings raising the question if there was an error obtained during measurement. Subjects recruited were also exercising on a regular basis at either the strong seniors or LEHP. Both of these programs currently

participate in exercise classes 2-3 days per week which could explain the above average HDL numbers.

## **CONCLUSION**

In summary, the results of the current study found that 12 weeks of the DPP curriculum significantly decreased weight, BMI, total cholesterol, HDL, triglycerides, diastolic blood pressure, waist circumference, and fat free mass in older adults who qualified based on inclusion criteria. Further research is needed to investigate these findings as the purpose of this study was to generate hypotheses. Future studies should also focus on these significant variables in a sedentary population and compare findings. We would also recommend assessing these variables for a longer period of time and using either underwater weighing or Bod Pod for body composition analysis to see if the same changes are noted.

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APPENDIX A  
INFORMED CONSENT

**1. INFORMED CONSENT FOR “Effects of a diabetes prevention program on glycemic control, body composition, and vascular function”**

**Principal Investigator:**

**Salvador Jaime, PhD  
UW-La Crosse  
142 Mitchell Hall  
La Crosse, WI 54601  
(608)785-6518**

- 2.** I, \_\_\_\_\_, give my informed consent to participate in this study designed to evaluate the effect of a standardized diabetes prevention recognition program on vascular function, body composition, and physical performance. I have been informed that the study is under the overall direction of Salvador Jaime, Ph.D. who is an Assistant Professor in the Department of Exercise and Sport Science at the University of Wisconsin-La Crosse. I consent to the presentation, publication and other release of summary data from the study which is not individually identifiable.
- 3.** I have been informed that my participation in this study will require 5 total visits to the human performance laboratory (Mitchell 225). Each visit to the lab requires fasting for at least 12 hours (food, alcohol, and caffeine), no strenuous exercise for at least 48 hours, and no morning medication (I will bring to the lab for consumption following the tests). The following measures will be taken at 0, 3, 6, 9, and 12 months:
- a.** A finger stick blood draw to evaluate my fasting glucose or HbA1c and lipid levels.
  - b.** Bioelectrical impedance analysis which involves a small current sent through my body
  - c.** Laying on my back while there is a pencil-like pressure-sensor on my neck and upper thigh. Following that, the researcher will place a cuff around my upper thigh and arm, both of which will inflate and deflate occasionally.
  - d.** After the resting measures, a researcher will lower my hand or foot into an ice-bath for 3 minutes while the cuffs mentioned previously will inflate and deflate
  - e.** Lastly, after sufficient time to rest I will perform the following physical performance measures:
    - i.** Walking speed – Walk at my usual speed along a straight 11-meter path on a flat floor.
    - ii.** Grip strength – The maximal strength of my dominant hand will be measured twice.
    - iii.** Static balance – I will stand on my preferred leg with my eyes open and hands placed on my sides. I will focus on a dot placed directly in-front of me during this test. The amount of time I can balance will be measured twice.
- 4.** I have been informed that there are no foreseeable risks associated with this study other than the pain associated with the cold exposure, fatigue associated with grip

strength and static balance tests, and the discomfort associated with providing the fingertip blood samples.

5. I have been informed that there are important benefits to myself such as learning about my overall health and how to best prevent type II diabetes mellitus.
6. I have been informed that the investigator will answer questions regarding the procedures throughout the course of the study.
7. I have been informed that I am free to decline to participate or to withdraw from the study at any time without penalty.
8. Concerns about any aspects of this study may be referred to Dr. Salvador Jaime at (608)785-6518. Questions about the protection of human subjects may be addressed to the Chair of the UW-L Institutional Review Board 608 785 6892.

