Title: Activity and Balanced Eating to Reduce Comorbidities and Symptoms of MS

NCT number: NCT03808545

Date: 1/3/2019

Human Subjects Protocol (HSP)

Form Version: February 1, 2017

- You are applying for IRB review of the research described in this form.
- To avoid delay, respond to all items in order and include all required approvals and documents. For more tips, see the UAB IRB website.
- To complete the form, click the underlined areas and type or paste in your text; double-click checkboxes to check/uncheck.
- All responses should be Times New Roman, Bold, and Underlined.
- Submit all materials to AB 470, 701 20th Street South, Birmingham, AL 35294-0104.

Indicate the type of review you are applying for:

☒ Convened (Full) IRB ***-OR-***

☐ Expedited - See the Expedited Category Review Sheet, and indicate the category(ies) here:

☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

1. IRB Protocol Title: Comprehensive Lifestyle Intervention for Reducing Cardiometabolic Risk and Symptom Burden in Adults with Multiple Sclerosis (Layman's title: Activity and Balanced eating to reduce Comorbidities and Symptoms of MS- ABC's of MS): A Pilot Study

2. Investigator and Contact Person

a. Name of Principal Investigator: **Brooks Wingo**

Degree(s)/Title: **PhD/Assist. Professor** BlazerID: **kbcotton**

Dept/Div: **Occupational Therapy** Mailing Address: **385 SHPB** UAB ZIP: **35294-1212**

Phone: **205-934-5982** Fax: **205-934-7787** E-mail: **bcwingo@uab.edu**

b. Name of Contact Person: **Same as above** Title: _____ Phone: _____

E-mail: _____ Fax: _____

INVESTIGATOR ASSURANCE STATEMENT & SIGNATURE

By my signature as Principal Investigator, I acknowledge my responsibilities for this Human Subjects Protocol, including:

- Certifying that I and all key personnel comply with reporting requirements of the UAB Conflict of Interest Review Board;
- Certifying that the information, data, and/or specimens collected for the research will be used, disclosed and maintained in accordance with this protocol and UAB policies;
- Following this protocol without modification unless (a) the IRB has approved changes prior to implementation or (b) it is necessary to eliminate an apparent, immediate hazard to a participant(s);
- Verifying that all key personnel listed on the protocol have completed initial IRB training and will complete continuing IRB training as required;
- Verifying that all personnel are licensed/credentialed for the procedures they will be performing, if applicable;
- Certifying that I and all key personnel have read the *UAB Policy/Procedure to Ensure Prompt Reporting of Unanticipated Problems Involving Risks to Subjects or Others to the IRB, Institutional Officials, and Regulatory Agencies* and understand the procedures for reporting;
- Applying for continuing review of the protocol at least annually unless directed by the IRB to apply more frequently;
- Conducting the protocol as represented here and in compliance with IRB determinations and all applicable local, state, and federal law and regulations; providing the IRB with all information necessary to review the protocol; refraining from protocol activities until receipt of initial and continuing formal IRB approval.

Signature of Investigator: _____ **Date: 1/3/19**

3. Protocol Personnel

Including the PI, list all key personnel (each individual involved in the design and conduct of this protocol). See the Key Personnel Flowchart.

Complete the UAB (3.a.) and non-UAB (3.b) tables, as applicable. Use the checkboxes to show each individual's role, whether the individual has financial interests as defined by the UAB CIRB, and briefly describe the individual's protocol responsibilities and qualifications to perform those responsibilities. **Insert additional rows as needed.**

FDA: For studies involving investigational drugs, list all investigators who will be listed on FDA Form 1572 and include a copy of the 1572. Send the IRB a copy of Form 1572 any time you update the form with the FDA.

a. UAB Personnel (includes UAB affiliates and Children's of Alabama personnel)

Name, Degree, and Dept.	Blazer ID	Role	Financial Interest?*	Protocol Responsibilities and Qualifications (indicate if this person obtains consent)
Name: **Brooks Wingo** Degree: **PhD** Department: **OT**	**Kbcotton**	Co-Principal Investigator	☒No ☐Yes	**Dr. Wingo is a health behaviorist with experience developing, implementing and determining the effectiveness in lifestyle interventions for obesity. As Co-PI of this study, she will oversee protocol development and all aspects of intervention implementation. She will oversee all aspects of data collection, management, analysis, presentation and dissemination. She will serve as direct supervisor for tele-coaches and measurement staff.**
Name: **Robert Motl** Degree: **PhD** Department: **PT**	**robmotl**	Co-Principal Investigator	☒No ☐Yes	**Dr. Motl is a Professor of Physical Therapy whose research focuses on the impact of physical activity on MS symptoms and outcomes. Dr. Motl has experience developing and testing physical activity interventions for MS, and will lend his expertise to the development of the proposed intervention. He will also work closely with Dr. Wingo in training the telecoach to ensure she is knowledgeable about the MS disease process and the unique barriers individuals with MS face when adopting new lifestyle behaviors. He will assist in ensuring recruitment goals are met and will be actively involved with data analysis, interpretation and planning of subsequent funding applications based on the results of this trial.**
Name: **John R. Rinker II** Degree: **MD** Department: **UAB SOM**	**rinkerj**	☒Sub-Investigator ☐Other	☒No ☐Yes	**Dr. Rinker is a neurologist and Associate Professor in the UAB School of Medicine, Department of Neurology and the UAB MS Center. He will provide medical oversight for this project, including review of any adverse events. Additionally, he will provide consultation during protocol development and will be involved with interpretation and dissemination of results, as well**

				as planning for future funding applications.
Name: **Brian Sandroff** Degree: **PhD** Department: **PT**	**sandroff**	☒ Sub-Investigator ☐ Other	☒ No ☐ Yes	**Dr. Sandroff is an Assistant Professor in the Dept. of Physical Therapy who conducts research in cognition and physical activity in people with MS. He will assist with cognitive testing for the data collection.**
Name: **Victoria Wicks** Degree: **BS** Department: **SHP Research Collaborative**	**viwicks**	☐ Sub-Investigator ☒ Other	☒ No ☐ Yes	**Ms. Wicks will fulfill the role of health coach. She will have the responsibility of interacting with participants during the intervention. Responsibilities include working with participants to set weekly goals, review weekly progress and conduct weekly conferences with participants.**
Name: **Thomas DeGrange** Degree: **BS** Department: **SHP Research Collaborative**	**Tdd22**	☐Sub-Investigator ☒Other	☒No ☐Yes	**Mr. DeGrange will assist with participant eligibility screening, scheduling, and all aspects of data collection and management.**
Name: **Kathryn Green** Degree: **BS** Department: **SHP Research Collaborative**	**kwgreen**	☐Sub-Investigator ☒Other	☒No ☐Yes	**Ms. Green will coordinate all aspects of the study. She will assist with participant eligibility screening, protocol development and implementation, data collection, consenting, and scheduling.**
Name: **Justin McCroskey** Degree: **MS** Department: **PT**	**jdm0039**	☐Sub-Investigator ☒Other	☒No ☐Yes	**Mr. McCroskey will manage the two websites.**
Name: **Katie Cederberg** Degree: **MS** Department: **PT**	**kcederb**	☐Sub-Investigator ☒Other	☒No ☐Yes	**Ms. Cederberg will assist with baseline and follow up testing for the data collection.**
Name: **Elizabeth Sikes** Degree: **MS** Department: **PT**	**ems0801**	☐Sub-Investigator ☒Other	☒No ☐Yes	**Ms. Sikes will assist with baseline and follow up testing for the data collection.**
Name: **Brenda Jeng** Degree: **MS** Department: **PT**	**bjeng**	☐Sub-Investigator ☒Other	☒No ☐Yes	**Ms. Jeng will assist with baseline and follow up testing for the data collection.**
Name: **Jessica Baird** Degree: **PhD** Department: **PT**	**jfbaird**	☐Sub-Investigator ☒Other	☒No ☐Yes	**Dr. Baird will assist with baseline and follow up testing for the data collection.**
Name: **Catherine Jones** Degree: **MS** Department: **PT**	**cdj88**	☐Sub-Investigator ☒Other	☒No ☐Yes	**Ms. Jones will assist with baseline and follow up testing for the data collection.**
Name: **Stephanie Silveira** Degree: **PhD** Department: **PT**	**slsilve**	☐Sub-Investigator ☒Other	☒No ☐Yes	**Dr. Silveira will assist with baseline and follow up testing for the data collection.**

b. Non-UAB Personnel Relying on UAB IRB - If you are requesting that the UAB IRB serve as the IRB of record for anyone not affiliated with UAB, list these individuals below.

Name and Degree	From Institution with or without own IRB?	Financial Interest?*	Protocol Responsibilities and Qualifications (indicate if this person obtains consent)

Name: **Lori Theriot** Institution: **Lakeshore Foundation**	☐Has own IRB but requests that UAB IRB serve as IRB of record?***-OR-*** ☒Does not have own IRB and needs to rely on UAB IRB. Already on file with UAB IRB	☒ No ☐ Yes	**Coordinates study recruitment, collect informed consent documentation, schedule data collection.**
Name: **Alex Yates, M.A**. Institution: **Lakeshore Foundation** Blazer ID: Afrench	☐Has own IRB but requests that UAB IRB serve as IRB of record?***-OR-*** ☒Does not have own IRB and needs to rely on UAB IRB.	☒ No ☐ Yes	**Alex will assist with participant eligibility screening, scheduling, and all aspects of data collection and management.**

***Financial Interest** – for each individual listed above, answer **Yes** or **No** as to whether the individual or an immediate family member has any of the following:

- An ownership interest, stock options, or other equity interest related to the investigator's institutional responsibilities of any value.
- Compensation greater than $5,000 in the previous two years when aggregated for the immediate family
- Proprietary interest including, but not limited to, a patent, trademark, copyright, or licensing agreement.
- Board of executive relationship, regardless of compensation.
- Any other Financial Interest as defined by the UAB CIRB.

UAB Personnel: If the individual or his/her spouse or dependent child has a Financial Interest, a disclosure has to be made to the UAB CIRB. A completed CIRB evaluation has to be available before the IRB can complete its review.

Non-UAB Personnel: If the individual has a Financial Interest, ***include a copy of the report from his/her own institution's conflict of interest review with this submission to the UAB IRB.***

c. Do the investigators listed above include any students using this research for their thesis or dissertation?

