Study Title: Health Coaching & Technology in a Weight Loss Center

NCT#: NCT03309787

Date: 6 May 2019

Documents: Study protocol (includes statistical analysis plan)

SPECIFIC AIMS

The obesity epidemic affects 37% of adults[1] and leads to major morbidity[2], absenteeism[3], mortality[4] and high health costs[5]. Effective obesity therapy goals are to attain weight loss through healthy lifestyle changes[6], reduce cardiac risk[6], and prevent chronic illness. Integrating practical and sustainable approaches in obesity care can improve short- and long-term outcomes[6]. Nurse or physician-delivered Intensive Behavioral Therapy (IBT) using the 5 A's (ask, advise, assess, assist, arrange)[7,8], motivational interviewing[9,10], and goal setting[11] is the standard behavioral treatment for achieving a healthy weight and sustained lifestyle changes. In recent studies, trained health coaches have successfully used IBT to assist patients in improving health outcomes[12,13].

Despite the potential benefits of IBT[10], access to trained providers is notably limited for rural adults[14,15] who face high obesity rates and related morbidity[16]. Barriers to accessing evidence-based obesity care include the need to travel distances for clinic visits, absence of local specialized obesity-related services, and the lack of trained staff in remote areas[17,18]. Telehealth offers practical and cost-effective solutions in overcoming such accessibility barriers[19] to obesity treatment and health promotion approaches. Yet, even when patients achieve weight loss, maintaining their weight is difficult[20]. Wearable monitors using adaptable sensors offer health care providers a means to obtain real-time information over time. Providing biometric measures and real-time data for motivation and feedback can augment standard obesity strategies and be delivered by health coaches[12,13].

Our goal is to identify effective, accessible, and sustainable means for improving long-term lasting weight loss, using scalable health-promoting devices in rural obese adults. *This proposal* aims to conduct a study of remote health monitoring using *Amulet*[21], a Dartmouth Computer Science developed mobile health (mHealth) device, incorporated into usual health coach visits and delivered in patients' homes using video-conferencing. *Amulet* provides an adaptable platform for behavioral change; unlike commercial devices, it uses an open source programming model capable of testing an array of other strategies and non-proprietary devices [21]. We previously described the challenges in delivering obesity care[22,23] and promises of virtual modalities in overcoming geographic barriers to care[24]. However, use of technology in isolation, without human interactions, is unlikely to lead to success[25]. Hence, we propose an *eHealth-delivered health coaching obesity intervention* that delivers IBT by trained health coaches using telehealth and *Amulet* to enhance behavioral change. Our *rationale* is to pilot the intervention with 30 Dartmouth-Hitchcock (D-H) Weight & Wellness Center patients to determine its potential effectiveness on weight loss, physical function, self-reported health, and care pathways in a specialty obesity clinic. If effective, the program will enhance in-home care and be disseminated to remote, low resource areas to rural obese adults lacking access to care. We will address the following *Specific Aims:*

Aim 1: Evaluate the feasibility and acceptability of an eHealth-delivered (remote monitoring and video-conferencing) health coaching obesity intervention in a rural, academic, specialty obesity clinic.
H1: An eHealth-delivered health coaching obesity intervention using video-conferencing and remote monitoring is: a) feasible (>80% of subjects will enroll; >80% of enrollees will complete the intervention); and b) acceptable in rural adults seeking treatment for obesity (using semi-structured interviews and Yip's Telemedicine survey).

Aim 2: Assess the potential effectiveness of an eHealth-delivered health coaching obesity intervention in improving weight, physical function and self-reported health in adults with obesity.
H2: Measures of improved weight (>5% loss), physical function (6-minute walk) & self-reported health (patient-reported outcome measurement system-PROMIS) will allow reliable estimates for designing an evaluative trial.

Aim 3: Ascertain the extent to which the intervention works within an existing specialty obesity clinic on implementation outcomes such as workflow adoption, organizational change and compatibility.
H3: Implementation will be adopted into the workflow (qualitative interviews and Haug's measure), lead to organizational change (General Organizational Index) and be perceived as having value (Willingness to Pay).

A transdisciplinary team will execute a pilot study for conducting a Type 2 hybrid effectiveness-implementation design[26] of this T3/T4 intervention. *Expected outcomes include* its feasibility and acceptability, the value added to specialized obesity care by improving outcomes, and the potential for eHealth integration into practice. The pilot builds logically to an R01 grant addressing critical gaps in pragmatic obesity strategies to improve health and care delivery pathways to with limited access to specialty care for long-term weight loss.