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Participant

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Date

## APPENDIX B

### DPP QUESTIONNAIRRE AND SCREENING SHEET

**University of Wisconsin - La Crosse**  
**Diabetes Prevention Program**  
**Screening Information**

**Name:** \_\_\_\_\_ **Code:** \_\_\_\_\_ **Date:** \_\_\_\_\_

Have you been fasting for 12 hours?	Yes	No	(Circle One)
Did you take your medications today?	Yes	No	(Circle One)
Have you consumed caffeine in the past 12 hours?	Yes	No	(Circle One)

Height: \_\_\_\_\_ inches      Weight: \_\_\_\_\_ lbs

Waist Circ. \_\_\_\_\_ cm      Hip Circ. \_\_\_\_\_ cm

Total Cholesterol: \_\_\_\_\_ mg/dl      LDL Cholesterol: \_\_\_\_\_ mg/dl

HDL Cholesterol: \_\_\_\_\_ mg/dl      Triglycerides: \_\_\_\_\_ mg/dl

Risk Ratio= Total Cholesterol/ HDL cholesterol= \_\_\_\_\_ <5:1 Keep Below  
 <3:5:1 optimal

Glucose: \_\_\_\_\_ mg/dl      HbA1c: \_\_\_\_\_

BIA:

Resistance: \_\_\_\_\_      5 Meter Walk Time: \_\_\_\_\_

Reactance: \_\_\_\_\_

Impedance: \_\_\_\_\_

Phase Angle: \_\_\_\_\_      One Leg Balance: \_\_\_\_\_

Blood Pressure: \_\_\_\_\_ mm/Hg

MVC: \_\_\_\_\_ kg      \_\_\_\_\_ kg      \_\_\_\_\_ kg

# DO YOU HAVE PREDIABETES?

## Prediabetes Risk Test

- 1 How old are you?  
Less than 40 years (0 points)  
40–49 years (1 point)  
50–59 years (2 points)  
60 years or older (3 points)
- 2 Are you a man or a woman?  
Man (1 point) Woman (0 points)
- 3 If you are a woman, have you ever been diagnosed with gestational diabetes?  
Yes (1 point) No (0 points)
- 4 Do you have a mother, father, sister, or brother with diabetes?  
Yes (1 point) No (0 points)
- 5 Have you ever been diagnosed with high blood pressure?  
Yes (1 point) No (0 points)
- 6 Are you physically active?  
Yes (0 points) No (1 point)
- 7 What is your weight status?  
(see chart at right)

Write your score  
in the box:









Add up  
your score:

### If you scored 5 or higher:

You're likely to have prediabetes and are at high risk for type 2 diabetes. However, only your doctor can tell for sure. If you do have type 2 diabetes or prediabetes (a condition that precedes type 2 diabetes in which blood glucose levels are higher than normal), talk to your doctor to see if additional testing is needed.

Type 2 diabetes is more common in African Americans, Hispanics/Latinos, American Indians, Asian Americans and Pacific Islanders.

Higher body weights increase diabetes risk for everyone. Asian Americans are at increased diabetes risk at lower body weights than the rest of the general public (about 15 pounds lower).

Height	Weight (lbs.)		
4'10"	119-142	143-190	191+
4'11"	124-147	148-197	198+
5'0"	128-152	153-209	204+
5'1"	132-157	158-210	211+
5'2"	136-163	164-217	218+
5'3"	141-168	169-224	225+
5'4"	145-173	174-231	232+
5'5"	150-179	180-238	240+
5'6"	155-185	186-246	247+
5'7"	159-190	191-254	255+
5'8"	164-196	197-261	262+
5'9"	169-202	203-269	270+
5'10"	174-208	209-277	278+
5'11"	179-214	215-285	286+
6'0"	184-220	221-293	294+
6'1"	189-226	227-301	302+
6'2"	194-232	233-310	311+
6'3"	200-239	240-318	319+
6'4"	205-245	246-327	328+
	(1 Point)	(2 Points)	(3 Points)

You weigh less than the amount  
in the left column  
(0 points)

Source: Know Your BMI, www.knowyourbmi.com  
© 2014, 2015 CDC  
Original data were calculated without  
gender-specific weights as part of the model.

## LOWER YOUR RISK

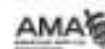
Here's the good news: It is possible with small steps to reverse prediabetes – and these measures can help you live a longer and healthier life.

If you are at high risk, the best thing to do is contact your doctor to see if additional testing is needed.

Visit [DoIHavePrediabetes.org](http://DoIHavePrediabetes.org) for more information on how to make small lifestyle changes to help lower your risk.

