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Blood Flow Improvement Trial: Design and Enrollment Developing Topics

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Abstract

Background

Midlife insulin resistance (IR) has previously been shown to be associated with lower cerebral blood flow (CBF), and is a potentially modifiable risk factor for dementia. The Blood Flow Improvement Trial (BFiT), NCT03117829 , tested a 12 week carbohydrate restricted diet (CRD) and exercise behavioral intervention to reverse IR, and aimed to 1) determine the extent to which improving or normalizing glucose homeostasis improves CBF and cognitive function in individuals with IR, 2) determine whether participants continue to maintain improved or normalized glycemic control for 6 months, and 3) determine changes in the human metabolome as individuals improve or normalize IR and glucose homeostasis through diet and exercise.

Method

Participants were recruited from the Wisconsin Alzheimer's Disease Research Center and screened for metabolic risk factor eligibility based on the criteria shown in Table 1. The design involved a 12 week diet and exercise intervention focused on self-monitoring to promote adherence. Exercise was conducted in a supervised group setting 3 days/week for 50 minutes and participants were instructed to exercise on their own an additional 2 days/week. Participants followed a CRD and monitored their own blood glucose with the goal of achieving and maintaining fasting blood glucose <100 mg/dL. Participants underwent baseline, 12 week, and 6 month procedures including urine and blood labs/metabolomics, cognitive testing, fitness testing, and blood flow imaging via MRI (Table 2).

Result

The enrollment goal was 40 participants. 118 individuals were screened for eligibility, and 72.5% of the target enrollment was met; of those participants, nearly 80% completed the 12 week intervention. Of the 23 participants that completed the intervention, mean attendance was 70% for supervised exercise sessions and 81% for weekly behavioral coaching sessions. Figure 1 summarizes screening, enrollment, and procedure completion.

Conclusion

IR may be a modifiable risk factor for dementia. The BFiT pilot trial was designed to test the feasibility of exercise and CRD to reduce IR and improve brain blood flow in middle-aged adults. Reasonable enrollment and completion N were achieved. Future analysis will center on barriers to enrollment and adherence, as well as analysis of the primary and secondary outcome measures.

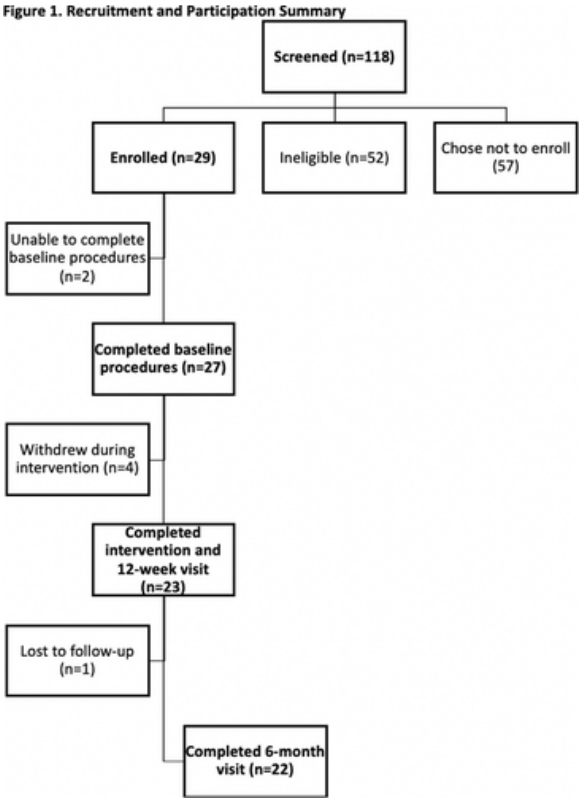

FIGURE 1

TABLE 1. Metabolic Eligibility Criteria

Option 1	**Option 2 (both)**	**Option 3 (any 3)**
Fasting blood glucose of 100 mg/dl or greater	Waist circumference greater than 40 inches for men and 35 inches for women	Fasting triglycerides greater than 150 mg/dl
	Fasting blood glucose of 100 mg/dl or greater	Fasting HDL less than 40 mg/dl for men and 50 mg/dl for women
		Blood pressure greater than 130/85 mm/Hg (systolic and/or diastolic above the cutoff)
		Waist circumference greater than 40 inches for men and 35 inches for women

TABLE 2. Baseline and Post-Intervention Procedures

Procedure	Details
MRI scan	~45 minute protocol completed on a SIGNA PET/MR 3-Tesla scanner with 8-channel head coil. Scans included Arterial Spin Labelling Perfusion, 4D Flow, Volumetric Tl -wieghted MRI, and T2FLAIR .
Questionnaires	Demographics; Nutrition beliefs; 7-day Physical Activity Recall; Food and Activity Questionnaire

Cognitive Testing	California Verbal Learning Test II; Delis Kaplan Executive Function System Test
Exercise Testing	6-minute walk test· Graded maximal exercise test
Clinical visit	Fasting blood and urine sample (12 hour fast); height, weight, anthropomorphic measures using DC-430U Tanita body composition analyzer scale