☒ No, continue with Item 3.d.
☐ Yes, complete the following

Student Name	Thesis/Dissertation Title

d. Is the principal investigator a student, fellow, or resident? ☐Yes ☒No

If Yes, complete items below and obtain signature of faculty advisor or supervisor:

Supervisor's Name: _____
Degree(s) / Job Title: _____
Additional Qualifications pertinent to the protocol: _____
Telephone: _____
E-Mail: _____
Signature: _____

e. Describe the principal investigator's activities related to this protocol and provisions made by the PI to devote sufficient time to conduct the protocol: **Dr. Wingo is a full-time, tenure-track Assistant Professor who dedicates nearly 100% of UAB time on research. Dr. Motl is a full-time tenured Professor who dedicates nearly 100% of UAB time on research. Both PI's have protected time to supervise all research activities.**

f. Is medical supervision required for this research? ☐Yes ☒No

If Yes, who will provide the medical supervision?

☐ PI will provide ***-OR-***
☐ Other:
Name: _____ Telephone: _____
If other than PI, obtain signature of person providing medical supervision:
Signature _____

g. Describe your process for ensuring all key personnel are adequately informed about the protocol and their research-related duties and functions: **All staff involved with research in our laboratories (e.g., the acquisition of data from human subjects or delivery of interventions) undergo extensive training regarding principles of human subjects research; maintenance of confidentiality; the**

importance of using research identification numbers rather than subject names when collecting data; and minimizing risks. This training includes one-on-one sessions and group sessions with the Co-PI's. We further engage in a system of supervised training wherein staff members practice on one another with oversight and feedback from the Co-PI's. All staff have training and experience with human subjects research and have all taken and passed the IRB and CITI certification courses.

4. Funding

Is this protocol funded? ☒Yes ☐No

If No, specify that costs of the protocol will be covered by funds from the UAB department or other source named: _____

If Yes, attach one copy of completed application or request for funding sent to sponsor, and complete a-d.

a. Title of Grant, Contract, or Agreement: **Comprehensive Lifestyle Intervention for Reducing Cardiometabolic Risk and Symptom Burden in Adults with Multiple Sclerosis**

b. UAB PI of Grant, Contract, or Agreement: **Brooks Wingo and Robert Motl**

c. Office of Sponsored Programs (OSP) Assigned Number: **NA**
(If not yet available, enter "Pending" and provide upon receipt from OSP.)

d. Sponsor, Funding Route:
(Check and describe all that apply)
(If subaward, list both the funding source and the institution receiving the direct award)

☐ Gov't Agency or Agencies—Agency name(s): _____
- ☐ Department of Defense (DoD): Identify DoD component: _____
- ☐ Department of Energy (DOE)
- ☐ Department of Justice (DOJ)
- ☐ Department of Education

☐ NIH Cooperative Group Trial - Group name: _____
☐ Private Nonprofit (e.g., Foundation) - Name:
☐ Industry, investigator-initiated - Name: _____
Describe the funding arrangement: _____
NOTE: The UAB IRB typically only reviews industry-sponsored protocols that are investigator initiated or when the protocol qualifies for expedited review or involves gene therapy.
☒ UAB Departmental/Division Funds—Specify: **UAB NORC Pilot/Feasibility Study**

5. Locations Involved

a. Indicate all performance sites that will provide space, services, or facilities for the conduct of this protocol.

☐ UAB Hospital
☐ UAB Hospital - Highlands
☐ The Kirklin Clinic of UAB Hospital
☐ The Kirklin Clinic at Acton Road
☐ UAB Callahan Eye Hospital
☐ UAB Clinical Research Unit
☐ Children's of Alabama
☐ Birmingham Veterans Affairs Medical Center
☐ Jefferson County Department of Health
☒ Other (i.e., any performance site not listed above, including those covered by subawards related to this protocol) - Describe: **UAB School of Health Professions Building, Webb Nutrition Sciences Building, and UAB/Lakeshore Collaborative Research Facility.**

NOTE: Documentation of IRB approvals from sites receiving subawards must be received by the UAB OIRB before funding will be released for that subaward.

b. Describe the space, service, or facilities available for the conduct of the research in the performance sites listed in Item 5.a (For research on UAB campus, include building names):
All baseline and follow-up measures for this study will be conducted at UAB/Lakeshore Collaborative Research Facility. Health coaches will be located at Lakeshore foundation. Serum storage and analysis will be conducted in the NORC laboratory in the Webb Nutrition Sciences Building.

c. Is this protocol a clinical trial requiring clinical services at one of the performance sites listed in Item 5.a above? ☐Yes ☒No
If Yes, will any of the services be billed to either participants/their insurance or to the study account through the Hospital Billing Office (PFS) or the HSF Billing Office (MSO)? ☐Yes ☒No

If Yes, submit a Full Fiscal Approval Process (FAP)-designated unit submission to s complete a FAP submission and send to fap@uab.edu. For more on the UAB FAP requirements, go to FAP - SiteMinder Processes.

d. Is this a field study? ☐Yes ☒No
If Yes, describe the community and include information about how the community will be involved in the design, implementation and analysis of the research. This would include focus groups, training local facilitators/community health advisors: _____

e. Has this protocol been rejected or disapproved by another review board (another IRB, similar review board, or departmental review committee(s)) that authorizes the use of its patient populations? ☐Yes ☒No
If Yes, provide name(s) of the review board(s) and reason(s) not approved: _____
Attach copies of the disapprovals.
NOTE: If this protocol is subsequently rejected or disapproved by another review board, promptly notify UAB IRB.

f. Will the protocol be conducted at or recruit participants from the Birmingham Veterans Affairs Medical Center (BVAMC)? ☐Yes ☒No
If Yes, describe the involvement of the BVAMC: _____
Attach the VA IRB approval and VA IRB-stamped consent form(s), if applicable.
NOTE: See the BVAMC section of the IRB Guidebook for more information.

g. Will the protocol be conducted at or recruit participants from the Jefferson County Department of Health (JCDH)? ☐Yes ☒No
If Yes, describe the involvement of the JCDH and list the JCDH clinics being used: _____
Attach the JCDH Research Review Panel approval, if applicable.
NOTE: Human subjects research conducted at certain JCDH clinics requires review by the JCDH Research Review Panel. See the JCDH section of the IRB Guidebook for more information.

6. Clinical Trial

Does this protocol meet the following definition of a clinical trial? ☒Yes ☐No
**A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. For more information, see the full definition of clinical trial here.*
If Yes, you will need to fulfill the following requirements (regardless of funding):

a. All key personnel must complete the Good Clinical Practices (GCP) training. For information on this requirement, visit the IRB website here.

b. This protocol must be registered on ClinicalTrials.gov. Provide the National Clinical Trial (NCT) identifier number: **Pending.**
If you have any questions regarding registering a study on ClinicalTrials.gov, email the UAB Center for Clinical and Translational Science at ccts@uab.edu.

7. Multi-Site Studies

a. Is this a multi-site study with the UAB investigator as the lead investigator? ☐Yes ☒No

b. Is this a multi-site study with UAB as a coordinating site? ☐Yes ☒No

c. If Yes to a or b, describe the management of information obtained in multi-site research that might be relevant to the protection of participants. Include, at a minimum, how the following items are managed:

- IRB approvals from other sites
- Unanticipated problems involving risks to participants or others. (For example, if there is an unanticipated problem involving risks to participants or others, which site is responsible for reporting it?)
- Interim results
- Protocol modifications

8. Drugs

Will any drugs or supplements be *used or studied* in this protocol? ☐Yes ☒No
If Yes, attach the completed Drug Review Sheet.

9. Devices

a. Will any devices be *studied* in this protocol? ☐Yes ☒No

b. Will any *not FDA-approved* devices be *used or studied* in this protocol? ☐Yes ☒No
If Yes to a or b, attach the completed Device Review Sheet.

10. Special Approvals

a. Does this protocol involve the use of radioisotopes? ☒Yes ☐No
If Yes, attach documentation of approval from the Radiation Safety Division. **See attached.**

b. Does this protocol include patients with contagious infections (e.g., mumps, measles, chickenpox, TB, meningitis)? ☐Yes ☒No
If Yes, attach documentation of approval from the Infection Control Committee of the appropriate facilities.

c. Does this protocol involve obtaining remnant biopsy or surgical material from the Department of Pathology or any other source? ☐Yes ☒No
If Yes, attach documentation of approval from the entity or individual providing the materials (e.g., the UAB Division of Anatomic Pathology Release of Pathologic Materials).

d. Does this protocol require obtaining any remnant clinical laboratory specimens, body fluids, or microbiological isolates from the Department of Pathology or any other source? ☐Yes ☒No
If Yes, attach documentation of approval from the entity or individual providing the materials (e.g., the UAB Division of Laboratory Medicine Release of Pathologic Materials).

e. Does this protocol use stored (existing) specimens from a repository? ☐Yes ☒No
If Yes, attach documentation of approval for use of specimens, and describe how existing specimens are labeled: _____

11. Use of Specimens

Does this protocol involve the collection of specimens? ☒Yes ☐No

If Yes, complete 11.a-11.h.
If No, skip to Item 12.

a. How will specimens be obtained, processed, distributed, and stored? **A fasting blood draw (7 mL) will be collected to assess fasting glucose, insulin, and a lipid panel. Serum will be stored in a -80 freezer in the Webb Nutrition Sciences Building.**

b. How will specimens be labeled (e.g., unique identifier, medical record number, Social Security number, name, date of birth)? **Unique identifier, date, and assessment point will be the only information included on the label.**

c. How will clinical data associated with the specimens be collected and stored? **Clinical data will be stored on a password-protected computer on the UAB server.**

d. What participant-identifying information will be collected and linked to the specimens? **Unique identifier and date of collection will be the only participant-identifying information.**

e. What steps will be taken to maximize the confidentiality of linked identifiers? For example, procedures could include using a password-protected computer database to link identifiers, with limited personnel knowledgeable of the password, or coded identifiers released without the ability to link to clinical data (also called "stripped" or "anonymized" specimens). **Documents connecting the participant with their associated identifier will be locked in a cabinet in the research department at Lakeshore Foundation and only those individuals on this protocol will have access to the files. Any identifiable information housed electronically will be password-protected.**

f. Is genetic testing planned as part of this protocol? ☐Yes ☒No
If Yes, describe the planned genetic testing here. _____

g. Will specimens be stored for future use? ☐Yes ☒No
If Yes, indicate whether they will be used for the disease under study in this protocol or research on other diseases. _____

h. Will specimens be shared with other investigators in the future? ☐Yes ☒No
If Yes, answer i. and ii.
i. What identifiers, clinical information and demographic information will be shared; or will the specimens be stripped of identifiers (i.e., anonymized)? _____
ii. Outline your procedure for assuring IRB approval for release and use prior to release of specimens.