For more information, visit us at

[DoIHavePrediabetes.org](http://DoIHavePrediabetes.org)





APPENDIX C  
REVIEW OF LITERATURE

## **REVIEW OF LITERATURE**

This review of literature discusses the prevalence of prediabetes and diabetes in the United States today. The Diabetes Prevention Program was established to help decrease the number of individuals who will develop type II diabetes as they age. There have been plenty of studies analyzing the progress of the Diabetes Prevention Program but there has not been much research on how effective the program has been at minimizing the risk for cardiovascular disease based on the ACSM guidelines. The ACSM guidelines identifies age, family history, smoking, sedentary lifestyle, Body Mass Index (BMI), hypertension, high cholesterol, and elevated glucose levels as risk factors for cardiovascular disease. This review of literature will discuss several of these risk factors including HbA1c, BMI, lipid profile, blood pressure (BP) and body composition.

### **Introduction**

The Diabetes Prevention Program (DPP) was established from a study that was conducted from 1996-2001 looking at the incidence of diabetics and pre-diabetics. Diabetes is a medical condition that causes patients to have fasting glucose levels of  $\geq 126$  mg/dL or HbA1c measurement  $\geq 6.5\%$ . Pre-diabetes is diagnosed when patients have above normal measurements but do not exceed the measurements required of the diagnosis of diabetes. Pre-diabetes, for the purpose of this study, is defined as having a fasting glucose level of 100-125 mg/dL or a HbA1c measurement of 5.7-6.4%. The DPP collected data on subjects with an increasing prevalence of pre-diabetes. This research looked at the differences between a lifestyle intervention group and a medication group (metformin) and the successfulness of delaying the diagnosis of diabetes. Individuals in the lifestyle intervention group learned about portion control, healthy food choices, and

the benefits of increasing physical activity (>150 minutes per week). The primary goal of the lifestyle intervention group was to lose seven percent of the subject's initial body weight. This was a longitudinal study that followed subjects for many years. Within the first three years, subjects in the lifestyle intervention group experienced a 58% reduction in the diagnosis of diabetes compared to the pharmaceutical group. After a ten year follow up, the lifestyle intervention group delayed their onset of diabetes by 34% compared to the subjects taking metformin (only delaying by 18%). Subjects over the age of 60 reduced a diabetes diagnosis by 49% (Diabetes Prevention Program (DPP) | NIDDK, n.d.).

This has continued to be important research due to the alarming increases in the diagnosis of obesity and diabetes. An estimated 30.3 million adults today are diagnosed with diabetes and 84.1 million adults are diagnosed with prediabetes. The total estimated health related cost of the diabetic diagnosis is \$327 billion dollars a year in the United States alone. Besides cost, uncontrolled diabetes causes the development of hypertension, cardiovascular disease and stroke (Long, A. N., & Dagogo-Jack, S., 2011).

### **Glycosylated Hemoglobin**

HbA1c is a common test used to identify type 1 and type 2 diabetes. This test looks at the amount of hemoglobin in the blood that is coated with glucose. The more hemoglobin coated or glycated, the more uncontrolled the levels of glucose are. A HbA1c measurement represents an overall average of the last two to three months of blood glucose levels (A1c test).

After it was discovered, HbA1c was a test commonly used to monitor for hyperglycemia in diabetic patients. Practitioners found that monitoring HbA1c was a reliable and valid method to evaluate a 3-month snapshot of overall glucose control. Huang et al. used HbA1c to track the progression of pre-diabetes and diabetes with HbA1c and developed a linear regression equation that could predict a timeline to progression of type II diabetes. They found HbA1c was reproducible and not significantly affected by a fasting state. This study was three years in duration and included individuals that were not medicated. For example, if an individual had a HbA1c level that was considered pre-diabetic, on average it would take 2.49 years for them to progress to a diabetic status. The closer the HbA1c measurements were to the 6.5 cut off, the faster the diabetes progression (Huang et al. , 2014).