SIGNIFICANCE

Standard obesity advice within primary care is often ineffective in the long-term[27,28], which can amplify the morbidity observed in this population. The need to refer to specialty obesity care is needed[6], yet access to care is lacking, especially in rural areas[24]. Most evidence-based practices require busy clinicians to add visits[29] for direct, in-person IBT. These pathways are impractical due to workforce shortages, time constraints, and caseloads[30,31]. Health coaches can assist in mitigating such challenges by effectively delivering IBT at higher

value[13], allowing clinicians to focus on other issues of high complexity. Our *eHealth-delivered health coaching intervention* can potentially surmount the problem of delivering obesity interventions in busy practices, while supporting remote activity monitoring. mHealth is a promising adjunct to conventional therapies that improve adherence using automated health behavior change[32-39]. It can overcome the limits of counseling which heavily rely on self-motivation[40]. Yet, devices alone insufficiently achieve sustained engagement in health behavior change in the absence of facilitation and support by coaches[41]. Emerging telehealth systems[42,43] can fill a coverage gap[44,45] by providing rural patients opportunities to access high quality specialty obesity care[46-49]. This modality can address the access and distance barriers faced by rural adults[50]. *The project conceivably may alter care delivery by offering innovative and practical strategies to improve patient, system and practice-based outcomes.* Our strategy aligns with the NIH Strategic Obesity Plan, the Institute of Medicine's call for Telehealth Research[51], and Medicare's population-health vision for improving access and delivering high-value care to an at-risk population[52] with obesity in rural areas[46,53]. The results will inform a future effectiveness study designed to improve outcomes and health of an emerging demographic with obesity[54], all which may reduce health costs[55]. Our approach may satisfy a significant service mismatch of improved health care quality[44,45] while redefining novel delivery processes for achieving efficiencies in an overburdened system.

INNOVATION

The proposed *eHealth-delivered health coaching obesity intervention* is innovative because it proposes to:

- Conduct the first pragmatic pilot using rural obese adults assessing health coach delivered IBT augmented by a remote monitoring device in a home-based program, with potential for scalability to other systems;
- Move beyond conventional methods of research-based obesity interventions using in-person clinician visits that integrates telehealth and mHealth into health coach based care to facilitate behavioral weight loss;
- Advance health promotion science using home-based Telehealth in rural areas allowing its incorporation into a real-world setting to support long-term adherence to lifestyle change;
- Use a unique mHealth approach with open-source application coding and a future basis for ecological momentary assessment extending beyond commercial devices that are at risk for becoming obsolete;
- Incorporates emerging technology into a comprehensive care model in obesity care;
- Create collaborations with mHealth technologists and telehealth experts allowing for translation of innovative laboratory-based technologies into practical applications for medically complex populations in rural settings;
- Use mixed-methods to identify factors leading to behavioral change using technology in the study population;
- Apply lessons learned from this study to other disadvantaged, low-income disparity populations.

APPROACH

Study Design: A single-arm, mixed-methods study that will adopt a pragmatic delivery approach to: a) assess the intervention's feasibility/acceptability; b) investigate the potential effectiveness; and c) ascertain outcomes of implementation. We will recruit 30 obese patients from the D-H Weight & Wellness Center (DH-WWC) to participate in a 12-week pilot that includes monthly assessments and qualitative semi-structured interviews.

Study Site: D-H, in Lebanon, NH, serves 1.5 million persons in New Hampshire and Vermont. Demographics mirror a typical rural New England town (95.4% Caucasian[56]). The DH-WWC is a specialty referral-based obesity clinic whose aim is to improve the health and wellness of patients with obesity. The clinic uses the Epic electronic health record (EHR), and has rooms for interviews, assessments, and video-conferencing.

Selection Criteria: For the purposes of this pilot, we limited inclusion criteria to: community-dwelling, English-speaking patients (age 18-65 years; BMI ≥30kg/m^2) with home Wi-Fi high-speed Internet and clearance from their clinician. Patients with dementia (lacking consent), bariatric surgery, severe mental or life-threatening illness, substance use, or exercise contraindications[57] are excluded as these criteria interfere with the possible efficacy of the intervention. Future pragmatic trials will relax the criteria to allow a pragmatic interpretation.

Study Population/Recruitment: The DH-WWC evaluated 315 new patients in 2016 (current waitlist ~3 mo.). As research director, the PI has access to subjects. To meet a target of n=30, ~10% of subjects would need to be enrolled. Staff will receive an overview at a weekly meeting. A research assistant (RA) will screen booked subjects by EHR review and identify eligible subjects. At the visit, the RA will proceed with a 2-way discussion focusing on the study goals, answering queries, providing contact details, and obtaining consent and baseline measurements. A Callahan score[58] ≥4 and no EHR diagnosis of dementia will assure competence for consent.

Retention: To minimize dropouts, we will provide feedback (ie: weight), frequent contacts, study incentives for assessments, and assertive outreach with the primary care provider (to engage partnerships). We anticipate that the duration of the pilot and patient motivation will lead to favorable retention.

Baseline Measures: We will review EHR records for: age, race, co-morbidity, education, medications, and habits. We will ask about social support[59,60] at baseline.