_____

NOTE: Investigators who receive and/or use these specimens must document approval from the appropriate IRB(s) before the specimens may be released.

12. Gene Therapy

Does this protocol involve gene therapy or administering recombinant materials to humans? ☐Yes ☒No
If Yes, submit the Gene Therapy Project Review Panel Report ***-OR-*** the Protocol Oversight Review Form For Clinical Vaccine Trials, as applicable.

13. HIPAA Privacy and Security

Will the PI or others obtain, review, or make other use of participants' "protected health information" (i.e., information, whether oral or recorded in any form or medium that (a) is created or received by a health care provider and (b) relates to past, present, or future physical or mental health or condition of an individual; or provision of health care; or payment for provision of heath care)? ☒Yes ☐No
If Yes, complete Items 13.a-13.f.
If No, skip to 14.

a. Will the data/information be stored or managed electronically (on a computer)?
☒Yes ☐No

b. Is the principal investigator requesting that the UAB IRB waive patient HIPAA authorization from another institution or entity (e.g., insurance company, collaborating institution)? ☐Yes ☒No
If Yes, attach copies of the privacy notices from each institution/entity, and provide the name of each institution/entity: _____

c. Indicate which of the entities would provide health information for this protocol, maintain health information as it was collected for this protocol, and/or store health information after it has been collected for this protocol.
☐ UAB Hospital or UAB Hospital - Highlands
☐ The Kirklin Clinic of UAB Hospital or Acton Road (and/or associated clinics)
☐ UAB Callahan Eye Hospital
☐ Children's of Alabama
☐ Jefferson County Department of Health
☐ School of Dentistry
☒ School of Health Professions
☐ School of Medicine
☐ School of Nursing
☐ School of Optometry
☐ University of Alabama Health Services Foundation
☐ UAB Health Centers
☐ Viva Health
☐ Ophthalmology Services Foundation
☐ Valley Foundation
☐ Medical West - UAB Health System Affiliate
☐ None - **If None, skip to Item 14.**

d. Indicate any information systems that will be the sources of information used for the protocol.
☐ A system maintained centrally by UAB Health System (these include the following: HealthQuest for registration, billing, and patient administration; PowerInsight (clinical data warehouse); Cerner IMPACT for PowerNotes for meds, Lab, Radiology, UED, Surgery

NOTE: If a researcher needs information in a specified format or a specified time, the researcher must confirm with the unit who can supply the information/service that the request can be met before writing the information/service into the research protocol. In addition, the researcher must be aware that these services may have a cost attached that should be considered in the research budget.

To request access to clinical systems for research purposes, visit https://www.oneuabmedicine.org/web/hsis/technical-support, click "Accounts Request" and complete the form indicating access for research purposed.

☐ Another system on a UAB server - Describe: _____

e. Indicate which of the listed identifiers will be accessed, associated and/or linked with the protected health information (PHI) used for this protocol.
☒ Names
☒ Geographic subdivisions smaller than a state
☒ Elements of dates (except year) related to an individual
☒ Telephone numbers
☒ Fax numbers
☒ Email addresses
☒ Social security numbers
☐ Medical record numbers

☐ Health plan beneficiary numbers
☐ Account numbers
☐ Certificate/license numbers
☐ Vehicle identifiers and serial numbers
☐ Device identifiers and serial numbers
☐ Biometric identifiers
☐ Web universal resource locators (URLs)
☐ Internet protocol address numbers
☒ Full-face photographic images
☐ Any other unique identifying number - Describe: _____
NOTE: Codes are not identifying as long as the researcher cannot link the data to an individual
☐ None - **If None, skip to Item 14.**

f. Choose one plan to describe your use of the personal health information:

☐ The data collected meet the specifications for a "limited data set" (LDS)
-If the LDS will leave the covered entity or will be received from another covered entity you will need a Data Use Agreement

☒ Research staff will obtain authorization from each participant to use the information
-Include the HIPAA Authorization form, complete except for participant name and IRB protocol number, as the final page of the consent form

☐ PI requests waiver of authorization to use the information
-Attach Waiver of Authorization and Informed Consent form

PROPOSED RESEARCH

- The IRB will not accept grant applications and/or sponsor's protocols in lieu of the items as outlined below.
- Do not separate responses from items. Instead, insert your response to each item below the item, keeping the information in the order of this form.

14. Purpose - in nontechnical, lay language

a. Summarize the purpose and objectives of this protocol in one short paragraph.

Multiple sclerosis (MS) is the leading cause of irreversible neurological disability among young women and the second leading cause of disability among young men in the U.S. Cardiometabolic risk factors including obesity and hyperlipidemia are common among people with MS, and these risk factors are associated with severity and frequency of MS relapses and disease progression. People with MS often experience symptoms of pain, fatigue, and depression, which make adhering to a healthy lifestyle difficult, as evidenced by the high rates of unhealthy behaviors including poor diet and physical inactivity among this group. Physical activity has reduced symptoms of MS and improved metabolic risk profiles, but little research has focused on the role of a dietary intervention combined with physical activity in this group. Therefore, the purpose of this study is to test the efficacy of a combined diet and physical activity intervention for reducing cardiometabolic risks and MS symptoms when compared to a physical activity intervention alone.

b. Describe how outcomes will be measured for this protocol.

The primary outcome of this study is cardiometabolic risk, as measured by total cholesterol, HDL-C, LDL-C, triglycerides, insulin and glucose, as well as anthropometric measures and body composition measured by DXA. Established clinical values for risk level of each of these variables will be used to define risk.

Secondary outcomes include MS Symptoms of fatigue, depression, anxiety, and pain measured by self-report.

We will collect feasibility measures related to the recruitment, implementation, adherence, and retention aspects of the study.

15. Background - in nontechnical, lay language

Summarize in 2-3 paragraphs past experimental and/or clinical findings leading to the design of this protocol. Include any relevant past or current research by the PI. For drug and device studies, summarize the previous results (i.e., Phase I/II or III studies).

Multiple Sclerosis is a chronic autoimmune disease of the central nervous system, characterized by demylenation of nerve cells and systemic inflammation. Symptoms of MS can include pain, fatigue, depression, loss of mobility, and cognitive decline. People with MS are known to have higher rates of unhealthy lifestyle behaviors including physical inactivity and poor diet than the general population, and these rates are associated with increased symptom burden. Multiple observational trials have reported that poor diet quality is associated with increased pain, fatigue and depression, as well as a higher rate of disease relapse. Adults with MS also have high rates of cardiometabolic risks including obesity and hyperlipidemia, which may be due, in part, to unhealthy lifestyle behaviors; and the presence of cardiometabolic risks is associated with poorer MS outcomes and higher hospitalization rates. A substantial research base has established the relationship between physical inactivity and symptom burden in MS, and intervention trials have established physical activity as an effective way to reduce MS symptoms and reduce cardiometabolic risk among this group; however, very little research has focused on dietary interventions. In the general population, diet and exercise are well established to have an additive effect, with interventions that focus on changing both diet and exercise yielding better results than those that focus only on physical activity. Given the disproportionately high rates of unhealthy behavior patterns among adults with MS, we hypothesize that a comprehensive approach that includes both diet and activity will have a greater impact on both symptom burden and cardiometabolic risk than the established interventions that only address physical activity.

We have developed and tested a behavioral intervention delivered through an Internet website based on Social Cognitive Theory(SCT)(7) for changing physical activity in MS(8,9). The first randomized control trial(RCT) included a dedicated Internet website and indicated that the intervention group self-reported a large increase in physical activity over a three-month period(10). Such results were replicated in a follow-up RCT using objectively-measured physical activity(11). The next RCT refined the dedicated Internet website and added one-on-one video chat sessions with behavioral coaches, and the modifications resulted in an increase in physical activity that was sustained for three months after the intervention ended(12). One recent RCT included the Internet website and one-one-one video coaching and demonstrated improvements in MVPA and symptoms of fatigue, depression, and anxiety over a six-month period(13).

We recently completed a 6-month, phase-II, randomized controlled trial(RCT) that examined the efficacy of a newly developed Internet website that delivered a SCT-based behavioral intervention using e-learning approaches for increasing physical activity and improving symptoms, walking impairment, and neurological disability(14); this program is called Behavioral Intervention for Physical Activity in Multiple Sclerosis (BIPAMS). Participants with MS(N=47) were randomly assigned into behavioral intervention(n=23) or waitlist control(n=24) conditions. Outcome assessments were administered before and after the 6-month study period. There were positive intervention effects on self-reported and objectively-measured moderate-to-vigorous physical activity(MVPA), as well as on fatigue, depression and anxiety symptoms, walking mobility, and disability status. Such outcomes provide proof-of-principle evidence for a large, phase-III RCT testing the effectiveness of this approach for improving physical activity and secondary outcomes as well as examining mediators based on SCT(e.g., self-efficacy or goal setting). These data supported an ongoing, phase-III, randomized controlled trial(RCT) that examines the effectiveness of a behavioral intervention based on social cognitive theory(SCT) and delivered through the Internet using e-learning approaches for increasing physical activity and secondary outcomes (e.g., symptoms) in a large sample of people with multiple sclerosis (MS) residing throughout the United States (15).

The current BIPAMS program will be delivered over a 16-week and will integrate a dietary component based on the DASH dietary pattern, which focuses on increasing intake of fruits, vegetables, and lean proteins while reducing saturated fat intake, into the BIPAMS program.

