Official Title:	Mobile Health Obesity Wellness Intervention in Rural Older Adults (MOWI): Amulet Technology Development & Validation
NCT number:	NCT0304189
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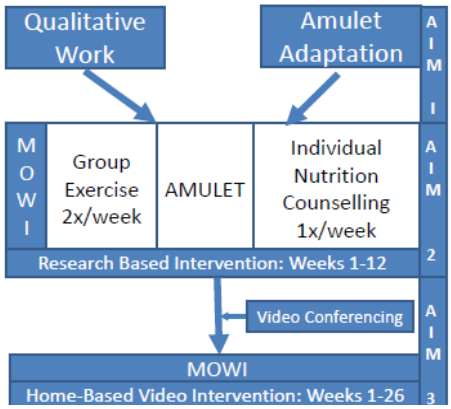
Overview: The study will: 1) Obtain input on feasibility, usability, and acceptability of using mHealth in behavior change by adapting a device for rural older adults; 2) Develop, refine and tailor MOWI in research settings; 3) Conduct MOWI in subjects' homes. The overall goal is to improve older adult physical function in rural areas and use the results as a basis for an R01 randomized trial testing the MOWI's delivery in the home.

Study Setting/Population: Dartmouth-Hitchcock (D-H) serves 1.5 million persons from a circumscribed area of rural New Hampshire/Vermont. The site of Lebanon, NH, is a typical rural New England town (16.2% aged ≥65 years; 95.4% Caucasian[83]). Of 13,293 primary care patients ≥65years old at D-H, 3,987 are study eligible (~30% obese[84]). The Center for Health & Aging (CHA) has rooms for study assessments. In-home evaluations will use CHA video equipment.

Recruitment: As a Geriatrician working with an interdisciplinary team, I have ready access to potential subjects from a practice panel of ~3000 older adults. In addition the Centers for Health and Aging provide a venue for recruitment, as indicated by successfully recruiting 111 elderly subjects this past year for pilot studies by 3 junior faculty. Patients meeting study criteria will be identified using record review and e-mailed/mailed letters describing the study (after HIPAA waiver). Posters/handouts will be placed strategically at D-H. Colleagues will give information materials to patients requesting permission for contact by the study research assistant. With respect to the qualitative component, the PI will recruit 6 clinicians (from 87 in the provider network) to participate in interviews. Dr. Bartels will use the CHA's extensive aging services network to recruit 4 leaders of aging services organizations for study participation.

FIGURE 2: STUDY OVERVIEW



Selection Criteria: Focus groups, interviews, and usability testing will target English-speaking obese older adults (age≥65years and BMI ≥30kg/m^2[17] or waist circumference ≥88/102cm[85] in females/males). Excluded from eligibility are adults with severe mental or life-threatening illness, dementia, substance use, history of bariatric surgery, suicidal ideation, unable to provide consent/perform measures, or residing in a nursing home. Aim 1a provider interviews will target English-speaking, licensed, outpatient, primary care clinicians and community aging service program directors. Older adult participants in Aims 2 & 3 will require the presence of home Wi-Fi high-speed internet, medical clearance, have less than a 5% weight loss in the past 6 months, and be without advanced co-morbidity, exercise restrictions[88] or involvement in other research studies.

Screening/Consent: Subjects expressing interest will be mailed/emailed forms, evaluated by chart review to confirm eligibility, and those meeting criteria invited to an RA-led session to verify final eligibility, review and complete consent forms, and answer queries. Competence for consent will be assured by: no diagnosis of dementia (all Aims) and a Callahan score ≥4 (Aims 2 & 3). Written consent will be obtained before enrollment. The RA will obtain screening/baseline measures, and provide a list of contact details (see Human Subjects).

