**Cover Page for ClinicalTrials.gov**

**Document:**
Protocol

**Official Study Title:**
Empowering the Management of Pain-Obesity-Weight through Enhanced Reward

**NCT Number:**
NCT04851587

**Document Date:**
07/11/2022

## Protocol

1. **Project/Grant Title:** Empowering the Management of Pain-Obesity-Weight through Enhanced Reward (EMPOWER)

2. **Investigators:** Emily J. Bartley, Ph.D. (PI)
   Megan A. McVay, Ph.D. (PI)
   Stephen Anton, Ph.D. (Co-I)
   Jeewon Chong, Ph.D. (Co-I)
   Shawn McGargill, M.D. (Co-I)

3. **Abstract:** Chronic low back pain (cLBP) is the leading cause of disability worldwide and is one of the top reasons for seeking healthcare. High-impact low back pain is particularly problematic, defined as chronic pain accompanied by significant restrictions in work, social, and/or self-care activities for six months or more. High-impact pain is associated with greater pain-related disability, opioid use, and healthcare costs compared to pain of lower impact. Thus, efforts to reduce chronic pain impact have become a public health initiative. Low back pain and overweight/obesity are highly comorbid; overweight and obese individuals are up to 43% more likely to have cLBP compared to normal weight individuals. Together, the additive effects of overweight/obesity and chronic pain may play a larger role in increasing the risk for other adverse health-related comorbidities. Therefore, the aim of this exploratory study is to examine the feasibility and acceptability of an integrated pain and weight management intervention (EMPOWER) for middle-aged and older adults with moderate-to-high impact low back ,knee, and/or hip pain by addressing mechanisms of environmental reward and positive affect. Forty adults (ages 45-80 years) with comorbid overweight/obesity (BMI≥25 kg/m$^2$) and moderate-to-high impact cLBP will be assigned to an 8-month intervention, whereby they will receive a group- and telephone-based program featuring integrated behavioral weight loss treatment and cognitive-behavioral pain coping therapy, including systematic pleasant activity scheduling and values-clarification techniques. Assessments will be conducted at baseline and at the 4- and 8-month time points. The proposed research will be a step toward the development of therapeutic modalities aimed at improving pain and weight management in adults with comorbid cLBP and overweight/obesity, and will provide essential information to guide a larger, randomized-controlled trial of the EMPOWER intervention.

4. **Background:** Chronic pain is prevalent and burdensome in older adults. More than 1 in 4 adults ages 45 and older have chronic pain (compared to 1 in 7 aged 25-44).[11] A particularly common age-related pain condition is chronic low back pain (cLBP). cLBP affects an estimated 13% of Americans, with adults in their 50s and 60s having twice the odds of experiencing cLBP as those in their 20s.[51] cLBP promotes decrements in mental health, physical mobility, social functioning, and activities of independent living.[23] cLBP is the leading cause of disability in the US and globally[8, 22, 40] and contributes substantially to healthcare utilization and costs.[39]

   In 2016, the US Department of Health and Human Services released the National Pain Strategy in an effort to reduce the burden of chronic pain in the US.[9] A key recommendation of this strategy was to address high-impact chronic pain (HICP), defined as significant pain-related restrictions in work, social, and self-care activities. Pain impact has also been an important focus of the NIH Task Force on Research Standards for low back pain, which recommended that cLBP be stratified according to the extent of pain impact.[13] It is estimated that approximately 20 million Americans are affected by HICP,[11] with greater impact associated with increased healthcare utilization and opioid usage,[27] as well as greater health and psychological comorbidities.[47] Further, the prevalence of HICP increases with advancing age from 4.4% among 25-44 year old's to 12.0% and 10.7% among adults ages 45-64 and 65-84, respectively.[11] Targeting pain impact among adults 45 and older is thus an important public health priority.