1. **Motl RW, Dlugonski D, Wójcicki TR, McAuley E, Mohr D. Internet intervention for increasing physical activity in persons with multiple sclerosis. *Mult Scler.* 2011;17:116-128.**
2. **Dlugonski D, Motl RW, McAuley E. Increasing physical activity in multiple sclerosis: replicating Internet intervention effects using objective and self-report outcomes. *J Rehabil Res Dev.* 2011;48:1129-1136.**
3. **Dlugonski D, Motl RW, Mohr DC, Sandroff BM. Internet-delivered behavioral intervention to increase physical activity in persons with multiple sclerosis: Sustainability and secondary outcomes. *Psychol Health Med.* 2012;17:636-651.**
4. **Motl RW, Dlugonski D. Increasing physical activity in multiple sclerosis using a behavioral intervention. *Behav Med.* 2011;37:125-131.**
5. **Pilutti LA, Dlugonski D, Sandroff BM, Klaren R, Motl RW. Randomized controlled trial of a behavioral intervention targeting symptoms and physical activity in mutliple sclerosis. *Mult Scler.* 2014;20:594-601.**
6. **Sandroff BM, Klaren RE, Pilutti LA, Dlugonski D, Benedict RHB, Motl RW. Randomized controlled trial of physical activity, cognition, and walking in multiple sclerosis. *J Neurol.* 2014;26:363-372.**
7. **Bandura A. Health promotion by social cognitive means. Health Educ Behav. 2004;31:143-164.**
8. **Ellis T, Motl RW. Physical activity behavior change in persons with neurological disorders : Overview and examples from Parkinson disease and multiple sclerosis. J Neurol Phys Ther. 2013;37:85-90.**
9. **Motl RW. Lifestyle physical activity in persons with multiple sclerosis: The new kid on the MS block. Mult Scler. 2014;20:1025-1029.**
10. **Motl RW, Dlugonski D, Wójcicki TR, McAuley E, Mohr D. Internet intervention for increasing physical activity in persons with multiple sclerosis. Mult Scler. 2011;17:116-128.**
11. **Dlugonski D, Motl RW, McAuley E. Increasing physical activity in multiple sclerosis: replicating Internet intervention effects using objective and self-report outcomes. J Rehabil Res Dev. 2011;48:1129-1136.**
12. **Dlugonski D, Motl RW, Mohr DC, Sandroff BM. Internet-delivered behavioral intervention to increase physical activity in persons with multiple sclerosis: Sustainability and secondary outcomes. Psychol Health Med. 2012;17:636-651.**
13. **Pilutti LA, Dlugonski D, Sandroff BM, Klaren R, Motl RW. Randomized controlled trial of a behavioral intervention targeting symptoms and physical activity in mutliple sclerosis. Mult Scler. 2014:20;594-601.**

Motl RW, Hubbard EA, Bollaert RE, Adamson BC, Kinnett-Hopkins D, Balto JM, Sommer SK, Pilutti LA, McAuley E. Randomized controlled trial of an e-learning designed behavioral intervention for increasing physical activity behavior in multiple sclerosis. Mult Scler J Exp Transl Clin 2017;3:2055217317734886. Motl, R.W., Sandroff, B.M., Wingo, B.C., McCroskey, J., Pilutti, L.A., Cutter, G.R., Bollaert, R.E., McAuley, E. (2018). Phase-III, Randomized Controlled Trial of the Behavioral Intervention for increasing Physical Activity in Multiple Sclerosis: Project BIPAMS. *Contemporary Clinical Trials*. In press.

16. Participants (Screening and Selection)

a. How many participants are to be enrolled at UAB (if other sites relying on UAB IRB, list the number for each site)? **24**

If multi-site study, total number at all sites/institutions: _____

b. Describe the characteristics of anticipated or planned participants (if multiple groups, repeat list for each group).

Sex: **18 Female & 6 Male based on 3:1 ratio of women: men, as is common in MS.**

Race/Ethnicity: **80% Caucasian/20% African-American is anticipated, though we will recruit without any discrimination towards race or ethnicity.**
Age: **18-65 years.**
Health status: **Diagnosis of relapsing-remitting MS; on disease modifying treatment for 6 months; no relapse within 30 days**

c. From what population(s) will the participants be derived? **We will recruit participants through flyers posted at Lakeshore Foundation, UAB Neurology clinics, and the UAB MS Center.**

Describe your ability to obtain access to the proposed population that will allow recruitment of the necessary number of participants: **Drs. Wingo and Motl are actively involved with the UAB/Lakeshore Research Collaboration and have access to study participants from this Lakeshore Foundation. Lakeshore has over 5000 active and inactive members with disabilities. Dr. Rinker is a physician at the UAB Neurology clinics and MS center and can recruit from the patient population in these clinics.**

d. Describe the inclusion/exclusion criteria:

Inclusion criteria:

1. **Relapsing-Remitting MS**
2. **On disease modifying treatment for 6 months**
3. **No relapse within the previous 30 days**
4. **BMI 25-55 kg/m^2**
5. **Self-identify as not currently meeting recommendations for healthy diet and physical activity, , as defined by an answer of "no" to the question, "Are you currently following any specific diet meant to improve your health or reduce disease?", and a score of less than 14 on the Health Contribution Score from the Godin Leisure-Time Exercise Questionnaire)**
6. **Ambulatory with or without assistance**
7. **Reliable access to the internet via computer or smartphone**
8. **Responsible for their personal food preparation or have input into the food prepared for them**
9. **Low cognitive functioning, defined as a score of less than 31 on the Telephone Interview for Cognitive Status assessment**

Exclusion criteria

1. **Physician does not approve participation**
2. **Use of the following diabetes medications: Acetohexamide, Chlorpropamide (Diabinese), Tolbutamide (Orinase, Tol-Tab), Tolazamide (Tolinase), Glipizide (Glucotrol, Glucotrol XL, Metaglip), Glyburide (Micronase, DiaBeta, Glynase, Glucovance), Glimepiride (Amaryl), Humalog or lispro, Novolog or aspart, Apidra or glulisine, Regular (R) humulin or novolin, Velosulin (for use in the insulin pump), NPH (N), Lente (L), Ultralente (U), Lantus, Levemir or detemir, Humulin 70/30, Novolin 70/30, Novolog 70/30, Humulin 50/50, or Humalog mix 75/25**
3. **Already on a specific diet meant to improve health**
4. **Heart attack, stroke, or heart bypass surgery less than 6 months ago**
5. **Pulmonary disease, cardiovascular disease or renal failure less than 6 months ago**
6. **Smoking**
7. **Cancer, HIV or liver/kidney disease**
8. **Inability to travel to Lakeshore for testing**

e. If participants will comprise more than one group or stratification, describe each group (e.g., treatment/intervention, placebo, controls, sham treatment) **and** provide the number of participants anticipated in each group. **The research will be conducted using a parallel group, RCT design. Twenty-four adults with relapsing-remitting MS will be randomized into either the BIPAMS condition or BIPAMS+Diet condition using a 1:1 allocation (12 participants in each group).**

f. Indicate which, if any, of the special populations listed below will be involved in the protocol. Include the Special Populations Review Form (SPRF) if indicated.

☐ Pregnant Women: Attach SPRF—Pregnant Women, Fetuses, Neonates/Nonviable Neonates
☐ Fetuses: Attach SPRF—Pregnant Women, Fetuses, Neonates/Nonviable Neonates
☐ Neonates/Nonviable Neonates: SPRF—Pregnant Women, Fetuses, Neonates/Nonviable Neonates
☐ Prisoners: Attach SPRF—Prisoners
☐ Minors (<18 years old): Attach SPRF—Minors
☒ Employees or students at institution where research conducted
☐ Persons who are temporarily decisionally impaired
☐ Persons who are permanently decisionally impaired
☐ Non-English Speakers

For each box checked, describe why the group is included **and** the additional protections provided to protect the rights and welfare of these participants who are vulnerable to coercion: **We are not directly recruiting persons who are employees or students, but such persons could by chance learn about the research and volunteer. We do not believe that this requires extra protection, as we will not be in a position of undue influence on such participants.**

g. List any persons other than those directly involved in the protocol who will be at risk. If none, enter "None": **None**

h. Describe the recruitment process (e.g., medical record review, referrals, letter of invitation, existing patients) that will be used to seek potential participants (e.g., individuals, records, specimens). Research recruitment by non-treating physicians/staff may require completion of Partial Waiver of Authorization for Recruitment/Screening.

Flyers will be posted in common areas around Lakeshore Foundation, UAB Neurology Clinic, and MS Center (see attached for flyer). The same flyers will be included in newsletters emailed and/or mailed to Lakeshore Foundation members. Lakeshore Foundation also maintains a database of members who are interested in participating in research and this database will be used for targeted recruitment. Lakeshore members are also aware of ongoing research and are welcome to visit the research office and lab at any time. Members who present to the research office and inquire about research opportunities will be made aware of the study by reading them the phone script in person.

We will also recruit participants with MS through the National MS Society webpage, support groups, and events; MS chapters; NARCOMS; and word of mouth. This will occur by posting flyers on the respective social media/webpages, sending via email to support group representatives for posting/distributing, or having staff attend events to distribute flyers.

Targeted mailings from databases (Lakeshore, NARCOMS) will be conducted by sending the attached letter and including a flyer.

i. If you will use recruitment materials (e.g., advertisements, flyers, letters) to reach potential participants, attach a copy of each item. If not, identify the source (e.g., IRB Protocol Number for approved databases) from which you will recruit participants. **The general advertisement (a flyer) for the study is attached. This flyer includes the relevant information that would be included in all recruitment materials. The actual format and display might vary based on the source of advertisement, but the contents will not vary (i.e. if flyer is emailed or posted to social media it may require different font, colors or formatting, but content will not change from what has been approved).**

j. Describe the screening process/procedures for potential participants. **Participants will call the phone number listed on the study flyer or come by the research office to inquire about research possibilities. Study staff will give potential participants additional information about the study**

using attached script. If the person is interested in participating, the staff will ask a series of questions to assess initial eligibility. This will include age, self-reports of height and weight, disease-modifying medication use, levels of activity, dietary habits, as well as primary mode of ambulation and internet access at home. If potential participant meets initial eligibility criteria, he/she will be scheduled for an appointment to meet study staff at Lakeshore Foundation and study staff will also ask participants to obtain a signed physician release form prior to their scheduled visit. During the screening visit at Lakeshore, study staff will review consent documents and have participants sign these.

See attached for Partial Waiver of Authorization Recruitment/Screening.

17. Protocol Procedures, Methods, and Duration - in nontechnical, lay language

a. Describe the procedures for all aspects of your protocol. Tell us what you are doing.