The American Diabetes Association, International Diabetes Federation, as well as the European Association for the study of diabetes have all deemed the measurement of HbA1C as a reliable and valid measurement to diagnose for diabetes. Martins et al. (2012) conducted a study on the relationship between HbA1c and other common risk factors such as obesity, functional fitness, and lipid profiles. The study consisted of 118 older subjects, ranging between 65-95 years of age. All subjects were from the same institution making it realistic to measure nutritional status, functional fitness, lipid profile, fasting glucose, HbA1c, blood pressure, and anthropometric measurements. The researchers found that HbA1c had a positive correlation with elevated glucose levels, triglycerides, body weight, BMI, waist circumference and a low level of HDL. The positive correlation between waist circumference and HbA1c leads us to assume that the distribution of fat, particularly across the abdomen, may serve as a valid predictor of

HbA1c. It was also found that women who had higher levels of HbA1c, had a higher BMI, blood glucose levels, and total cholesterol (Martins, Jones, Cumming, e Silva, Teixeira, & Veríssimo, 2012).

A systematic review was also performed from a clinical trial to observe how weight loss effected HbA1c. Researchers found 58 studies that met criteria for inclusion and included 17,204 subjects. From the data collected, a linear mixed model examined HbA1c in relation to weight loss. Overall, results showed that for each kilogram lost a decrease in HbA1c of 0.1% occurred. They also found that there was a significant decrease in HbA1c in individuals with poorly managed diabetes compared to well controlled levels (Gummesson, A., Nyman, E., Knutsson, M., & Karpefors, M., 2017). Another systematic review was conducted to evaluate the impression of physical activity on HbA1c. Peer reviewed research articles were found following the PRISMA guidelines using a search in the PubMed database. After exclusions, 125 articles met the criteria for inclusion. The researchers found that exercising for 150 minutes per week, according to the World Health Organization recommendations, would decrease HbA1c by an average of 0.21%. These results focused solely on duration of exercise and did not differentiate between the type or intensity (Boniol, M., Dragomir, M., Autier, P., & Boyle, P., 2017).

## **BMI**

BMI is a measurement that is calculated using weight in kilograms divided by height in meters squared. This measurement was first used in Belgium where a mathematician saw that people with a normal frame size had a proportional height. Categories for BMI include: Underweight = <18.5, Normal weight = 18.5–24.9, Overweight = 25–29.9, Obesity = BMI of 30 or greater. Due to ease of measurement in

assessing for level of obesity, BMI has been used in many studies and is commonly used in a clinical setting. Obesity status is an important measurement because of the positive association that has been found between obesity and other diseases such as diabetes, hypertension and coronary artery disease. Results of studies assessing the level of sensitivity of the BMI measurement have been inconclusive. A meta analysis was completed using 25 studies, and 32 different samples with a total of 31,968 adults. Results found that BMI had good specificity but poor sensitivity. They found that 50% of the time, people who had excessive body fat, were not labeled as obese, and were under diagnosed. However, this meta-analysis found that a BMI measurement  $\geq 30 \text{ kgm}^{-2}$  was nearly perfect at predicting excess body fat in both sexes. However, BMI less than  $30 \text{ kgm}^{-2}$  had shortcomings in differentiating between body fat and lean body mass because the measurement is only using weight and not body composition (Okorodudu, D. O., et al., 2010).

### **Body Composition**

Obesity is defined as having excessive body fat. Body fat distribution is strongly associated with developing glucose intolerance or type 2 diabetes. Gomez- Ambrosi et al. performed a study looking at body fat as it relates to the incidence of prediabetes and diabetes. The study was a cross sectional analysis looking at 4,828 white subjects that were either prediabetic or diabetic. BMI, obesity status, and obesity, defined with percent body fat, were compared. The researchers found that 32% of people classified as lean, according to BMI, were in fact considered obese according to their body fat percentage, and 82% of people deemed obese by BMI were seen as obese looking at body fat percentage. The results of this study concluded that body fat percentage is a more

efficient measurement for prediabetics and diabetics for both lean and obese subjects (Gómez-Ambrosi, J., et al., 2011).