Intervention Description: The pilot comprises of five components listed below which provide access to specialty obesity care to rural obese adults, and enhance it with technology (telehealth and remote monitoring):

a) *Team-based care:* As in other US-based specialty obesity centers, the DH-WWC is an interdisciplinary, team-based, specialty clinic overseeing each patient's care: a physician or associate provider formulates a medical plan and counsels on obesity's adverse effects; a nurse assists in triaging medical concerns and manages drug therapy; a psychologist evaluates the patient for barriers to weight-loss such as untreated or underdiagnosed mental health disorders; and a dietician counsels the patient on nutrition/energy needs for achieving weight loss through nutritional therapy. The health coach is supervised by the clinician.

b) *Health coaching*: In the DH-WWC Healthy Lifestyle Program, a health-coach led program plays an integral role in assisting with patient tracking, data gathering, self-monitoring, facilitating educational sessions and connecting patients and families with local resources. Coaches are trained in avoiding weight bias and, undergo specific motivational interviewing training, use shared decision-making, and reframe obesity as a chronic disease. They complete select wellness coaching programs, pass certification exams and serve as the program anchor, facilitating care coordination, executing treatment plans and setting SMART goals (specific, measurable, agreed upon, realistic, time-based). Content is based on national guidelines[6].

c) *Telehealth*: Weekly coaching sessions will be conducted by video-conferencing in lieu of in-person visits. Dr. Pletcher's telehealth team will configure an Android tablet (using the HIPAA compliant software, Vidyo[61]) to the subject's home intranet remotely, and will provide training to both patients and staff. The interface has easy access using simple taps. The coach's computer will have similar software. Added coaching support is offered ad-hoc, as in usual care, using on-demand connectivity. Subjects will be located in their homes.

d) *Messaging:* Currently, coaches send messages via the Epic integrated EHR patient portal, used in >40% of US medical centers. 'Push' message notifications to the tablet's face screen are received indicating a message is waiting for review. Within 48 hours, coaches are notified if messages are read, and if not, the coach can contact the patient by phone. Communication is confidential, documented, and tracked.

e) *Remote Monitoring*: The *Amulet* is an mHealth wrist-worn device with remote sensing and self-monitoring capabilities, functioning independently of a smartphone (battery life lasts >9 days). A 9-axis gyroscope, accelerometer, magnetometer and sensor captures motion, activity type, exercise, and speed data. As part of Dr. Batsis' K23, *Amulet* applications were developed to measure steps, strength, and activity (sedentary, walking, running). Two-way data transfer occurs via a micro-SD card, or low-energy Bluetooth 4.0 to a secure cloud-based repository that is accessible to the team. Predetermined one-line automated scripts (if goals are not met), prompts, and asynchronous messaging can be sent by staff. Programmable reminders (blinking lights, text, haptic buzzer) and audio-visual feedback allow the *Amulet* to celebrate goal attainment.

Outcomes Measures: These were chosen based on their validity, brevity and presence within the HER:

Table 1: Study Variables and Objective Outcome Measures

Aim 1: Feasibility and acceptability of an eHealth-delivered health coaching obesity intervention						**Timepoint**			
Domain	**Outcome/Co-Variate**	**Instrument**	**Adm**	**Length**	**Source**	**0**	**1**	**2**	**3**
Feasibility	Recruitment/Retention	Eligibility, enrollment, dropout data	RA	---	Study Log	✓	✓	✓	✓
	Engagement/Assessments	>80% attend + complete sessions	RA	---	Study Log	✓	✓	✓	✓
Acceptability	Satisfaction of Intervention	Semi-structured interview	RA	30 min	Participant				✓
	Patient Satisfaction	Yip Telemedicine questionnaire[62]	Self	15 item	Participant				✓
Aim 2: Potential effectiveness in improving weight, physical function and self-reported health						**Timepoint**			
Domain	**Outcome/Co-Variate**	**Instrument**	**Adm**	**Length**	**Source**	**0**	**1**	**2**	**3**
Participant Level Outcomes	Anthropometry	Weight/body mass index	CS	---	Participant	✓	✓	✓	✓
	Physical function	6 minute walk test (6MWT)[63]	CS	6 min	Participant	✓			✓
	Diet/Exercise Measures	REAP-S[64]/IPAQ[65]	Self	16/7 items	Participant	✓			✓
	Subjective Health	PROMIS general health 10[66]	Self	10items	Participant	✓			✓
	Readiness to Change	URICA[67]	Self	12 item	Participant	✓	✓	✓	✓
Aim 3a: Ascertain the extent to which the intervention works on implementation outcomes						**Timepoint**			
Domain	**Outcome/Co-Variate**	**Instrument**	**Adm**	**Length**	**Source**	**0**	**1**	**2**	**3**
Adoption	Workflow adoption	Qualitative Interviews	RA	30 min	Staff				✓
	Staff adoption	Evidence-based practice adoption[68]	RA	12 item	Staff				✓
Implementation	Organizational Change	General Organizational Inventory[69]	RA	12 item	Staff				✓
Compatibility	Patient Perception of Value	Willingness to Pay[70]	Self	2 item	Participant	✓			✓

ADM- Administration; CS – clinical staff; IPAQ – International Physical Activity Questionnaire; PROMIS: Patient Reported Outcome Measures Information Systems; RA: research assistant; REAP-S: Rapid Eating Assessment for Participants – Shortened Version; 6MWT: 6-minute walk test; URICA: University of Rhode Island Change Assessment: Short Form for Physical Health Behavior State.

Aim 1: Evaluate the feasibility and acceptability of an eHealth-delivered (remote monitoring and video-conferencing) health coaching obesity intervention in a rural, academic, specialty obesity clinic.