Defined as a body mass index (BMI) ≥30 kg/m$^2$, obesity affects approximately 40% of American adults,[24] with an additional 32% being overweight (BMI 25.0-29.9).[42] Excess weight is associated with negative health and psychological outcomes, including cardiovascular and metabolic diseases, lower quality of life, and mortality.[21, 32, 34, 45] Individuals who are overweight or obese are up to 43% more likely to have cLBP compared to adults with a BMI≤25kg/m.[50] Thus, obesity or overweight is present in the vast majority of US adults with cLBP. The comorbidity of excess weight places individuals with chronic pain at greater risk for disability, depression, and chronic opioid consumption,[15, 43, 55] as well as increasing the risk for cardiovascular disease, sleep disorders, depression, cognitive impairment, and mortality.[6, 20, 43, 46, 53, 62]

Existing evidence indicates that the relationship between pain and weight is bidirectional and multifaceted.[30, 43] We have developed a conceptual model explicating key pathways by which pain and weight influence each other, drawing from previous literature, our own recent work in this area[3, 4] and existing theory (Figure 1).[10, 17, 25, 33, 60] This model shows that pain (due to injury or other precipitants) results in a sequelae of adverse behavioral and affective consequences. Two of these consequences—reward deprivation and decreased positive affect—may be of particular importance for the pain-weight relationship. Reward deprivation occurs when chronic pain alters the reward value of activities, thereby leading to reduced enjoyment in and withdrawal from activities that offer potential pleasure, meaning, and value.[33, 38] Overgeneralized fear of pain can also increase withdrawal and loss of reward, consistent with the "fear avoidance model" of pain.[10, 60] Both due to this loss of reward and directly to the pain itself, individuals also experience reductions in positive affect.[7]

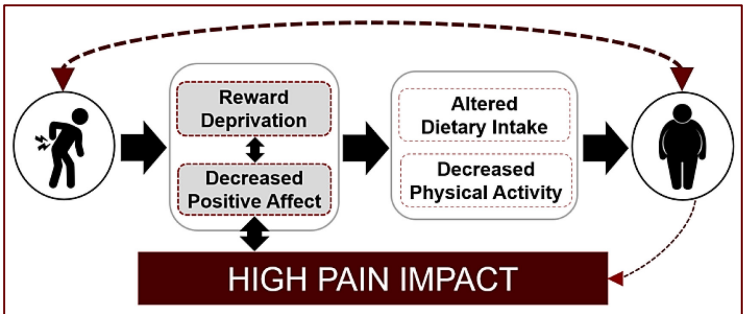


**Figure 1.** *Conceptual Model of the Bidirectional Relationship between Chronic Pain and Weight.* Our model posits that pain facilitates deficits in environmental reward and positive affect, and consequently negatively alters dietary intake and physical activity, thereby leading to weight gain and greater pain impact.

In turn, reward deprivation and decreased positive affect can increase dietary intake and decrease physical activity. In particular, when sources of non-food reward are limited, high calorie food may have greater reinforcing value, resulting in greater caloric intake. This is predicted by behavior choice theory, which posits that engagement with a reinforcer, such as food, is likely to be greater in the absence of alternative reinforcers.[17] Low levels of positive affect may also lead to reduced physical activity.[49] The collective result of increased food intake and diminished physical activity is weight gain, which in turn worsens pain and pain impact (via joint loading, biochemical mediators, inflammation, etc.),[43, 59, 65] and increased pain and pain impact in turn can contribute to further weight gain. Additionally, excess weight can facilitate loss of environmental reward via weight-related limitations on activities, further perpetuating pain impact and weight gain.[12, 35, 64]

To increase environmental reward and engagement in pleasant activities, we will adapt approaches that have successfully addressed those targets in other populations. From Behavioral Activation for depression,[7, 33, 35] we will adapt pleasant activity planning techniques, which include activity monitoring, assigning increasingly more difficult activities that include the potential for increased pleasure or mastery, and problem solving roadblocks to activity engagement.[29] These techniques have demonstrated effects on engagement in pleasant activities, environmental reward, and positive affect.[37, 48, 57] From Acceptance and Commitment Therapy (ACT; an evidence-based psychotherapy) we will adapt values clarification therapeutic techniques, which involves

identifying personal value systems that patients find meaningful and encouraging the engagement in activities that are in accordance with core values. We anticipate that these techniques will increase involvement in pleasant activities, which will enhance environmental reward and positive affect; in the context of weight loss treatment, this increased reward and positive affect will result in reductions in food intake and increased physical activity.