Additionally, obesity is a risk factor for cardiovascular disease. A study done by Carl J. Lavie looked at body fat and lean body mass index in people with stable coronary artery disease over three years to determine overall mortality and morbidity. This study included 570 subjects that were referred to cardiac rehabilitation, and used skin fold measurements to calculate body fat and lean mass index using  $(1-BF) \times BMI \text{ Kg/m}^2$ . They found that mortality was inversely related to lean mass index and low body fat and low lean mass had the highest mortality rate. The lowest mortality rates were found in patients with high body fat and high lean mass, concluding that high lean mass and high body fat are both predictors for survival in stable coronary artery disease. This study suggested further research be conducted to validate these results as well as to determine optimal composition for the prevention of coronary heart disease (Lavie, C. J., De Schutter, A., Patel, D. A., Romero-Corral, A., Artham, S. M., & Milani, R. V., 2012). Finding high body fat along with high lean mass leading to higher survival rates is known as the Obesity Paradox. This theory is not fully understood mechanistically, however the limited available data suggests that the lean mass associated with the obesity label is a more accurate depiction of survival (Chase, P. J., Davis, P. G., & Bensimhon, D. R., 2014).

In order to achieve optimal body composition, it is important to understand what interventions significantly alter body composition. Lifestyle habits have been found to play a significant role in maintaining good health by increasing quality of life while decreasing morbidity and mortality rates. Body mass typically decreases with the

implementation of increased physical activity and dietary portion control but this does not take into account the changes in amount of body fat and lean mass. Lifestyle interventions should focus on increasing lean mass to maintain and even increase resting metabolic activity, skeletal integrity, and maintain functional capacity. Miller et al., compared diet intervention to diet intervention and exercise within 5 different studies and found inconclusive evidence on whether diet alone or diet accompanied with exercise is best for promoting fat loss and maintaining or increasing lean mass (Miller, C. T., Fraser, S. F., Straznicky, N. E., Dixon, J. B., Selig, S. E., & Levinger, I., 2013)

### **Waist and Hip Measurements**

Qiao and Nyamdori (2010) conducted a meta analysis comparing BMI, waist circumference, and waist to hip ratio (WHR) at predicting type II diabetes in patients of various ages with the diagnosis of diabetes. They found contradicting results on which measurement was the best predictor with wide variability across different ethnic groups. However, all of the studies found BMI, WHR, or waist circumference had a positive correlation with the risk for diabetes when accounting for other variables. Most of the studies concluded that WHR or waist circumference was a better indicator compared to BMI (Qiao, & Nyamdorj, 2010)

Bray et al. (2008) evaluated which measurement was the best predictor for increased risk of diabetes amongst: BMI, waist circumference, WHR, and waist to height ratio. CT scan was used to determine if simple anthropometric measurements were equally as effective. Measurements were taken at baseline and at the 3.2 year follow up and the lifestyle intervention group was found to have significantly better outcomes. All measurements looked at CT, BMI, WHR, waist circumference, and waist to height ratio.



High visceral fat via CT at L2-L3 or L4-L5 was a good predictor of future diagnosis of diabetes. None of the measurements were significantly better. Therefore, CT showed no advantages and less expensive measurements could be used in making these predictions. They also found that fat distribution and type of fat differed by gender (Bray et al., 2008).

### **Lipid Profile**

Kansal and Kamble (2016) conducted a study that looked at lipid profiles of pre-diabetics to see if dyslipidemia was an issue that could be improved with changes in lifestyle intervention or if medication alone would decrease mortality rates. They found dyslipidemia was a common diagnosis alongside diabetes contributing to the increased risk of cardiovascular disease. A 24-month study was completed on pre-diabetics measuring fasting glucose, impaired glucose tolerance, and a lipid profile. A significant correlation was found between higher blood glucose levels and elevated LDL levels. Increased blood glucose was also correlated to a lower HDL levels. Total cholesterol and triglycerides were also found to be higher in pre-diabetic patients. The findings suggested increased insulin resistance increased levels of glucose in the blood negatively affecting lipid profile, which may contribute to the plaque buildup in arteries promoting cardiovascular disease. (Kansal & Kamble, 2016)

Plant, Mowar & Chandra (2018) performed a study on the relationship between HbA1c, lipid profile, and the relationship to Acute Coronary Syndrome (ACS) in diabetic populations. Coronary angiography, HbA1c and lipid profiles were measured on 51 patients present with ACS. The patients with ACS had a positive correlation with the highest levels of HbA1c, LDL, and had low HDL measurements. The severity of ACS strongly correlated with the level of total cholesterol. Approximately 79.5% of patients

with HbA1c levels of 6.5-8.5, had a single vessel that was diseased. The researchers concluded that poor control of blood glucose levels puts individuals at a much higher risk for developing ACS. Early intervention was the key to decreasing mortality rates with this study. No research was conducted on lifestyle intervention or dietary habits (Pant, Mowar, & Chandra, 2018).