I. Once a potential participant has been deemed eligible, the study staff will discuss obtaining physician permission for the participant. The physician of choice should be the participant's neurologist, or, in the case that a primary care physician has been seen more recently, and therefore can speak to the participant's more recent health status, then a primary care physician can be the physician of choice. Physician Permission can be obtained a number of ways:

- **a. The participant may wish to take the "Physician Release" form directly to their physician to have him or her sign and then fax the form back to the study staff (fax number indicated on the "Physician Release" form).**
- **b. The participant may choose to sign the "Permission to Contact Physician" form allowing the study staff to obtain the "Physician Release" form. In this case, the participant may sign the "Permission to Contact Physician" form (if screening in person), may choose to come by the Lakeshore Foundation to sign the form, or may choose to have the form mailed to his or her home address. If the latter is chosen, then the staff can mail the form with a stamped, return addressed envelope to the participant's home. After receiving the "Permission to Contact Physician" form, study staff can then fax the "Physician Release" form directly to the indicated physician for his or her completion.**
- **c. The participant cannot participate until his or her doctor has signed off on the Physician Release. In the case that a physician does not indicate that this study is a good fit for the participant, study staff will call the participant and let them know of this and indicate that the participant is not eligible for the study.**

II. BASELINE DATA COLLECTION

At the baseline visit, study staff will review the consent forms with the participant and the participant will sign them. After signing the consent forms, all baseline measures will be collected. Baseline measures include:

1. **Anthropometric measures: Waist circumference will be measured twice al at the level of the umbilicus after normal expiration, with participants standing. If the two values differ by >1 cm, a third measurement will be taken and the results of the two or three trials averaged. Height will be measured with participants standing against the wall. Weight will be assessed using a digital scale. BMI will be calculated using the formula weight/height^2 (kg/m^2). Blood pressure will be obtained and participants will also be asked to inform study staff of all current medications and supplements being taken.**
2. **Labs: Fasting insulin, glucose, hs-CRP and a lipid panel will be collected on all participants. Two (2) vials of blood will be drawn (7 mL or 1.4 teaspoons) via venipuncture.**
3. **DXA: Total and regional body composition will be measured on a Lunar iDXA with enCORE software version 13.6 (GE Healthcare, Chicago, IL). Participants will undergo a total body scan requiring about 20 minutes, while lying on their back on a padded table with metal objects removed. The scan provides estimates of soft tissue attenuation ratios, fat and lean tissue mass, and bone mineral density. Individuals who are too large to scan in a single scan will be scanned twice (one scan for the left half of body, one for the right). The software is able to merge the two scans to assess total body composition. If a female participant is of child-**

bearing age, a pregnancy test will be required to confirm that the participant is not pregnant before undergoing the DXA scan. This is for the safety of the participant.

4. **Accelerometer: Participants will wear an Actigraph accelerometer Version 6.13.3 for 14 days. We will classify activity counts into sedentary behavior, light, moderate and vigorous activity. We will record total minutes of activity in each category and total MET-min for the week.**
5. **Timed 25-Foot Walk (T25-FW): The T25-FW is a quantitative mobility and leg function performance test based on a timed 25-walk. The participant is directed to one end of a clearly marked 25-foot course and is instructed to walk 25 feet as quickly as possible, but safely. The time is calculated from the initiation of the instruction to start and ends when the participant has reached the 25-foot mark. The task is immediately administered again by having the participant walk back the same distance. Participants may use assistive devices when doing this task.**
6. **9-Hole Peg Test (9-HPT): The 9-HPT is a brief, standardized, quantitative test of upper extremity function. Both the dominant and non-dominant hands are tested twice. The participant is seated at a table with a small, shallow container holding nine pegs and a wood or plastic block containing nine empty holes. On a start command when a stopwatch is started, the participant picks up the nine pegs one at a time as quickly as possible, puts them in the nine holes, and, once they are in the holes, removes them again as quickly as possible one at a time, replacing them into the shallow container. The total time to complete the task is recorded. Two consecutive trials with the dominant hand are immediately followed by two consecutive trials with the non-dominant hand.**
7. **Symbol Digit Modalities Test (SDMT): The SDMT is a five minute assessment that quickly screens the participant for any kind of cerebral dysfunction using a simple substitution task. When undertaking the SDMT, a participant is given a reference key that they must use to help them connect basic roman numerals to a series of geometric shapes. Responses can be verbal or written, and the entire test should be finished in 90 seconds. Scoring and evaluation of the test takes a further five minutes to complete. Because responses can be written or spoken, it can be used with a broad spectrum of participants, including those suffering from motor disabilities and speech impediments.**
8. **Expanded Disability Status Scale (EDSS): The EDSS is a method of quantifying disability in multiple sclerosis and monitoring changes in the level of disability over time. It is widely used in clinical trials and in the assessment of people with MS. This assessment will be made by Dr. Brian Sandroff.**
9. **Questionnaires: Symptoms of fatigue, depression, anxiety, and pain will be measured by the Fatigue Severity Scale (FSS), Modified Fatigue Impact Scale (MFIS), Hospital Anxiety and Depression Scale (HADS), and short-form McGill Pain Questionnaire (SF-MPQ) respectively. The FSS is a 9-item unidimenional measure of fatigue and its disabling consequences over the past week in medical populations including MS. The MFIS is a 21-item measure of physical, cognitive, and psychosocial impact of fatigue on daily life over the past 4 weeks. The HADS contains 14 items that measure the frequency of anxiety and depressive symptoms over the past week. The SF-MPQ has a 15-item adjective checklist that captures sensory and affective dimensions of pain experienced over the past week. These variables will be measured at baseline, 8 and 16 weeks.**
10. **Dietary adherence: Participants will be asked to will complete three 24 hour dietary phone recalls over a 14 day period. These calls will be unannounced and participants will be informed that they will be asked to recall all they consumed within the last 24 hours at the time of the call. They will receive two of the three recall phone calls during the week, and one on a Monday morning to capture a weekend recall. Research staff will follow standard protocols for performing a 24 hour food recall and study staff will provide participants with materials at baseline to help them answer the food recall questions. Participants will receive three more 24 hour dietary recall phone calls at the 16 week mark.**

At the end of the baseline visit, research staff will give the participant information for accessing the questionnaires on-line. Participants will be given the option to complete the questionnaires while at the visit or at home. Participants will be given an accelerometer to wear for 14 days, along with a pre-stamped envelope and instructions to mail back the accelerometer after the 14 days. Participants will also receive instructions on for completing the 24 hour dietary recall phone calls. All participants will receive a take home folder containing instructions for the two weeks following baseline as well as information for depression in individuals with MS, provided by the National MS Society.

At 14 days after baseline, staff will contact participants to remind them to return their accelerometer via mail, complete any questionnaires that have not been completed, and to schedule their first coaching appointment.

III. INTERVENTION

The intervention consists of a 16 week internet-based health coaching intervention. All participants (both groups) will interact with the BIAPAMS website weekly, and have one-on-one video chats with a health coach in weeks 1-12, 14, and 16. In addition to the BIPAMS website, participants in the BIPAMS+Diet group will be asked to log their food intake using a mobile app, beginning in week 9. All participants (both groups) will work toward physical activity goals focused on increasing daily steps. In addition to these goals, participants in the BIPAMS+Diet group will be given weekly dietary goals related to intake of various food groups each week, beginning in week 9. All goals are individualized the participant and therefore will be different for each participant.

The intervention consists of 3 components: the BIPAMS website (both groups), HealthWatch 360 mobile/desktop app (BIPAMS+Diet group only), and One-on-One video chats (both groups). All participants will receive the standard BIPAMS intervention for the first 8 weeks of the trial. At the completion of the eighth week, participants will receive their randomization assignment. Those in the BIPAMS+Diet arm will begin receiving dietary materials in week 9. Those in the comparison group (BIPAMS) will continue receiving the established BIPAMS intervention for the remainder of the trial.

We have chosen to structure the intervention in this way for two reasons. First, persons with MS often report symptom burden as reasons for difficulty in establishing new health behaviors. For this reason, initiating multiple behaviors simultaneously may be more difficult for this group than the general population. By initiating physical activity first, we hope to maximize participants' adherence to the recommendations by reducing the potential psychosocial and physical stressors of concurrent behavior changes. Secondly, starting with the portion of the intervention that has already been established as efficacious will allow us to use the first 8 weeks as a run-in period and better differentiate the effects of the combined approach of diet and exercise compared to the exercise-alone intervention.

1. ***BIPAMS Website:*** **The Internet website represents a medium for disseminating information on the skills, techniques, resources, and strategies for becoming and staying physically active with MS. The behavioral intervention does not provide a prescription for exercise or physical activity itself (i.e., the program does not specifically recommend mode, duration, frequency, or intensity of movement). The primary content of the Internet website is based on SCT and represents the transformation of an effective and empirically validated, face-to-face intervention approach that increased adherence with supervised exercise training in middle-aged adults and persons with MS. The content is delivered through interactive video courses based on E-learning principles (i.e., content and instructional methods delivered on a computer with interactive materials that build knowledge and skills for behavior change). The interactive video courses were developed using Storyline in Articulate 360 (Articulate, New York, NY) based on operationalizing principle elements of SCT including self-efficacy, outcome expectations, impediments, and goal-setting. The interactive video courses follow a similar template of Introduction and Overview, Primary Content, and Take Home Message. The interactive video courses received formative evaluation from representative persons with MS and are organized into four "Modules" for the behavioral intervention, namely Getting Started; Planning for Success; Beating the Odds; and Sticking with It. The *Getting Started* module includes interactive video courses on the benefits of physical**

activity for persons with MS, instructions for becoming physically active, completing daily activity logs, and self-monitoring of behavior via a Yamax SW-200 pedometer and an embedded website feature called Tracker for reporting weekly physical activity. The *Planning for Success* module includes interactive video courses on goal setting and feedback again via a Yamax SW-200 pedometer and Tracker, developing realistic outcome expectations, and increasing self-efficacy. The *Beating the Odds* module includes interactive video courses on identifying barriers to physical activity and strategies of overcoming barriers as well as developing social support. The *Sticking with It* module includes interactive video courses on maintaining an active lifestyle and prevention of relapse into a sedentary lifestyle. Those interactive video courses are supplemented with embedded options of "Learn More" and "Resources." The "Learn More" option includes passive videos on content that aligned with the course, and the "Resources" option includes research articles for documenting the statements within the courses; manuals on stretching, aerobic, and resistance modes of physical activity; and worksheets and questionnaires for further developing the personal relevance of the stories. The interactive video courses along with embedded options became "accessible" in a titrated fashion of seven times during the first 2 months, four times during the second 2 months, and twice during the final 2 months of the intervention.

The Tracker feature of the website was designed for self-monitoring and goal-setting within the website itself, and the participants' data are directly accessible by the behavioral coaches for discussions within the one-on-one video chats. Tracker includes four elements of Ready (directly entering baseline week of step counts), Set (setting a step count goal for the program), Go (directly entering step counts weekly during the program), and See (graphical display of step counts for monitoring progress over the program compared with the goal). This is further supplemented with direct, on-screen feedback regarding progress with the behavioral goal on a weekly basis. We again received formative evaluation from representative persons with MS for refinement of the new Tracker feature.