5. **Hypotheses and Specific Aims:** The central objective of research is to examine the feasibility and acceptability of an 8-month (4-month if only 8 core intervention sessions are completed) single-arm behavioral intervention (i.e., EMPOWER) among overweight/obese middle-aged and older adults with moderate-to-high impact musculoskeletal pain. Intervention content will focus on standard behavioral weight loss treatment and standard cognitive-behavioral pain coping therapy, which will be delivered in a fully integrated manner to take advantage of overlapping techniques used in each (e.g., addressing negative cognitions related to weight and pain in a single session).

   **Specific Aim 1:** Evaluate the acceptability of the EMPOWER intervention, as indicated by treatment engagement and participant reported treatment credibility and satisfaction, and potential for treatment efficacy.

   **Specific Aim 2:** Determine trial feasibility, including the ability to meet pre-specified recruitment and retention metrics.

6. **Research Plan:**

   **Recruitment**

   **Institutional Data Repository (IDR) Invitational Messages**. We will have an IDR search performed for patients who (1) have had appointments in the UF health care system over the last month, (2) have agreed to be contacted for future research ("Consent2share" patients), (3) have a diagnosis consistent with musculoskeletal pain, (4) have a BMI from the past 2 years over 24 $kg/m^2$, and (5) are age 45-80. We will obtain a list of patients' names, email addresses, and mailing addresses. We will also obtain patient sex and race to inform our goals of recruiting a diverse sample. We will send these patients one mailed letter and one email informing them of the study and invite them to share their contact information through a REDCap link provided. In addition to the letter from the study team, the mailing will include a study flyer and a return postcard that patients can mail to study investigators if interested in participation. The email and letter will include a link to a video to learn more about the study. Patients who share their contact information will then be called by study staff to complete the phone screening.

   In addition, we will also send an email and letter to patients who have had an appointment in the prior month with a UF health care provider who has agreed to allow us to send letters to his/her patients. We will obtain the list of patients by conducting an IDR pull to identify patients with appointments in the prior month who have a diagnosis consistent with musculoskeletal pain, a BMI from the past 2 years over 24 kg/m2, and are age 45-80. IDR will provide patients' names, provider name, patient email address, and mailing address so we can send them the letter from their provider, as well as their race and gender so that we can over-recruit minority individuals to ensure representativeness of our sample. We will send a signed letter from the provider from the study email address. We will also send a study flyer and a return postcard that patients can mail to study investigators if interested in participation.

**Provider Referral**. All providers in the UF Comprehensive Spine Clinic (CSC) will be informed of the study via email and via discussion with study Co-I and CSC physician, Dr. Shawn McGargill. When Dr. McGargill or other providers identify a patient who may be eligible, they will have two options to refer the patient to the study. First, they can send a message through EPIC to our study coordinator. Second, they can fill out a contact postcard that will be available in the clinic, then place that contact card in a box provided (that will only have a slot to enter cards, for security purposes). These cards will have study contact information, and providers will also be encouraged to give cards to patients to take home and reach out directly, if desired. Study staff will check for new contact cards weekly.

**In-clinic recruitment**. Research staff will approach patients before or after their clinic visit in the clinic room to introduce the study to them and determine if they are interested in joining the study. Patients will only be approached after their medical provider has asked them if they would like to hear about the study and then respond affirmatively. Participants will be given a short introduction to the study and if they are interested they will be asked to provide their contact information.

**Other recruitment.** Participants will also be recruited from clinic and community flyers, newspaper advertisement, UF HealthStreet, and the UF Pain Research and Intervention Center of Excellence (PRICE), Institute on Aging Pepper Center, and the University of Florida Jacksonville Aging Studies Center Research Participant Recruitment registries.

**Screening.** All potential participants will undergo an initial phone screening interview, via telephone or in person. We have requested a waiver of written informed consent to retain this information; we will provide verbal consent information and allow participants the chance to ask questions. The initial screening will include questions regarding pain, age, weight, and additional health history information to ensure that no exclusion criteria are present. For participants not affiliated with the University of Florida Health Care system, we will be asking a series of questions to assess any instability of the spine. If instability is determined, the participant must contact their own physician for written permission to partake in the study. If still eligible, participants will be scheduled for an individual in-person baseline assessment during which informed consent will be reviewed, medical and demographic history will be obtained to ensure eligibility, questionnaires will be administered, and a physical performance battery will be conducted to examine lower extremity function. At the completion of the baseline assessment, eligible participants will be scheduled for the intervention program (90 min/session).