The American Diabetes Association (2005) conducted research that looked at the DPP participants and tested lipid profiles to get a better understanding of the risk for developing cardiovascular disease. A randomized study, including 3,819 participants was performed and many were not on any lipid lowering medications. Measurements were taken at baseline and over 25% of the subjects were eligible for hyperlipidemia medications. Overall, women had better lipid profiles when compared to men. Another significant finding was that weight gain and increases in waist to hip measurements (WHR) had little effect on lipid profiles. However, insulin resistance or increased levels of blood glucose had a greater effect on the level of dyslipidemia. This study concluded that the more severe and unmanaged the diabetes, the more risk an individual is at for future health related issues (American Diabetes Association, 2005).

### **Blood Pressure**

Blood pressure is a measure of systolic and diastolic blood pressure. Systolic blood pressure (SBP) is the pressure in the blood vessels when the heart is contracting and diastolic blood pressure (DBP) is the pressure in the vessels when the heart is relaxing and filling. An accurate blood pressure is obtained when the patient relaxes in silence for at least five minutes. They should have not participated in heavy exercise, had any caffeine and their bladder should be empty. The measurement must be taken on bare

skin with a cuff that is the correct size, their back must be supported, their feet flat on the floor, and their arm should be elevated to heart level. When listening, the practitioner will hear a series of five sounds, known as the Korotkoff sounds. Systolic blood pressure is the first Korotkoff sound and diastolic blood pressure is the fifth and final Korotkoff sound (Whelton et. al).

Current guidelines consist of four classifications: normal, elevated and hypertension stage 1 and 2. Blood pressure is considered elevated with a SBP of 120-129 mmHg or a DBP of <80 mmHg. Stage 1 hypertension is defined as a SBP of 130-139 mmHg or a DBP of 80-89, stage 2 hypertension is a SBP  $\geq 140$  mmHg or a DBP  $\geq 90$  mmHg (Whelton et. al).

Blood Pressure has been identified as a factor that increases the risk for cardiovascular disease. A meta-analysis found that a SBP 20 mmHg higher or a DBP this 10 mmHg higher doubled patient's risk for heart and other vascular diseases (Lewington et.al). Hypertension and diabetes are also closely related, and approximately 80% of people with diabetes also have hypertension. These two comorbidities combined put individuals at higher risk for cardiovascular death, peripheral artery disease, stroke and coronary heart disease. There is currently little evidence on specific guidelines for a target blood pressure in patients with diabetes (Whelton et. al).

Research has begun to look at the relationship between cardiovascular disease and diabetes. Evidence has shown that men with diabetes are at a much higher absolute risk for cardiovascular disease death compared to men who did not have diabetes (Stamler, J., Vaccaro, O., Neaton, J. D., Wentworth, D., & Multiple Risk Factor Intervention Trial Research Group.,1993). The Framingham study has been collecting data on the

relationship of cardiovascular disease and diabetes since 1948. They have found that diabetes doubles the risk for men and triples the risk for women to develop cardiovascular disease (Kannel, W. B., & McGee, D. L., 1979). The American Diabetes Association has conducted a 3 year longitudinal study with the goal of observing how DPP influenced hypertension, dyslipidemia and cardiovascular disease events. Researchers saw that the intervention reduced cardiovascular risk factors such as hypertension, high triglyceride, and low HDL, reducing overall cardiovascular disease events (American Diabetes Association., 2005). The purpose of this study is to measure changes in cardiovascular disease risk factors such as HbA1c, lipid profile, BP, BMI, and body composition over the course of a 12 week intervention.

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