The website further includes "Voices" of audio files of persons with MS discussing physical activity that were supplemented by a loop of pictures. The "Voices" change weekly and are included for engaging people with MS in social modeling as a source of self-efficacy information based on SCT. The Internet website further includes an ongoing and seeded participant "Forum" for discussions of physical activity behavior change amongst participants (i.e., another form of vicarious experience). The website is supported by automated e-mail announcements about updates and tips of the week, and includes information on News (i.e., late breaking research results) and Events that further support the website content.

In addition to these intervention aspects, which all participants will receive, the BIPAMS+Diet group will access additional information beginning in Week 9. Participants in the BIPAMS+Diet group will receive a calorie prescription intended to create a 500 kcal/day energy deficit, as recommended in current obesity treatment guidelines. Study staff will derive calorie prescriptions from the Harris-Benedict formula, which uses individual data to calculatean individualized prescription. Dietary content will focus on increasing fruit and vegetable intake, consumption of lean protein, reduced-fat dairy, whole grains, and reduction of saturated fat intake. Participants will receive nutrition education content via the BIPAMS website and video chats will consist of discussion of both physical activity and dietary goals. Each participant in this group will be given additional resources that will be provided on the "resources" page, which include information on meal planning, snack ideas, goal setting for dietary behaviors. Participants in the BIPAMS group will be given a single link to healthy eating resources for people with MS from the National MS Societywebsite, but no other healthy eating content will be given and no individualized recommendations or goals will be given related to nutrition. All resources provided from the NMSS website can be found at https://www.nationalmssociety.org/Living-Well-With-MS/Diet-Exercise-Healthy-Behaviors/Diet-Nutrition

2. **HealthWatch 360: Participants in the BIPAMS+Diet group will be asked to track all food consumption in the HealthWatch 360 mobile app. We will use the research portal available through Healthwatch360 website and app. This allows researchers to track participant entries in**

real time and monitor the nutrition goals of participants. The research portal is HIPAA-compliant. Upon completion of the study, the participant may continue to use the HealthWatch 360 application as it is free to the public, but the research portal license will expire so the researchers will no longer be able to track the entries and nutrition goals of the participants. If the participant prefers to remove the application from their mobile device, study staff will assist in the deletion of the program from the mobile device per the application deletion procedure for the specific type of mobile device.

3. ***One-on-one Video Chats:*** **The one-on-one video chats support adherence with the intervention, discussion and elaboration of website material, supportive accountability, and reporting adverse events/injuries; these further provide vicarious experience (i.e., social interaction) for promoting behavior change. The video chats are modeled for maximizing adherence with Internet interventions, provide an ongoing interaction between the behavioral coach and the participant, and are conducted face-to-face through the web-based program Zoom™. The video chats are semi-scripted and based on principles of supportive accountability. The video chats consist of an ongoing review of goal-setting and progress toward goal attainment through Tracker as well as discussion of strategies and facilitators of behavioral change based on SCT and current website content. Supportive accountability, for example, is accomplished by encouraging participants to wear the pedometer daily, and monitor behavioral change and goal attainment throughout the 4-month intervention. The chats occur weekly during the first 3 months (12 total calls), and bi-weekly during the last month (2 total calls) of the intervention.**

IV. FOLLOW UP DATA COLLECTION

At the half-way point of the intervention (week 8), participants will be asked to wear the accelerometer again for 1 week, and complete the questionnaires online again. Participants will not be asked to come into the lab at this point. Accelerometers will be mailed to them and questionnaires will only be done online.

At completion of the 16-week intervention, participants will be scheduled to return to Lakeshore Foundation. All baseline testing will be repeated following the same protocols as baseline.

b. What is the probable length of time required for the entire protocol (i.e., recruitment through data analysis to study closure)? **1 year.**

c. What is the total amount of time each participant will be involved? **20 weeks (2 weeks baseline data collection, 16 weeks intervention, 2 weeks follow up data collection)**

d. If different phases are involved, what is the duration of each phase in which the participants will be involved? If no phases are involved, enter "None." **NA**

e. List the procedures, the length of time the procedure takes, the total # of times the procedure is performed, and indicate whether each is performed solely for research or would already be performed for treatment or diagnostic purposes (routine care) for the population.
-Insert additional table rows as needed.
-If procedure is sometimes research and sometimes routine care, include on separate lines with number of times as each.

Procedure	Length of Time Required of Participants	Total # of Times the Procedure is Performed	Research (Res) –OR- Routine Care
Anthropometrics	**15 minutes**	**2**	☒Res ☐Routine
Bloodwork (insulin, glucose, lipids)	**10 minutes**	**2**	☒Res ☐Routine
DXA	**20 minutes**	**2**	☒Res ☐Routine
Pregnancy Test	**5 minutes**	**2**	☒Res ☐Routine

(females of child-bearing age only)			
24 Hour Dietary Recall	**3 days**	**2**	☒Res ☐Routine
Timed 25-Foot Walk (T25-FW)	**1-5 minutes**	**2**	☒Res ☐Routine
9-Hole Peg Test (9-HPT)	**10 minutes or less**	**2**	☒Res ☐Routine
Symbol Digit Modalities Test (SDMT)	**Less than 5 minutes**	**2**	☒Res ☐Routine
Expanded Disability Status Scale (EDSS)	**20 minutes**	**1**	☒Res ☐Routine
Questionnaires	**20-45 minutes**	**3**	☒Res ☐Routine
Accelerometer	**7 days**	**3**	☒Res ☐Routine
Video Chats	**10-15 minutes**	**14**	☒Res ☐Routine

f. Will an interview script or questionnaire be used? ☒Yes ☐No

If Yes, attach a copy.

g. Will participants incur any costs as a result of their participation? ☒Yes ☐No

If Yes, describe the reason for and amount of each foreseeable cost. **There is a potential for participants to incur cell phone and internet data usage charges while using the Healthwatch 360 system or one-on-one video calls.**

h. Will participants be compensated? ☒Yes ☐No

If Yes, complete i-v.

i. Type: (e.g., cash, check, gift card, merchandise): **Check**

ii. Amount or Value: **$50**

iii. Method (e.g., mail, at visit): **mail**

iv. Timing of Payments: (e.g., every visit, each month): **At completion of baseline data collection and completion at follow up data collection.**

v. Maximum Amount of Compensation per Participant: **$100**

18. Benefits

Describe the potential benefits of the research. **The benefits to the participants are potentially numerous. The physical and psychological benefits that reliably result from regular physical activity and following a healthy diet far outweigh the minimal risks. Beyond the common physical and psychological benefits, there are additional benefits of becoming more physically active for participants including improvements in walking and cognitive function, weight reduction, and improvment in cardiometabolic health.**

19. Risks - in nontechnical, lay language

a. List the known risks for participants as a result of participation in the research. This should not include the minimal risk of loss of confidentiality. However, it should include any physical, psychological, social, economic, and/or legal risks. If there is a greater than minimal risk of loss of confidentiality describe why this is so. Do not list risks associated with the standard-of-care procedures.

NOTE: Risks included here should be included in the consent form or information sheet, as applicable.

1. **Fasting prior to bloodwork: Participants may experience a drop in blood sugar causing lightheadedness, dizziness, nausea, sweating, and shakiness as a result of fasting before their baseline and follow up visits.**

2. **Blood draw: Participants may experience pain and/or bruising during venipuncture.**

3. **DXA: A DXA scan is an x-ray scan that uses a very low-level of radiation. In this study subjects will be exposed to a very low level of radiation during the DXA scan. The radiation dose received from scans is equivalent to about 8 days natural background radiation. Background radiation is radiation normally received from sources such as cosmic rays and natural radioactivity in building materials and the ground. A small risk of cancer and other radiation effects, which may not be known at this time, may develop from each scan you receive.**

4. **Intervention: There are risks of injury for individuals engaging in a lifestyle physical activity program after a prolonged period of inactivity. Such risks include strains, sprains, and muscle soreness, but serious physical injury such as sudden death or heart attack is considered unlikely given the screening for contra-indications via physician referral. We will attempt to reduce risks of injury and harm by promoting gradual increases in physical activity behavior across time. We will fully inform participants of the risks associated with initiating a physical activity program in the informed consent.**
    a. **During the intervention, there is a potential risk of a participant voicing a depressed mood or verbiage of suicidal ideation. In the case that this occurs, we will provide resources for seeking mental health treatment and encourage the individual to call their primary care or mental health provider if they have one. We will write this up as an adverse event to report to the IRB.**

5. **Symptom Measures: There are minimal risks associated with completing the patient-rated outcomes included in this protocol. All outcomes are questionnaire-based. One forseeable risk may be psychological in that participants may experience feelings of discomfort or embarassment when reporting on their symptoms or experiences of MS. We will fully inform participants of such risks in the informed consent.**

6. **Physical Activity Measures: There are minimal psychological, social, or legal risks associated with completing the measures for this study. One foreseeable risk may be psychological in that non-active participants may experience some guilt, discomfort, or embarrassment with reporting inactivity. We will fully inform participants of such risks in the informed consent.**

7. **Risk of falling: There is a risk of falling while completing the exercises.**

8. **Risk of starting a new diet: There is a risk of feeling hungry when changing dietary patterns or reducing food intake.**

b. Estimate the frequency, severity, and reversibility of each risk listed.

Risks associated with fasting prior to blood draw are typically rapidly reversible upon ingesting food and drink or lying down and should not result in severe harm to the participant. Discomfort associated with venipuncture is rapidly reversible. Bruises from venipuncture will heal in several days. The risks associated with other testing may occur in 5% of subjects, and are preventable/reversible through clear instructions and strategies for remediation as outlined above. Risks associated with changing dietary habits are typically mild and reversible within 1-2 weeks.

c. Is this a therapeutic study or intervention? ☐Yes ☒No

If Yes, complete i.-iii.

i. Describe the standard of care in the setting where the research will be conducted: _____

ii. Describe any other alternative treatments or interventions: _____

iii. Describe any withholding of, delay in, or washout period for standard of care or alternative treatment that participants may be currently using: _____

d. Do you foresee that participants might need additional medical or psychological resources as a result of the research procedures/interventions? ☐Yes ☒No

If Yes, describe the provisions that have been made to make these resources available. _____

e. Do the benefits or knowledge to be gained outweigh the risks to participants?

☒Yes ☐No

If No, provide justification for performing the research: _____

20. Precautions/Minimization of Risks

a. Describe precautions that will be taken to avoid risks and the means for monitoring to detect risks.

Intervention: We will attempt to reduce risks of injury and harm by promoting gradual increases in physical activity behavior across time. We will fully inform participants of the risks associated with initiating a physical activity program in the informed consent. We will obtain phsyician approval to participate prior to enrollment in the study.