**Participants.** A total of 40 middle-aged and older adults with moderate-to-high impact chronic musculoskeletal pain (e.g., lower back, knee, hip) and overweight/obesity (BMI≥25 kg/m$^2$) will be targeted. Assuming a 20% attrition rate, an additional 8 subjects will be enrolled, leaving a total of 48 participants to be recruited for study intervention procedures (we anticipate recruiting a total of 60 people to account for screen failures). Participants will still be included if they report the presence of medical pain comorbidities; however, subjects must identify musculoskeletal pain as their primary pain condition.

**Inclusion Criteria**

- 45-80 years of age
- Have a BMI≥25kg/m$^2$
- Endorse pain in the lower back region (i.e., space between the lower posterior margin of the rib cage and the horizontal gluteal fold), knees, or hips
- Pain must occur on at least 50% of the days in the previous six months
- Pain must be rated, at minimum, of moderate intensity (rating of 3 on a numeric rating scale ranging from 0-10)

- Pain impact must be rated as moderate to severe (as determined from the RTF Impact Stratification Score).
- Study physician, Shawn McGargill, MD, reviews medical record and declares patient medically appropriate for exercise protocol.

**Exclusion Criteria**

- Current participation in another psychological treatment or structured weight loss program
- Severe psychiatric illness not adequately controlled by medication or other conditions anticipated to impair intervention engagement (e.g., substance abuse/dependence)
- Presence of chronic, malignant pain (e.g., cancer)
- Significant cognitive impairment (<26) on the Montreal Cognitive Assessment (MoCA)[41]
- Inability to read and write English
- Currently undergoing radiation or chemotherapy for cancer
- Self-reported cardiac event in the past 6 months or self-reported Heart Failure (CHF)
- Currently pregnant or breastfeeding, or planning to become pregnant during the study time period
- Back, knee, or hip surgery within the past six months of study entry (or planned surgical interventions for pain during forecasted study participation)
- If currently taking prescription analgesic or psychotropic medication, must be stabilized on these treatments for ≥4 weeks prior to the baseline assessment
- Blood pressure higher than 180/100 mm Hg at baseline assessment
- Has had bariatric surgery in the past year or is planning to have it in the next year
- If participant reports the presence of systemic inflammatory disease (e.g., rheumatoid arthritis), the study physician will be consulted to determine eligibility

All participants attending assessments will be required to wear Personal Protective Equipment (PPE) during in-person visits. PPE (masks) will be provided by study staff upon participant arrival or participants may bring their own. In addition, all participants who attend in-person group sessions are required to show proof of COVID-19 vaccination. If proof of COVID-19 vaccination is unavailable, participants will still be eligible to participate through PHI Zoom group sessions. If intervention sessions are conducted through PHI Zoom, study staff will ensure participants have access to Zoom as well as a stable internet connection. Study staff will also ask participants if they have access to a space that will provide confidentiality (e.g., not conducting Zoom call where other people may overhear, inform other household members about confidentiality expectations, ensure no identifying information is visible through camera). Zoom tutorials will be provided during the Baseline Session.

Participants will be compensated $30 for attending assessment sessions and $15 per group intervention session. This is comparable to subject remuneration for studies of similar time commitment and invasiveness. Participants will receive partial payment if they do not complete the entire study. For participants traveling more than 25 miles each way to complete in-session study visits, we will reimburse some travel expenses at up to the federal mileage rate (cap of $200). Payments for participation will occur after completion of each study session and will be handled through the University of Florida's Human Subject Payment Program.