Feasibility: The following rates will be computed: screened for inclusion (# screened ÷ # potentially eligible); eligibility [# screen positive ÷ # screened for inclusion]; enrollment [# enrolled ÷ (# screen positive & eligible)]; completion (# completing sessions ÷ # enrolled); assessment (# completing all assessments ÷ # enrolled). We will assess entry criteria (reasons for dropout/non-adherence) and time to collect data. Enrollment success will be defined as 30 patients. Adequate retention is defined as a dropout rate of <20%. Completion of >80% of post-study measures will be defined as adequate. Attending >80% of sessions will be considered acceptable. Staff will track equipment, software or technical issues (malfunctions, data loss, hardware) in a journal.

Acceptability*: Qualitative interviews* will ensure the appropriateness of the pilot and its strengths/weaknesses. The RA will conduct, record, and transcribe each 30min interview. Field notes, questions, and themes outlining the content/context allows for codebook development, tailoring it to the subject's needs in the future. Topics include: feasibility, acceptability; missing features; telehealth's impact (including sound/video quality); Amulet's usability and perceived barriers to use; complexity and flaws; strategies for improving compliance; feedback. *Quantitative data* will be measured using the 15-item, 5-point scale (*Telemedicine satisfaction questionnaire*[62]).

Data Analysis: The analysis of Aim 1 is primarily descriptive. Data will be analyzed as follows:

- Qualitative Data: Thematic analysis[71-73] will be conducted by two researchers who will independently read transcripts, and conduct open coding[74]. This enhances research rigor by allowing for different viewpoints[75]. Through data immersion, focused coding using themes identified during open coding permits defined analyses[74]. Codes will be derived *a priori* from interviews, and inductively derived from qualitative data, after which, the query tool will retrieve text by code, reviewed for content, relevance, and prevalence of themes.
- Statistical Analyses: Descriptive statistics (means, medians, proportions, 95% confidence intervals [CI]) will be computed for feasibility/acceptability. Telemedicine satisfaction will be assessed only at 12 week follow-up
- Sample Size Considerations: For the pilot, we estimation the proportion of patients attending and completing 10 of 12 scheduled sessions. If this proportion is 80%, then the half width of the expected 95%CI based on 30 enrolled patients is 14.3%, based on a normal approximation for binomial data.

Aim 2: Assess the potential effectiveness of an eHealth-delivered health coaching obesity intervention in improving weight, physical function and self-reported health in adults with obesity.

Objective & Subjective Participant-Level Outcomes:

- Weight & BMI: Weight will be measured using a Seca 770 analyzer (in clinic) and by the Omron HBF-514 (at home remotely). Target weight loss is defined by >5% of weight. BMI is calculated by Quetelet's formula[76].
- Physical function: *6-Minute Walk (6MWT)*[63] is a cardiovascular fitness surrogate measuring distance (normal 400-700m)[77,78] related to function. A clinically important difference is 50-55m[79].
- Diet/Exercise: The Rapid Eating Assessment for Participants (REAPS)[64] is a 16 item survey (score 13-39) of diet habits. The 7-item international physical activity questionnaire (IPAQ) measures health-related activity[65].
- Subjective Health*:* The 10-question, non-proprietary *Patient Reported Outcomes Measurement Information Systems General Health-10* (PROMIS)[66] captures physical, mental and social aspects of quality of life.
- Readiness to Change: The University of Rhode Island Change Assessment[67] is a 12 item questionnaire assessing one's stages of change based on contemplation, action, maintenance and pre-contemplation.

Data Analysis: Aim 2 will evaluate potential effectiveness of the intervention on patient outcomes:

- Statistical Analyses: We will assess % weight loss and BMI change (primary outcomes), and change in the 6MWT, REAP-S, IPAQ, PROMIS and URICA (secondary outcomes). Linear/non-linear mixed effects models will evaluate weight, BMI and URICA change over time. To account for repeated measures and variation in trajectory over time, models will include random individual-level intercepts and time trends. A significant coefficient for the mean trend over time will indicate changes in outcomes. All data will be included as the models are robust to data missing at random under the assumptions of a linear mixed model. Paired t-tests will assess the change between baseline and follow-up in 6MWT, REAP-S, IPAQ and PROMIS.
- Sample Size Considerations: This pilot study intends to help develop future studies to evaluate recruitment, feasibility, acceptability and outcomes. Given the longitudinal nature of the data, a key parameter driving the future design is the intraclass correlation coefficient (ICC), a measure of dependence between observations taken on the same person. With 30 participants and a mean of 10 observations/person, we should be able to distinguish between a fairly low ICC of 0.15 versus an alternative of 0.34, based on a one-sample hypothesis test with a significance level of 0.05 and a power of 90%[80]. For the primary outcome of % weight loss, using

a SD of 10.1%, the 95% CI would have half width of 3.6% based on our sample of 30, assuming a normal distribution.

Aim 3: Ascertain the extent to which the intervention works within an existing specialty obesity clinic on implementation outcomes such as workflow adoption, organizational change and compatibility.