Symptom Measures: One forseeable risk may be psychological in that participants may experience feelings of discomfort or embarassment when reporting on their symptoms or experiences of MS. We will fully inform participants of such risks in the informed consent.

Physical Activity Measures: There are minimal psychological, social, or legal risks associated with completing the measures for this study. One foreseeable risk may be psychological in that non-active participants may experience some guilt, discomfort, or embarrassment with reporting inactivity. We will fully inform participants of such risks in the informed consent.

Participants will be asked a set of questions each week to assess their general health (see attached Adverse Event form). If a participant reports any notable changes for 2 consecutive weeks, that information will be given to Dr. Rinker for review.

Any serious adverse events will be promptly reported to the Institutional Review Board at UAB. Safety reports will be sent to the PI from the intervention staff, or data collection staff if the event occurs during baseline/follow up testing. The PI will be responsible for reviewing the data with Dr. Rinker.

If the protocol involves drugs or devices skip Items 20.b. and 20.c. and go to Item 21. Instead include this information in the Drug Review Sheet or Device Review Sheet, as applicable.

b. If hazards occur to an individual participant, describe (i) the criteria that will be used to decide whether that participant should be removed from the protocol; (ii) the procedure for removing such participants when necessary to protect their rights and welfare; and (iii) any special procedures, precautions, or follow-up that will be used to ensure the safety of other currently enrolled participants.

The PIs will monitor protocol adherence. Throughout the study, study staff will inform the PIs of adverse events. Events determined by the PIs and Dr. Rinker to be unanticipated serious problems involving risks to subjects will be reported by the PI to the IRB within 5 working days of occurrence. Non-serious adverse events will be reported per IRB policy at the time of continuing review. If any protocol changes are needed as a result of an adverse event, the PI will submit a modification request to the IRB. Protocol changes will not be implemented prior to IRB approval.

c. If hazards occur that might make the risks of participation outweigh the benefits for all participants, describe (i) the criteria that will be used to stop or end the entire protocol and (ii) any special procedures, precautions, or follow-up that will be used to ensure the safety of currently enrolled participants.

If the risks involved in participating appear to exceed the benefits during review of occurrences of serious adverse events, the PIs will consult with the complete investigator team to decide to

terminate the study. If the study is terminated, participants will be given information related to the study risks that may have affected them or their health.

21. Informed Consent

a. Do you plan to obtain informed consent for this protocol? ☒Yes ☐No

If Yes, complete the items below.

If No, complete and include the Waiver of Informed Consent or Waiver of Authorization and Informed Consent, as applicable.

b. Do you plan to document informed consent (obtain signatures) for this protocol? ☒Yes ☐No

If Yes, complete the items below.

If No, complete the items below **and** include the Waiver of Informed Consent Documentation.

c. How will consent be obtained?

The recruitment coordinator at Lakeshore Foundation and all intervention staff who will be recruiting participants will be knowledgeable of the purposes of the study. Once interest is determined, the recruitment coordinator or intervention staff will provide a detailed description of the study, screen the participant for eligibility, answer any questions, and if appropriate, schedule their first visit. At the beginning of the first visit, consent will be obtained prior to any testing.

d. Who will conduct the consent interview?

The recruitment coordinator at Lakeshore Foundation or the project coordinator.

e. Who are the persons who will provide consent, permission, and/or assent? **Study participants**

f. What steps will be taken to minimize the possibility of coercion or undue influence?

Participants will be self-referred. As described above, the consent form will be carefully reviewed with participants. Further, they will have 24 hours to consider participation in the study.

g. What language will the prospective participant and the legally authorized representative understand?

English

h. What language will be used to obtain consent? **English**

i. If any potential participants will be, or will have been, in a stressful, painful, or drugged condition before or during the consent process, describe the precautions proposed to overcome the effect of the condition on the consent process. If not, enter "None." **None**

j. If any protocol-specific instruments will be used in the consenting process, such as supplemental handouts, videos, or websites, describe these here and provide a copy of each. If not, enter "None."

None

k. How long will participants have between the time they are told about the protocol and the time they must decide whether to enroll? If not 24 hours or more, describe the proposed time interval and why the 24-hour minimum is neither feasible nor practical. **A minimum of 24 hours**

22. Procedures to Protect Privacy

Describe how you will protect the privacy interest of the participants. Include how you will make sure others cannot overhear your conversation with potential participants and that individuals will not be publicly identified or embarrassed. **There will be a password protected link between data and the participant's name during this study, but this link will be destroyed upon study completion. We will retain screening data for those who qualify and volunteer to participate, and destroy screening data from those who do not qualify or do not volunteer.**

23. Procedures to Maintain Confidentiality

a. Describe how you will store research data to maintain confidentiality (both paper records and electronic data), including how access is limited. If data will be stored electronically anywhere other than a server

maintained centrally by UAB, identify the department and all computer systems used to store protocol-related data. **All participants will be assigned an identification number and all data collection, as well as data analyses, will be conducted with the coded non-identifiable data. All data will be kept in a locked file cabinet and only aggregated data will be used for presentation or publication purposes. There will not be a link between the identification number and participant for purposes of tracking participants over time. We will not maintain a link between identification number and the subject's name after completion of the study procedures, and there is no intention of linking data collected in the current project with data collected in another project. We will retain screening data for those who qualify and volunteer, and destroy the screening data for those who are excluded or do not volunteer.**

b. Will any data from this protocol be given to any person, including the subject, or any group, including coordinating centers and sponsors? ☐Yes ☒No

If Yes, complete i-iii.

i. Who will receive the data? _____

ii. What data will be shared? _____

iii. How will the data be identified, coded, etc.? _____

24. Genomic Data Sharing (GDS)

Researchers who collect genomic data as part of a NIH grant funded after January 25, 2008 may be required to submit those data to a NIH database for broad scientific sharing. See Genomic Data Sharing in the IRB Guidebook for more information.

a. Does this protocol involve the proposed submission of genetic data into genomic repositories created to share genetic information for research purposes? ☐Yes ☒No

b. Will UAB be uploading the final genomic data to the central repository (e.g., dbGaP)? ☐Yes ☐No

If Yes to both a and b, submit a Detailed Data Sharing Plan to the IRB for review. This plan should include any known data use limitations and indicate whether aggregate-level data are appropriate for general research use. For guidance see the NIH Genomic Data Sharing Policy.

c. Submit a copy of the NIH Institutional Certification Form.

To determine which certification form to include, answer i-ii.

i. Was this protocol funded prior to January 25, 2015? ☐Yes ☐No

- **If yes,** and consent will be obtained, submit the Extramural Institutional Certification - Before January 25 - With Consent.
- **If yes,** and consent will not be obtained, submit the Extramural Institutional Certification - Before January 25 - Without Consent.

ii. Was this protocol funded after January 25, 2015? ☐Yes ☐No

- **If yes,** submit the Extramural Institutional Certification - After January 25.

25. Additional Information

In the space below, provide any additional information that you believe may help the IRB review the proposed research, or enter "None." **None.**

Analysis plan

Planned: We will explore descriptive statistics including means, standard deviations, and confidence intervals for all variables. Aim 1 and Aim 2 are similar from the perspective of data analysis. We will use mixed-factor ANOVA to determine differences in outcomes over time by group. There will be no adjustment for multiple testing of outcomes because the goal of this study is to collect preliminary data. Data collected for feasibility will mostly be descriptive. The data will be summarized for guidance in designing the main trial supported by this pilot study.

Actual: Due to small sample which led to early termination, only descriptive statistics for each group were analyzed.

CONSENT FORM

Title of Research: Comprehensive Lifestyle Intervention for Reducing Cardiometabolic Risk and Symptom Burden in Adults with Multiple Sclerosis: A Pilot Study

UAB IRB Protocol #: IRB-300002096

Principal Investigator: Brooks C. Wingo, Ph.D.

Co-Principal Investigator: Robert W. Motl, Ph.D.

Sponsor: UAB Nutrition Obesity Research Center

Sponsor Protocol #:

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of the study is to compare two versions of an Internet-delivered program for improving health behaviors, including physical activity and healthy eating, among people with multiple sclerosis (MS).
Duration & Visits	You will come to Lakeshore Foundation campus twice over a 20 week time period.
Overview of Procedures	You will come to a beginning visit that includes a physical exam, blood draw, physical and cognitive assessments measuring the disability and symptoms of MS, and completion of surveys related to symptoms of MS. For two weeks after the first visit, you will wear an activity monitor on your wrist and answer 3 food recalls with a registered dietitian. Once you have completed the two weeks of testing, you will complete a 16-week telehealth program. You will have access to a telehealth website, BIPAMS, and weekly video chats with a telehealth coach. You will come back to Lakeshore Foundation campus after completing 16 week program to complete the same testing you completed at the beginning.
Risks	The most common risks include dizziness or lightheadedness while fasting for testing, the possibility of injury during the program, pain or bruising from the blood draw, and loss of confidentiality. Additionally, a small risk of cancer and other radiation effects, which may not be known at this time, may develop from each DXA scan you receive.
Benefits	You may or may not benefit from participating in this study.
Alternatives	If you do not want to take part in the study, the alternative is to not participate in this study.

Purpose of the Research

We are asking you to take part in a research study. The purpose of this research is to compare two versions of an Internet-delivered program for improving health behaviors, including

physical activity and healthy eating, among people with multiple sclerosis (MS). This study will enroll 24 individuals with MS.

Explanation of Procedures

Before you can begin the intervention, you will complete baseline assessments at the Lakeshore Foundation. The visit will take approximately 2 hours.

Baseline Visit: During this visit, we will measure your height, weight, waist circumference, and blood pressure. We will also measure body composition and collect blood work using tests explained below.

- **Blood Work –** We will draw 2 vials of blood (7 mL or 1.4 teaspoons) via venipuncture to measure your blood glucose, insulin, and lipids (cholesterol and triglyceride levels). You will be asked to not eat or drink anything after 12:00 am the morning of your blood draw.
- **Body Composition –** We will measure your body composition (body fat percentage, fat mass and muscle mass) using a DXA scan. The DXA uses very low level radiation to measure your total body composition including fat mass and bone density. To complete the DXA, you will lie on a table and a machine will pass over your body. Prior to completing the scan, all women of child bearing potential will undergo a urine pregnancy test to ensure that there is no risk of undue harm to the child. Pregnant women will not be enrolled in the study. In the event that your whole body does not fit into a single scan, we will conduct 2 scans- one of the right half of your body and one of the left half.