Aim 1b (*Adapt Amulet*)**: Adapt a novel mHealth device (Amulet) to assess geriatric functional measures in a sample of older, obese adults**: Amulet will be modified to measure functional outcomes (activity type, strength, gait speed) in older adults supporting MOWI's exercise component using self-monitoring and feedback. This device (Figure 3) provides an adaptable platform for remote sensing and health behavior change. I chose Amulet due to its potential for team science and as a ecologic momentary assessment system[96]. It measures more about human activity unlike devices[82,97] that measure steps, expenditure, or sleep[81,98,99]. Custom body-area health network applications measure, monitor and provide continuous, secure user feedback[100]. The prototype wrist-worn device does not rely on other devices (ie: smartphone) to function. Battery life will likely exceed 7 days. The Amulet display provides personalized programmable reminders (blinking lights, textual display, or vibration) and audio-visual feedback to allow goal attainment. A 9-axis gyroscope, accelerometer, and magnetometer integrates sensors capturing motion, speed, isometric exercise data and activity type (sedentary, walking, running). Low-energy Bluetooth 4.0 can connect with other nearby devices. A mini-USB port and micro-SD card will allow for a 2-way data transfer.

Dr. Kotz's Amulet team will develop and configure applications assessing: steps/distance; strength; activity type; activity feedback. Objective measures will be validated with Amulet. Amulet will sample data and detect stepping motion using algorithms ascertaining activity type[101,102] and step counts[103]. Distance is calculated as steps × distance/step. Upper limb strength will be assessed using sensors placed on a Thera-

band[104] handle connected to a strain gauge placed in series reading the combined force experienced using an analog-to-digital converter[105], communicating back to Amulet.

Usability evaluations during technology deployment will ensure a user-centered design, using videotaped sessions to enable careful review by the development team. Open-ended semi-structured interviews to the first 5 subjects will consist of subject-initiated tasks involved in Amulet's operation. Continuous commentary (Think Aloud usability method[109,110]; see Appendix) with non-verbal/verbal reactions will be used to evaluate Amulet's ease of use, complexity, and design flaws. Subjects will rate their confidence in using the system (see Appendix). A semi-structured approach will be employed including questions such as: What are helpful formats for feedback messages?; What types of Amulet data will be most useful?; How can mHealth be of maximum utility to users?; What are the highest priorities for feedback? Adaptive testing will be performed as it is difficult to fully develop messages prior to pilot testing.

Aim 1 informing future work: Focus groups, interviews and usability testing will be used to create the intervention manual, adapt the Amulet, and optimize Aim 2 (and to the Amulet/Telehealth teams, allowing refinement prior to integration into future cohorts and tailoring content to meet older adult needs. Formative mixed methods will be used to identify and address design and content flaws and unanticipated challenges as part of a critical feedback loops using staged, iterative, usability testing.

Recruitment and Retention Strategies

Participants will be recruited from referrals from Family Medicine/General Internal Medicine providers (Primary Care), providers from the Dartmouth Weight & Wellness Center, and community members attending the Dartmouth Center for Health and Aging (DCHA). I will inform clinicians of Family Medicine and General Internal Medicine and the staff at the Weight & Wellness Center of the proposed study during section meetings. Dr. Bartels has an extensive network of community-care providers and will send e-mails/letters to the CHA's listserv and mailing list requesting participation. Posters will be placed in each examination room, in the patient waiting areas and in common areas of the DCHA. All posters will have been pre-approved by DHMC patient/family advisors and the Committee for the Protection for Human Subjects. Additionally, postings in the DCHA quarterly newsletter, the DHMC weekly D-H Today online bulletin, the weekly Geisel School of Medicine at Dartmouth newsletter, and electronic mailing lists will promote the study. We anticipate advertising in the local newspaper as well. A dedicated phone number and e-mail will be assigned to this study.
Patients will be identified from the PI's clinical practice group at D-H, word of mouth, or other means as indicated below. We will also identify prospective individuals fulfilling basic eligibility criteria after obtaining a HIPAA waiver for electronic record review from the Committee for the Protection of Human Subjects. A pre-assessment eligibility would be performed to limit the burden on patients should they be ineligible after full informed consent for the requisite aims. This will allow the investigators to query our electronic medical record and if necessary send targeted messages and/or letters to individuals that may possibly qualify for this study. If needed, the study staff will send a letter to prospective individuals requesting their involvement either by mail or email (through the electronic medical record). This letter will describe the study and provide contact information for those interested. The CTO will also have details of the study. Any individuals that have expressed interest will be contacted by the team by phone or by email which will be the most preferable method of communication. A pre-screening questionnaire or electronic link to RedCAP (See below) or by phone will be mailed/emailed to participants (depending on patient preference).
As part of Aim 1a, eligible patients will be asked to participate in qualitative focus groups and individual semi-structured interviews with a member of the team. It is anticipated that the focus group will occur 4-6 weeks after interest is expressed. The investigators will perform four separate patient focus groups. Semi-structured interviews will take place for clinicians and community leaders of health and senior centers. At the time of communication, the consent form will be sent to these individuals for review (paper or electronic) and if they agree to the terms of the consent, the individuals will attend these sessions at a mutually convenient time for the study participants and the Research Team. A reminder letter will be sent either via myDH (through the electronic medical record) by the PI, and/or a hard copy letter to the patient's address.
As part of Aim 1b, eligible patients will be asked to attend the DCHA to confirm eligibility and informed consent process by the RA/PI (See Section on *Informed Consent Procedures* for Full details). Those ineligible will be informed by the team and any information will be destroyed. We anticipate that eligibility to study onset will be roughly 4-6 weeks after screening.
As part of Aim 2 and 3 (including the pre-pilot Aim 2), eligible patients will be asked either to attend a baseline visit with the RA or PI at the DCHA to confirm study full eligibility for measurements and full informed consent process by the RA/PI (See Section on *Informed Consent Procedures* for Full Details*)*. Those ineligible will be informed by the team and any information will be destroyed. We anticipate that eligibility to study onset will be roughly 4-6 weeks after screening. The patient's primary care provider will provide medical clearance prior to study enrollment and sign a paper or electronic form allowing the individual to undergo this intervention. They will be kept informed of any abnormal symptoms or problems throughout the study.