Objective and Subjective Adoption, Implementation and Compatibility-Level Outcomes:

- Adoption Domain**:** *Workflow Adoption:* Questions using semi-structured interviews (methods per Aim 1) from the staff's experience with the intervention (whether it enhances/interferes with workflow; sustainability; technical or other difficulties in delivering care) will be explored. *Staff Adoption*: Haug's 12-item *Measure of Evidence-Based Practice Adoption*[68] assesses stage of change, experience, attitudes, organization barriers and strategies to support evidence-based practices (1-5 point scale - strongly disagree to agree).
- Implementation Level: *Organizational Change:* General Organizational Index (GOI)[69] is an interview of 11 domains with a 5-point rating of: program philosophy, commitment, client eligibility and identification, health promotion plan and its treatment, training, process and outcome monitoring, assessment, quality assurance, choice supervision, & penetration. It has reliable inter-rater agreement and internal consistency.
- Compatibility: *Patient Perception of Value*: Two questions will assess *Willingness to Pay (WTP)*[70] – whether they would pay for telemedicine delivery of the intervention in lieu of in-person travel time or cost.

Data Analysis: We will use mixed-methods to analyze data from Aim 3 as follows:

- Qualitative Data: Interview data will be managed and analyzed using *Dedoose* as described in Aim 1.
- Statistical Analyses: Descriptive statistics (means, medians, 95% CI) for adoption, organizational change will be assessed at follow-up only. Changes in WTP will be estimated using a paired 2-sample t-test.
- Sample Size Considerations: For changes from baseline on WTP, there will be 80% power to detect large differences in change from 0.32 to 0.28 times a SD assuming a range of within-person correlations (0.2-0.4).

Data Management: Our team is experienced in pilot delivery, data management/acquisition, and validation procedures including: a) health coach training; b) continuous feedback; and c) final data editing. The PI and co-I's will meet staff regularly, supervise and identify quality control issues early to address them promptly. Non-HER entered measures will be collected by the RA using REDCap[81], a secure web/tablet based data collection tool. The Analytics Institute manages a DH-WWC patient registry who will facilitate data extraction. Interviews will be recorded in duplicate using a digital tape recorder. Records will be kept in a locked cabinet. Identifiers will be assigned at enrollment and kept behind the D-H firewall, with a password protected linked file. Data will be exported to *Dedoose* and *R* for analysis with complete labeling intact (variables, labels, missing values)

Potential Problems/Alternative Strategies: We anticipate that: a) adults may lack technology skills – our team can provide ongoing user support to participants; b) attrition will occur – yet, due to the recruitment of motivated persons and ongoing support[82,83] this will be low; c) minorities will be under-represented consistent with rural New England's demographics - our region's socioeconomic diversity can create a strategy that can be adopted in other regions to enrich the sample with minorities; d) our criteria maximize external validity and limit internal validity used in randomized trials – consistent with pragmatic trials[84]; e) technology advances quickly raising the potential of obsolescence - *Amulet* was purposefully designed for capabilities of advanced capacity; and f)adverse outcomes exist - exercise contraindications and medical clearance are considered with symptoms prompting further evaluation. We do not anticipate an increase in risk with video-conferencing and eHealth. All other elements are components of standard care and hence would not alter the treatment plan.

Study Timeline/Benchmarks to Success: The schedule for the anticipated funding is presented below:

MONTH	1	2	3	4	5	6	7	8	9	10	11	12
Staff Training/Preparation of Site	X											
Recruitment & Enrollment		X	X	X	X	X	X	X	X			
Intervention/Data Management/Analysis			X	X	X	X	X	X	X	X	X	X
Manual Development/R01/Manuscript											X	X

PROPOSED R01 PROJECT GRANT

This knowledge will generate promising data to support the design and submission of an adequately powered randomized trial to the National Institute of Diabetes, Digestive and Kidney (PA16-17-021) evaluating the effectiveness of the *eHealth-delivered health coaching obesity intervention.* The results will permit sample size calculations to detect a range of effect sizes for an eHealth arm (intervention) vs. usual clinic-based care. These methods will allow diverse recruitment across the regional D-H system, and be applied to other sites (ie: primary care) and populations. If effective, we can adapt the pilot to focus on sustainability of weight loss.