  We are performing imaging solely for the research purposes described above. It is not a clinical scan intended for diagnostic or therapeutic purposes. Under no circumstance will the investigator, research staff, or imaging staff interpret the scan as normal or abnormal. They are unable to make any medical comments about your scan. The scan will not be looked at or read for any healthcare treatment or diagnostic purpose. If you want your scan to be reviewed by a physician so the physician can look for medical issues, you can request a copy of your scan. We will provide an electronic copy at no charge.

- **MS symptoms and functional limitations-** You will be asked to complete a series of assessments including brief walking tests and tests of cognitive function, which will be performed by our trained research staff. These assessments are intended to measure the disability and symptoms of MS.
- **Questionnaires-** You will also be asked to complete a series of questionnaires related to symptoms of MS such as pain and fatigue. You may choose to complete these questionnaires while you are at Lakeshore, or you may complete them on your home computer/tablet after the visit.

14 days after baseline:

- **Accelerometer:** At the end of the baseline visit, you will be given an accelerometer to wear on your arm for 14 days, along with instructions for use. You will also be given a pre-stamped envelope in order to return the accelerometer. We will call you at the 14 day mark as a reminder, and we will also use this time to schedule your first one-on-one video chat.

- **24 Hour Food Recalls:** During these 14 days you will also be asked to participate in 3 phone interviews to complete 24-hour food recalls. A research staff person from the UAB will call you on three different days and review what you had to eat on the previous day.

During the Intervention:

- As a participant, you will have access to a website called BIPAMS (Behavioral Intervention for Physical Activity in MS). All participants will have access to the same website for the first 8 weeks of the study.
- During the last 8 weeks of the study, participants will have access to one of two versions of the BIPAMS website. The first, (BIPAMS) will continue to focus on increasing physical activity while the second version (BIPAMS+) will focus on increasing physical activity and improving healthy eating. You will be randomly assigned (like the flip of a coin) during week 8 to the version of the website you will see during the last 8 weeks of the study.
- Both websites were specifically designed for this project and provide information on the benefits of physical activity and healthy eating behaviors, including incorporating physical activity into your daily life, goal setting and monitoring progress, and resources for increasing and maintaining physical activity and healthy diet behaviors.
- Both groups will have modules added into the website across the 16-week period and we will send you an e-mail about accessing the new content.
- Across the 16-week period we will ask that you wear a pedometer for tracking your daily physical activity. We will further ask that data from the pedometer be entered into the website. We will also ask the BIPAMS+ group to log their daily food intake into an app called HealthWatch 360.
- Both groups will also have additional opportunities for engaging in daily and weekly forums for posting and answering questions.
- All participants will be assigned a health coach, and you will have a brief video chat with your coach weekly during weeks 1-12. You will also have a call during week 14 and week 16. These calls will be conducted via a secure website called Zoom, and will take 15-20 minutes.

Follow up Measures:

- At the half-way point (week 8), you will be asked to complete the questionnaires again, complete 3 additional 24-hour food recalls, and wear the accelerometer again for 14 days. You will not have to come into the lab for this. The questionnaires will be available online and we will mail you the accelerometer. When these measures are completed, you will be randomly assigned to the website group you will be in for the second half of the study.
- At the end of the 16-week program, you will be scheduled for a visit at Lakeshore Foundation so that we can repeat all the measures from baseline (height, weight, waist circumference, DXA, blood work, questionnaires).
- In addition to the measures collected at baseline, you will also have the opportunity to complete a brief optional interview to provide feedback to help us find ways to improve the program. This interview will last approximately 15-20 minutes and is optional. You may still participate in the study even if you choose not to participate interview.

Yes, I choose to participate in the optional interview ☐

No, I choose not to participate in the optional interview ☐

- During the 14 days after the follow up visit, you will again be given an accelerometer to wear. You will also complete 3 additional 24-hour food recall phone interviews. At the end of the 14 days, you will return the accelerometer to Lakeshore using the pre-stamped, pre-addressed envelope provided to you at your follow up appointment.

Risks and Discomforts
All risks and discomforts apply to both groups within this study.

Fasting Prior to Testing: You may experience a drop in your blood sugar causing lightheadedness, dizziness, nausea, sweating, and shakiness. If you experience any of these symptoms prior to or during testing, please notify the researcher or technician so they may assist you.

Bloodwork: You may experience pain, bruising, and/or fainting during venipuncture.

DXA: A DXA scan is an x-ray scan that uses a very low-level of radiation. In this study you will be exposed to a very low level of radiation during the DXA scan. The radiation dose received from the 1 to 2 scans is equivalent to about 8 days of natural background radiation. Background radiation is radiation normally received from sources such as cosmic rays and natural radioactivity in building materials and the ground. A small risk of cancer and other radiation effects, which may not be known at this time, may develop from each scan you receive.

Physical Activity during the Study: There are potential risks and discomforts when increasing walking or other forms of physical activity you may choose to perform as part of this program. These may include muscle soreness (in particular, when starting new exercises the body is not accustomed to), joint pain, falling, fatigue, shortness of breath, chest pain, or remote chance of sudden death.

Changing diet habits: There is a potential risk of hunger when you make changes to your diet. We will attempt to reduce this risk by providing options for healthy foods that will not leave you hungry.

Loss of Confidentiality: There is a potential risk of loss of confidentiality regarding exposure of personal information obtained by our researchers. All information you enter in the POWERS platform will be kept on a secure, encrypted server. While using this type of server reduces your risk of loss of confidentiality, some risk does remain.

Risk of Being Randomized: You will be assigned to a group by chance, which may prove to be less effective or to have more side effects than the other study group or alternatives.

Intervention: There are risks of injury for individuals engaging in a lifestyle physical activity program after a prolonged period of inactivity. Such risks include strains, sprains, and muscle soreness, but serious physical injury such as sudden death or heart attack is considered unlikely given the screening for contra-indications via physician referral. We will attempt to reduce risks of injury and harm by promoting gradual increases in physical activity behavior across time.

If, at any point during the intervention, you feel or express a depressed mood or suicidal ideation, we will provide resources for seeking mental health treatment and encourage you to call your primary care or mental health provider if you have one. We do not anticipate this happening during the intervention.

Questionnaires: There are minimal risks associated with completing the questionnaires with this study. One foreseeable risk may be psychological in that participants may experience feelings of discomfort or embarrassment when reporting on their symptoms or experiences of MS.

Benefits

A benefit is that you may be able to do more activities due to improved strength and fitness. Participants may lose weight or have changes in body composition. This may result in prevention of heart disease or diabetes and improved quality of life and function. However, it is possible that you will not benefit from this research.

Alternatives

If you choose not to participate in this research, you may still begin an exercise and/or nutrition program on your own. Also, you may choose not to begin an exercise program at this time. If you decide to participate in another research study, you should contact the investigator as this may affect your activities and exercises.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with people or organizations for quality assurance or data analysis, or with those responsible for ensuring compliance with laws and regulations related to research. They include:

- the UAB Institutional Review Board (IRB). An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- UAB Nutrition Obesity Research Center
- The Lakeshore Foundation
- the Office for Human Research Protections (OHRP)

The information from the research may be published for scientific purposes; however, your identity will not be given out.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Voluntary Participation or Withdrawal

Your taking part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution.

You may be removed from the study without your consent if the sponsor ends the study, if your doctor decides it is not in the best interest of your health, or if you are not following the study rules.

If you are a UAB student or employee, or an employee of Lakeshore Foundation, taking part in this research is not a part of your UAB class work or work duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or your job at UAB or Lakeshore Foundation. You will not be offered or receive any special consideration if you take part in this research and your participation will not be shared with your supervisor.

Cost of Participation

All tests and materials, including the DXA scan and the accelerometer will be provided to you at no cost during the study.
You should check with your internet and cell phone provider to see about any extra costs. Cell phone and internet data usage charges may be incurred during this study which you will be responsible for paying.

Payment for Participation in Research

You will be paid $50 after you complete all baseline measures and $50 when you complete all follow up measures. If you complete the entire study, you will be paid a total of $100. Ask the study staff about the method of payment for this study (e.g. check, cash, gift card, etc.).

Payment for Research-Related Injuries

UAB has not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

Significant New Findings

You will be told by study staff if new information becomes available that might affect your choice to stay in the study.

Questions

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, you may contact Dr. Brooks Wingo or Dr. Rob Motl. They will be glad to answer any of your questions. Dr. Wingo's number is 205-934-5982, and Dr. Motl's number is 205-934-5904.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this informed consent document.

Email Communication

During this study, we may offer the option to have appointment reminders sent to you by unencrypted email. There is a potential risk of loss of confidentiality when communicating via unencrypted email. Unencrypted email communication is considered a non-secure method of sharing information. There is no guarantee that such communication (and any other data associated with it) is private and will only be viewed by the intended recipient. By using unencrypted email, you acknowledge and accept this risk.

Please initial your choice below:

_____ I would like to communicate via unencrypted email.

_____ I do not wish to communicate via unencrypted email.

Signatures

Your signature below indicates that you agree to participate in this study. You will receive a copy of this signed document.

Signature of Participant Date

Signature of Investigator or Other Person Obtaining Consent Date

University of Alabama at Birmingham
AUTHORIZATION FOR USE/DISCLOSURE OF
PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Participant Name: _____
Research Protocol: Comprehensive Lifestyle Intervention for Reducing Cardiometabolic Risk and Symptom Burden in Adults with Multiple Sclerosis

UAB IRB Protocol Number: IRB-300002096
Principal Investigator: Brooks C. Wingo, Robert W. Motl
Sponsor: UAB Nutrition Obesity Research Center

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your protected health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your protected health information may be used for the research.

Why do the researchers want my protected health information? The researchers want to use your protected health information as part of the research protocol listed above and as described to you in the informed consent.

What protected health information do the researchers want to use? All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills, and any other information related to or collected for use in the research protocol, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes.

Who will disclose, use and/or receive my protected health information? All Individuals/entities listed in the informed consent documents, including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, Children's of Alabama, Eye Foundation Hospital, the Jefferson County Department of Health, Lakeshore Foundation as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees and agents, including any CRO; and any outside regulatory agencies, such as the Food and Drug Administration, providing oversight or performing other legal and/or regulatory functions for which access to participant information is required.

How will my protected health information be protected once it is given to others? Your protected health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel this Authorization? You may cancel this Authorization at any time by notifying the Principal Investigator, in writing, referencing the research protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the protected health information that was provided before you cancelled your authorization.

Can I see my protected health information? You have a right to request to see your protected health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: _____ Date: _____
or participant's legally authorized representative: _____ Date: _____
Printed Name of participant's representative: _____
Relationship to the participant: _____