The investigators recognize that this intervention may lead to attrition. To reduce the risk of participant drop-out, participants will be reminded of sessions with a phone call, e-mail, and Amulet messaging reminder from the RA. Individuals will be compensated with sandwiches/snacks plus $25 gift card for the focus groups of the qualitative aim (Aim 1a), $25 gift card for the subject semi-structured interviews, a nominal $10/hour payment for the prevalidation phase of Aim 1b (cash, gift-card), a $25 gas card each for Aim 1b, $100 for completing >80% of the visits and assessments for the three-month program (Aim 2) - $25 per assessment, and $200 for completing >80% of the visits and assessments at 6-months (Aim 3). Payment will be made at study conclusion according to institutional policies. They will also receive a fixed schedule of items (pens, notepads, thank you cards) to recognize their participation to date. Participants will have the option of declining such incentives at any time. We will provide a $25 gas card or equivalent for each visit (Aim 4).

No involvement of special vulnerable population such as fetuses, neonates, pregnant woman, children, prisoners, institutionalized individuals or others who may be considered vulnerable will be included in this study. The study will be a single-arm study and there will be no assignment to a study group for this study.

Retention

We recognize that attrition rates in obesity studies range between 25-50%. For Aim 1a (qualitative studies), we will target 4 focus groups of 6-8 individuals (24-32 individuals total), 6-8 individual semi-structured interviews, 6 primary care clinicians, and 4 community leaders for a maximum total of 50 individuals. For Aim 1b, we anticipate recruiting 75 individuals for a target of 60 individuals. Conservative estimates suggest that 14 individuals need to be recruited to allow for 16 individuals for Aim 2 at study conclusion. For Aim 3, our target is 40 individuals. We anticipate recruiting 53 individuals. We believe that these targets are feasible with our local population. We anticipate recruiting individuals in one wave for Aim 1, two waves for Aim 2, and in 4 waves for Aim 3 to reach target enrollment and completion. Should we exceed target enrollment and completion, we will continue gathering measurements on all individuals. With the new arm (MOWI-P), we anticipate recruiting an additional 16 subjects. For Aim 4 (Weight Maintenance), we anticipate recruiting 60% of each of the original sample for Aim 2 (ie: 4 waves @ 8 = 32 x 0.6 = approximately 19 subjects).

STATISTICAL DESIGN AND POWER

Aim 1 (*Qualitative assessment*) will use mixed-methods to adapt Amulet and MOWI for use in rural older obese adults.