LITERATURE CITED

1. Flegal KM, Kruszon-Moran D, Carroll MD, Fryar CD, Ogden CL. Trends in Obesity Among Adults in the United States, 2005 to 2014. *JAMA.* Jun 7 2016;315(21):2284-2291.
2. Gregg EW, Cheng YJ, Cadwell BL, et al. Secular trends in cardiovascular disease risk factors according to body mass index in US adults. *JAMA.* Apr 20 2005;293(15):1868-1874.
3. Andreyeva T, Luedicke J, Wang YC. State-level estimates of obesity-attributable costs of absenteeism. *J Occup Environ Med.* Nov 2014;56(11):1120-1127.
4. Flegal KM, Graubard BI. Estimates of excess deaths associated with body mass index and other anthropometric variables. *Am J Clin Nutr.* Apr 2009;89(4):1213-1219.
5. Finkelstein EA, Trogdon JG, Cohen JW, Dietz W. Annual medical spending attributable to obesity: payer-and service-specific estimates. *Health Aff (Millwood).* Sep-Oct 2009;28(5):w822-831.
6. Jensen MD, Ryan DH, Apovian CM, et al. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. *Circulation.* Jun 24 2014;129(25 Suppl 2):S102-138.
7. Carroll JK, Antognoli E, Flocke SA. Evaluation of physical activity counseling in primary care using direct observation of the 5As. *Ann Fam Med.* Sep-Oct 2011;9(5):416-422.
8. Jay M, Gillespie C, Schlair S, Sherman S, Kalet A. Physicians' use of the 5As in counseling obese patients: is the quality of counseling associated with patients' motivation and intention to lose weight? *BMC Health Serv Res.* 2010;10:159.
9. Mettler FA, Jr., Huda W, Yoshizumi TT, Mahesh M. Effective doses in radiology and diagnostic nuclear medicine: a catalog. *Radiology.* Jul 2008;248(1):254-263.
10. Wadden TA, Butryn ML, Hong PS, Tsai AG. Behavioral treatment of obesity in patients encountered in primary care settings: a systematic review. *JAMA.* Nov 5 2014;312(17):1779-1791.
11. Fitzpatrick SL, Wischenka D, Appelhans BM, et al. An Evidence-based Guide for Obesity Treatment in Primary Care. *Am J Med.* Jul 31 2015.
12. Bartels SJ, Pratt SI, Aschbrenner KA, et al. Pragmatic replication trial of health promotion coaching for obesity in serious mental illness and maintenance of outcomes. *Am J Psychiatry.* Apr 2015;172(4):344-352.
13. Leahey TM, Wing RR. A randomized controlled pilot study testing three types of health coaches for obesity treatment: Professional, peer, and mentor. *Obesity (Silver Spring).* May 2013;21(5):928-934.
14. Geyman JP, Hart LG, Norris TE, Coombs JB, Lishner DM. Educating generalist physicians for rural practice: how are we doing? *J Rural Health.* Winter 2000;16(1):56-80.
15. MacDowell M, Glasser M, Fitts M, Nielsen K, Hunsaker M. A national view of rural health workforce issues in the USA. *Rural Remote Health.* Jul-Sep 2010;10(3):1531.
16. Befort CN, Niaman; Perri, Michael. Prevalence of Obesity Among Adults From Rural and Urban Areas of the United States: Findings From NHANES (2005-2008). *The Journal of Rural Health.* 2012;28:392-397.
17. Gamm L, Hutchison L, Bellamy G, Dabney BJ. Rural healthy people 2010: identifying rural health priorities and models for practice. *J Rural Health.* Winter 2002;18(1):9-14.
18. Goins RT, Williams KA, Carter MW, Spencer M, Solovieva T. Perceived barriers to health care access among rural older adults: a qualitative study. *J Rural Health.* Summer 2005;21(3):206-213.
19. Haugen HA, Tran ZV, Wyatt HR, Barry MJ, Hill JO. Using telehealth to increase participation in weight maintenance programs. *Obesity (Silver Spring).* Dec 2007;15(12):3067-3077.
20. MacLean PS, Wing RR, Davidson T, et al. NIH working group report: Innovative research to improve maintenance of weight loss. *Obesity (Silver Spring).* Jan 2015;23(1):7-15.
21. Molina-Markham A, Kotz D, Peterson R, et al. Amulet. 2014:16-21.
22. Batsis JA, Huyck KL, Bartels SJ. Challenges with the Medicare obesity benefit: practical concerns & proposed solutions. *J Gen Intern Med.* Jan 2015;30(1):118-122.
23. Aleem S, Lasky R, Brooks WB, Batsis JA. Obesity perceptions and documentation among primary care clinicians at a rural academic health center. *Obes Res Clin Pract.* Jul-Aug 2015;9(4):408-415.
24. Batsis JA, Pletcher SN, Stahl JE. Telemedicine and primary care obesity management in rural areas - innovative approach for older adults? *BMC Geriatr.* Jan 05 2017;17(1):6.