Aim 1b (*Adapt Amulet*): *Adapt Amulet to assess functional measures*: Agreement/reliability for upper/lower strength (Thera-bands and STS), gait speed, and steps will be calculated. Descriptive statistics will outline distributions, mean differences/ ratios assessing Amulet's measures to corresponding steps, speed or strength, and for usability testing. Relative/absolute test-retest reliability of mean differences between test/retest using 95% confidence intervals and standard error of mean to examine bias and intra-class coefficients will be reported. Paired t-test will test for bias. Scatterplots and Bland-Altman plots for miscalibration will be viewed, and a relation of variance to mean (data heteroscedasticity) to assess agreement between measures.

Data and Safety Monitoring Plan

Per the instructions for the "Human Subjects" section of PHS-398/SF424 (R+R) the proposed study intervention could have harmful effects but does NOT meet the criteria for an NIH-defined Phase III trial.

To ensure participant safety, data integrity and validity, the Research Assistant will meet with the Principal Investigator monthly, and will be responsible for reviewing the following: number of subjects completing the protocol; subject withdrawal and sources of data loss; any serious or minor adverse consequences and actions taken to remedy the issue; new, timely information that could impact efficacy and/or safety of the program or procedures. The meeting reports will be forwarded to the Committee for the Protection of Human Subjects at the time of annual review and serious events will be reported per institutional regulations.

The current intervention is not an experimental agent and its proposed risk to individuals is likely considered low. We anticipate that there will be a low risk of adverse medical events associated with this intervention. A physician will be available on the premises during all intervention sessions and monitor patient progress and/or adverse events during each session and be responsible for monitoring the data and safety for this proposal. However, we intend on establishing an independent data safety monitoring process that will include an independent data safety monitoring board (DSMB). The committee will consist of experienced researchers in the Department of Medicine and The Dartmouth Institute at the Geisel School of Medicine at Dartmouth. Such members will consist of researchers who are not involved in the development or execution of this proposal. Per institutional policies, no investigators will have any conflict of interests with or financial stakes in the research outcome. This independent board will follow the policy for data and safety monitoring published by NIH and be responsible for reviewing the following information: adverse consequences (whether serious or minor) to any subject and actions taken to remedy the problem; data quality, completeness, timeliness; performance of the study site; reviewing the entire IRB-approved study protocol, manual of procedures with regard to safety, recruitment, intervention, data management, quality control, analysis and informed consent documents with regard to applicability and readability; recruitment and retention; adherence to protocol; maintenance of confidentiality; external factors impacting safety or ethics of the study; and new or evolving information regarding the expected efficacy and/or safety of the MOWI intervention. Additionally, the DSMB will review the study in relation to intervention effects, gender and minority exclusion; propose appropriate analyses and periodically review developing data on safety and endpoints; consider the rationale semi-annually for continuing the study; review and make recommendations on proposed protocol changes during the trial. All recommended changes to the protocol will be adhered to by the PI. The board will identify relevant data parameters and the format of how the information will be regularly reported. Written reports of each meeting will be sent to the program officer and additional reports as needed, in addition to providing timely advice on issues regarding data discrepancies. They will review manuscripts of trial results. In addition, they will recommend subject recruitment be initiated after receipt of a satisfactory protocol and/or postpone recommendations for initiation of subject recruitment until after the receipt of satisfactory revised protocols. Summary reports of the meetings will be sent to the CPHS at the time of annual reviews. The monitoring committee will ensure safe and effective conduct of the intervention and recommend conclusion of the intervention when significant benefits or risks have developed or the intervention is unlikely to be concluded successfully. All monitoring will be timely and effective. Data from the Research Assistant and Biostatistician will be forwarded to the DSMB for review (and to the Program Officer upon request). The DSMB will conduct reviews of the study every 6 months.

All information will be kept confidential during all phases of the intervention, including monitoring, preparation of interim results, review and response to monitoring recommendations. Monitoring will also consider external study factors when interpreting data, including scientific or therapeutic developments that can impact participants. The results of the trial will be forwarded upon publication of its results to all subjects at the conclusion of the intervention. The team will also provide the subject's healthcare providers with appropriate information, as needed, concerning the individual.

Adverse Event Reporting

Serious, unexpected adverse events (SAE) related to study participation are anticipated to be rare. Study personnel will be trained to report all adverse events. In addition, screening for adverse events potentially related to the study intervention will occur during the routine administration of study assessment measures. These interview-based indicators will augment required SAE reports by study personnel, including specific items in the assessment interviews evaluating episodes of muscle or fall-related injuries, unexpected medical events, medical emergency room admissions, medical hospitalizations, or unplanned medical clinic

visits. If an SAE occurs, the PI will report the event to the Dartmouth CPHS using the CPHS Adverse Event Form, to the DSMB, and to the NIA Program Officer within 10 days of the study's knowledge of the SAE (if unanticipated) unless otherwise requested by the DSMB. The PI, in consultation with co-investigators and others, as needed, will review the adverse event report and gather other information as needed to investigate the event and determine the need for subsequent action. Any subsequent action will be documented and reported to the CPHS. In addition, any SAE will also be reported to the NIH program officer and they will be informed of any actions taken by the CPHS as a result of its continuing review. The CPHS will review each reported adverse event to determine whether: the participants in the study should receive additional information related to continuing their participation; the protocol, study plan or consent form should be modified; or the study should be temporarily suspended. If the CPHS determines that some action in response to the adverse event is necessary, the CPHS will promptly inform the PI. All deaths will be reported in an expedited manner, normally within 24 hours of the study's knowledge. The report of death will also be submitted to the NIA Program Administrator and to the CPHS and to the DSMB Chair.

CONSENT TO TAKE PART IN RESEARCH

Dartmouth-Hitchcock Medical Center and Dartmouth College

Study title: **Mobile Obesity Wellness Intervention in Rural Older Adults with Obesity Aim 1B-Theraband Multiday Study**

Principal Investigator: John A. Batsis, MD

You are being asked to take part in a research study. Taking part in research is voluntary.

Your decision whether or not to take part will have no effect on the quality of your medical care. Please ask questions if there is anything about this study you do not understand.

What is the purpose of this study?

This component of the study will evaluate one specific component using a Resistance Exercise Band by testing the device's ability to capture data with repeated exercise measurements.

Will you benefit from taking part in this study?

You may or may not personally benefit from being in this research study. We hope that the information we gather will be helpful in advancing our research to help adults who need to lose weight in the future.

What does this study involve?

Your participation in this study may last up to one hour for three specific sessions. During this time, we will provide each person with a mobile health device (Amulet) that was designed by Dartmouth researchers. We will also be videotaping you during this time. We shall measure the following and relate it to the information that the Amulet measures:

- Strength using 'thera-bands' which are resistant bands that are helpful for strength
- Completion of demographic and usability questionnaires that could help us improve this technology

What are the options if you do not want to take part in this study?

You do not have to take part in this study if you do not wish to nor do you need to take part in this study to receive medical care or treatment.

What are the risks involved with being enrolled in this study?

We cannot be sure how your body may respond to the movements promoted using the TheraBand. Unknown problems may happen. Problems are likely to be small, such as a minor side effect such as muscle strains. It is unlikely using the resistance bands that any other side effects will result from their use. You should report any problems to your doctor or to the director of this study**: John A. Batsis, MD, 603-653-9500.**

Other important items you should know:

• **Leaving the study:** You may choose to stop taking part in this study at any time. If you decide to stop taking part, it will have no effect on the quality of medical care you receive. Any equipment must be returned to the study director. The investigator reserves the right to stop the study participant from continuing without participant consent.

• **Number of people in this study:** We expect 30 people to enroll in this study here

• **Funding:** The National Institutes on Aging and the Department of Medicine provides funding to Dartmouth College for this research.

• **Product Development:** If the results of this research are used to develop a product sold for a profit, you will not share in the profit.

How will your privacy be protected?

The information collected as data for this study includes: any demographic or personal data will be obtained from questionnaires administered to you and from any videotaped information. No information will be obtained from the Dartmouth-Hitchcock electronic medical record. Study data will be maintained for a period of six (6) years or longer if needed for other purposes. At that time, data will be deleted from computer hardware or shredded on the DHMC campus.