25. Batsis JA, Naslund JA, Pletcher SN, et al. Use of a Wearable Activity Device in Rural, Older Obese Adults: A Pilot Study. *Geriatrics & Gerontology International.* 2016.
26. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care.* Mar 2012;50(3):217-226.
27. Wadden TA, Berkowitz RI. Advancing the revolution in the behavioral treatment of obesity. *Obesity (Silver Spring).* Oct 2016;24(10):2029-2030.
28. Tsai AG, Wadden TA. Treatment of obesity in primary care practice in the United States: a systematic review. *J Gen Intern Med.* Sep 2009;24(9):1073-1079.
29. Digenio AG, Mancuso JP, Gerber RA, Dvorak RV. Comparison of methods for delivering a lifestyle modification program for obese patients: a randomized trial. *Ann Intern Med.* Feb 17 2009;150(4):255-262.
30. Mohr DC, Benzer JK, Young GJ. Provider workload and quality of care in primary care settings: moderating role of relational climate. *Med Care.* Jan 2013;51(1):108-114.
31. DesRoches CM, Buerhaus P, Dittus RS, Donelan K. Primary care workforce shortages and career recommendations from practicing clinicians. *Acad Med.* May 2015;90(5):671-677.
32. Geraedts HA, Zijlstra W, Zhang W, Bulstra S, Stevens M. Adherence to and effectiveness of an individually tailored home-based exercise program for frail older adults, driven by mobility monitoring: design of a prospective cohort study. *BMC Public Health.* 2014;14:570.
33. Dobkin BH, Dorsch A. The promise of mHealth: daily activity monitoring and outcome assessments by wearable sensors. *Neurorehabil Neural Repair.* Nov-Dec 2011;25(9):788-798.
34. Darwish A, Hassanien AE. Wearable and implantable wireless sensor network solutions for healthcare monitoring. *Sensors (Basel).* 2011;11(6):5561-5595.
35. Chen KY, Bassett DR, Jr. The technology of accelerometry-based activity monitors: current and future. *Med Sci Sports Exerc.* Nov 2005;37(11 Suppl):S490-500.
36. Carrasco MP, Salvador CH, Sagredo PG, et al. Impact of patient-general practitioner short-messages-based interaction on the control of hypertension in a follow-up service for low-to-medium risk hypertensive patients: a randomized controlled trial. *IEEE Trans Inf Technol Biomed.* Nov 2008;12(6):780-791.
37. Blasco A, Carmona M, Fernandez-Lozano I, et al. Evaluation of a telemedicine service for the secondary prevention of coronary artery disease. *J Cardiopulm Rehabil Prev.* Jan-Feb 2012;32(1):25-31.
38. Appelboom G, Camacho E, Abraham ME, et al. Smart wearable body sensors for patient self-assessment and monitoring. *Arch Public Health.* 2014;72(1):28.
39. Allen JK, Stephens J, Dennison Himmelfarb CR, Stewart KJ, Hauck S. Randomized controlled pilot study testing use of smartphone technology for obesity treatment. *J Obes.* 2013;2013:151597.
40. Spring B, Schneider K, McFadden HG, et al. Multiple behavior changes in diet and activity: a randomized controlled trial using mobile technology. *Arch Intern Med.* May 28 2012;172(10):789-796.
41. Jakicic JM, Davis KK, Rogers RJ, et al. Effect of Wearable Technology Combined With a Lifestyle Intervention on Long-term Weight Loss: The IDEA Randomized Clinical Trial. *JAMA.* Sep 20 2016;316(11):1161-1171.
42. Spring B, Duncan JM, Janke EA, et al. Integrating technology into standard weight loss treatment: a randomized controlled trial. *JAMA Intern Med.* Jan 28 2013;173(2):105-111.
43. WHO. Call to Action on Global eHealth Evaluation. WHO Global eHealth Evaluation Meeting; September 2011, 2011; Bellagio.
44. Krupinski E. High Volume Teleradiology Service: focus on radiologist and patient satisfaction. In: Kumar S, Krupinski E, eds. *Teleradiology*. Berlin: Spring-Heidelberg; 2008:240-252.
45. Weinstein RS, Lopez AM, Joseph BA, et al. Telemedicine, telehealth, and mobile health applications that work: opportunities and barriers. *Am J Med.* Mar 2014;127(3):183-187.
46. Marsch LA, Gustafson DH. The Role of Technology in Health Care Innovation: A Commentary. *J Dual Diagn.* 2013;9(1):101-103.
47. Muller AM, Khoo S. Non-face-to-face physical activity interventions in older adults: a systematic review. *International Journal of Behaviroal Nutrition and Physical Activity.* 2014;11(35):1-12.
48. Bergmann JH, Chandaria V, McGregor A. Wearable and implantable sensors: the patient's perspective. *Sensors (Basel).* 2012;12(12):16695-16709.

49. Bergmann JH, McGregor AH. Body-worn sensor design: what do patients and clinicians want? *Ann Biomed Eng.* Sep 2011;39(9):2299-2312.
50. Weinhold IaG, S. Understanding shortages of sufficient health care in rural areas. *Health Policy.* 2014;118.
51. Lustig T. *The Role of Telehealth in an Evolving Health Care Environment: Institute of Medicine.* 2012.
52. Lewis VA, Colla CH, Carluzzo KL, Kler SE, Fisher ES. Accountable Care Organizations in the United States: market and demographic factors associated with formation. *Health Serv Res.* Dec 2013;48(6 Pt 1):1840-1858.
53. Wicks P, Stamford J, Grootenhuis MA, Haverman L, Ahmed S. Innovations in e-health. *Qual Life Res.* Feb 2014;23(1):195-203.
54. Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of childhood and adult obesity in the United States, 2011-2012. *JAMA.* Feb 26 2014;311(8):806-814.
55. Mann WC, Ottenbacher KJ, Fraas L, Tomita M, Granger CV. Effectiveness of assistive technology and environmental interventions in maintaining independence and reducing home care costs for the frail elderly. A randomized controlled trial. *Arch Fam Med.* May-Jun 1999;8(3):210-217.
56. Census Bureau Statistics. 2012; http://www.census.gov. Accessed January 20th, 2013, 2013.
57. Garber CE, Blissmer B, Deschenes MR, et al. American College of Sports Medicine position stand. Quantity and quality of exercise for developing and maintaining cardiorespiratory, musculoskeletal, and neuromotor fitness in apparently healthy adults: guidance for prescribing exercise. *Med Sci Sports Exerc.* Jul 2011;43(7):1334-1359.
58. Callahan CM, Unverzagt FW, Hui SL, Perkins AJ, Hendrie HC. Six-item screener to identify cognitive impairment among potential subjects for clinical research. *Med Care.* Sep 2002;40(9):771-781.
59. Decker JW, Dennis KE. The Eating Habits Confidence Survey: reliability and validity in overweight and obese postmenopausal women. *J Nurs Meas.* 2013;21(1):110-119.
60. Sallis JF, Pinski RB, Grossman RM, Patterson TL, Nader PR. The development of self-efficacy scales for healthrelated diet and exercise behaviors. *Health Education Research.* 1988;3(3):283-292.
61. http://www.vidyo.com. 2014. Accessed October 14.
62. Yip MP, Mackenzie A, Chan J. Patient satisfaction with telediabetes education in Hong Kong. *J Telemed Telecare.* 2002;8(1):48-51.
63. ATS. Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories: ATS statement: guidelines for the six-minute walk test. *Am J Respir Crit Care Med.* Jul 1 2002;166(1):111-117.
64. Segal-Isaacson CJ, Wylie-Rosett J, Gans KM. Validation of a short dietary assessment questionnaire: the Rapid Eating and Activity Assessment for Participants short version (REAP-S). *Diabetes Educ.* Sep-Oct 2004;30(5):774, 776, 778 passim.
65. Mader U, Martin BW, Schutz Y, Marti B. Validity of four short physical activity questionnaires in middle-aged persons. *Med Sci Sports Exerc.* Jul 2006;38(7):1255-1266.
66. Cella D, Riley W, Stone A, et al. The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005-2008. *J Clin Epidemiol.* Nov 2010;63(11):1179-1194.
67. Prochaska JO, Norcross JC, Fowler JL, Follick MJ, Abrams DB. Attendance and outcome in a work site weight control program: processes and stages of change as process and predictor variables. *Addict Behav.* 1992;17(1):35-45.
68. Haug NA, Shopshire M, Tajima B, Gruber V, Guydish J. Adoption of evidence-based practices among substance abuse treatment providers. *J Drug Educ.* 2008;38(2):181-192.
69. Bond GR, Drake RE, Rapp CA, McHugo GJ, Xie H. Individualization and quality improvement: two new scales to complement measurement of program fidelity. *Adm Policy Ment Health.* Sep 2009;36(5):349-357.
70. Stahl JE, Dixon RF. Acceptability and willingness to pay for primary care videoconferencing: a randomized controlled trial. *J Telemed Telecare.* 2010;16(3):147-151.
71. Boyatzis RE. *Transforming qualitative information: Thematic analysis and code development.* Thousand Oaks, London & New Delhi: SAGE Publications; 1998.
72. Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative Research in Psychology.* 2006;3(2):77-101.
73. Braun V, Clarke V. What can "thematic analysis" offer health and wellbeing researchers? *Int J Qual Stud Health Well-being.* 2014;9:26152.

74. Emerson R, Fretz R, Shaw L. *Writing Ethnographic Fieldnotes.* Chicago, IL: University of Chicago Press; 1995.
75. Shenton AK. Strategies for ensuring trustworthiness in qualitative research projects. *Education for Information* 2004;22:63-75.
76. Smalley KJ, Knerr AN, Kendrick ZV, Colliver JA, Owen OE. Reassessment of body mass indices. *Am J Clin Nutr.* Sep 1990;52(3):405-408.
77. Balke B. A SIMPLE FIELD TEST FOR THE ASSESSMENT OF PHYSICAL FITNESS. REP 63-6. *Rep Civ Aeromed Res Inst US.* Apr 1963:1-8.
78. Harada ND, Chiu V, Stewart AL. Mobility-related function in older adults: assessment with a 6-minute walk test. *Arch Phys Med Rehabil.* Jul 1999;80(7):837-841.
79. Casanova C, Celli BR, Barria P, et al. The 6-min walk distance in healthy subjects: reference standards from seven countries. *Eur Respir J.* Jan 2011;37(1):150-156.
80. Walter SD, Eliasziw M, Donner A. Sample size and optimal designs for reliability studies. *Stat Med.* Jan 15 1998;17(1):101-110.
81. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform.* Apr 2009;42(2):377-381.
82. Clark MM, Hurt RD, Croghan IT, et al. The prevalence of weight concerns in a smoking abstinence clinical trial. *Addict Behav.* Jul 2006;31(7):1144-1152.
83. Clark MM, Jenkins SM, Limoges KA, et al. Is usage of a wellness center associated with improved quality of life? *Am J Health Promot.* May-Jun 2013;27(5):316-322.
84. Lurie JD, Morgan TS. Pros and cons of pragmatic clinical trials. *J Comp Eff Res.* Jan 2013;2(1):53-58.
85. Gill LE, Bartels SJ, Batsis JA. Weight Management in Older Adults. *Curr Obes Rep.* Sep 2015;4(3):379-388.
86. Folstein MF, Folstein SE, McHugh PR. "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res.* Nov 1975;12(3):189-198.
87. Artinian NT, Fletcher GF, Mozaffarian D, et al. Interventions to promote physical activity and dietary lifestyle changes for cardiovascular risk factor reduction in adults: a scientific statement from the American Heart Association. *Circulation.* Jul 27 2010;122(4):406-441.
88. Haskell WL, Lee IM, Pate RR, et al. Physical activity and public health: updated recommendation for adults from the American College of Sports Medicine and the American Heart Association. *Circulation.* Aug 28 2007;116(9):1081-1093.
89. Masud T, Morris RO. Epidemiology of falls. *Age Ageing.* Nov 2001;30 Suppl 4:3-7.