We are careful to protect the identities of the people in this study. We also keep the information collected for this study secure and confidential. All data will be kept in a locked office, and all computer data will be on a password protected encrypted computer or server as outlined by the Committee of Protection of Human Subjects. The information collected for this study will be used only for the purposes of research as stated earlier in this form.

Who may use or see your health information?

By signing this form, you allow the research team to use any supplied health information and give it to others involved in the research. The research team includes the study director plus others working on this study at Dartmouth-Hitchcock Medical Center and elsewhere.

The information collected for this study may be used by researchers or officials of the following institutions.

- Dartmouth College
- Mary Hitchcock Memorial Hospital
- Dartmouth-Hitchcock Clinic
- Dartmouth-Hitchcock Medical Center
- Mayo Clinic Rochester
- University of New Hampshire, Durham
- Committee for the Protection of Human Subjects

All information that is collected will be de-identified outside of Dartmouth. During this study, information that identifies you may be given to some organizations that may not have a legal duty to protect it. These organizations may also use and disclose your information for other purposes.

Your permission to use your information for this study will not end until the study is completed. During this study, you and others who take part in the study may not have access to the study data. You may ask for study data once the study is over.

It is possible for a court or government official to order the release of study data including information about you.

What if you decide not to give permission to use and share your personal health information?

If you do not allow use your supplied information for this study, you may not take part in this study. If you choose to stop taking part in this study, you may cancel permission for the use of your information. You should let the researcher know if you want to cancel your permission. The study team will assist you in putting your wishes in writing. Information collected for the study before your permission is cancelled will continue to be used in the research.

What about the costs of this study?

There are no costs charged to the participant

Will you be paid to take part in this study?

As a token for completing this session, study participants will be provided $10 token as an appreciation for participation. If you take part in this study, the sessions will be done only for research purposes and paid for by the sponsor.

Whom should you call with questions about this study?

If you have questions about this study or need to report a study related injury, you can call your doctor or the research director for this study: Dr. John A. Batsis, MD, (603) 653-9500 normal business hours. If Dr. Batsis is not available, all concerns should be addressed by your primary care provider's office who will be available to answer your questions during normal business hours. An emergency contact number is (603) 650-5000, the main hospital number.

If you have questions, concerns, complaints, or suggestions about human research at Dartmouth, you may call the Office of the Committee for the Protection of Human Subjects at Dartmouth College (603) 646-6482 during normal business hours.

CONSENT

I have read the above information about:

Mobile Obesity Wellness Intervention in Rural Older Adults with Obesity

and have been given time to ask questions. I agree to take part in this study and I have been given a copy of this signed consent form.

Participant's Signature and Date / PRINTED NAME

Researcher or Designee Signature and Date PRINTED NAME

DARTMOUTH-HITCHCOCK MEDICAL CENTER

RESEARCH PROJECT INFORMATION SHEET

This research project is being conducted by John A. Batsis, MD, from the Department of Medicine at Dartmouth-Hitchcock Medical Center. It is a study that will validate core components of the Amulet mHealth device with standard instruments of activity, steps, strength and other application-based features. This will allow researchers to gather information in determining its validity and refine it for future implementation into study protocols.

Your participation is voluntary. You may choose to not participate or to participate in only parts of the validation exercise

If you agree to participate, we will use only basic demographic information that you provide us. No information will be obtained from your medical record.

The information collected will be maintained confidentially. Names and other identifying information will not be used in any presentation or paper written about this project. Data collected for this study will be maintained until the study is completed. The information collected for this study will be used only for purposes of research as stated earlier in this form. Research data may be shared with officials of Dartmouth College, Dartmouth-Hitchcock, and others involved in the oversight of this study as permitted by law. Not participating in this study does not in any way impact the care you will receive here at Dartmouth-Hitchcock.

As a token for completing this session, study participants will be provided with a nominal monetary token at $10/hour, up to $20, for this part of the study in the form of a gift card or equivalent. Participants will need to supply their name, address and email to the study team.

Should you wish NOT to participate in this study or if you have questions about this study, please check this box for our staff to discuss this with you. ☐

Questions about this project may be directed to:
John A. Batsis, MD
Associate Professor of Medicine and The Dartmouth
Institute for Health Policy & Clinical Practice
MOWI@hitchcock.org
603-650-5000