**Intervention Procedure.** The intervention includes 8 core in-person group sessions and 8 optional in-person group sessions (1.5 hours each) targeting standard weight loss and pain treatment content and eight individual phone calls (30 minutes each) focusing primarily on increasing environmental reward and positive affect. Due to COVID-19, intervention sessions may be delivered online through PHI Zoom. Group sessions will be delivered every-other week and phone

calls will occur every-other week (during weeks with no group). Sessions will be administered by a study interventionist with bachelors- or masters-level training and certification in health education or a related field (e.g., Certified Health Education Specialist), and materials will be developed to be appropriate for delivery by this level of training, given the potential for greater availability of these types of health professionals. To standardize the application of the intervention and ensure treatment fidelity, the intervention will be manualized and will include interventionist and client workbooks written at the 6th grade reading level.

The standard weight management intervention components are closely adapted from the Diabetes Prevention Program[14] protocol—considered a gold standard weight loss intervention—while the pain coping content is adapted from empirically-supported pain management protocols.[26, 44, 58] (Table 1). Consistent with standard behavioral weight loss treatments, participants will be assigned a goal of losing 5-7% of baseline weight over the 8-month intervention (with a daily 500 kcal deficit goal) and given recommendations for dietary intake based on the American Heart Association guidelines (e.g., emphasis on whole grains, limitation of saturated fat). They will be asked to engage in daily monitoring of their food and drink intake, either via a free commercial app of their choosing or paper and pen. Physical activity goal setting and monitoring will be integrated in the pleasant activity planning portion of the intervention. To increase non-food environmental reward and positive affect, the first two group sessions will include psychoeducational content addressing the importance of pleasant activities as a way of disrupting the chronic pain and weight cycle, and values clarification techniques to motivate engagement in pleasant activities. At these sessions, participants will also review a list of commonly enjoyed pleasant activities and brainstorm additional activities to include on the list.

All phone sessions will focus on pleasant activity scheduling and values clarification, including setting new activity goals, evaluating prior goal progress, and problem-solving challenges to meeting goals. Interventionists will guide participants from setting easily achievable to more challenging goals as treatment progresses. In order to encourage exposure to a variety of potentially reinforcing activities and to increase overall physical activity level, participants will be asked to select at least one goal from each of three categories: a social activity, a cognitively enriching activity, and an activity that involves at least a moderate level of physical exertion. At the end of each phone call, interventionists will record participant goals. At the beginning of each phone and group session, participants will be given a list of their prior goals and will respond to standardized questions regarding which specific goals they achieved since the prior session, how much time they spent on these activities, and how much pleasure and value they received from them.

**Study Measures.** As shown in Table 2, several questionnaires will be administered to assess feasibility and acceptability, pain-related symptoms, and psychological functioning.

***Anthropometric and Medical History.*** At baseline, blood pressure will be measured, height will be assessed to the nearest cm using a wall stadiometer, and participants will complete a thorough Medical History Questionnaire assessing the reported duration of musculoskeletal pain, current and past treatments for musculoskeletal pain, comorbid conditions, and current medication use. At baseline and at the 4- and 8-month in-person visits, body weight will be measured to the nearest 0.1 kg using a digital scale with participants in light clothing and shoes removed. Health status will be monitored at each group session.

***Cognitive Testing.*** At baseline, the Montreal Cognitive Assessment (MoCA),[41] a widely used screening assessment for detecting cognitive impairment, will be adminstered. It was validated in the setting of mild cognitive impairment and has subsequently been adopted in numerous other settings clinically. Participants with scores <26 (or under PI discretion) will be excluded from

participation as this could interfere with completion of the study intervention. The alternative/equivalent version of the MoCA (Version 7.2) will be used to decrease possible learning effects when the MoCA (Version 7.1) has been administered within the past 3 months of study participation. This will serve as a safeguard for test-retest effects for participants who may have recently participated in studies requiring the administration of this instrument.

***Measures of Treatment Acceptability.*** We will obtain acceptability data at each session and at study assessment points. After each group/phone session, the study interventionist and participants will complete treatment engagement questions adapted for the current study to assess participants' effort exerted during group activities/phone calls, completion of homework, and engagement in discussions. They will also answer open-ended questions on their satisfaction with and usefulness of the session components. At the baseline assessment, participants will complete an adapted measure of treatment credibility and expectancy[5] to assess the perceived credibility of treatment and expectation for improvement. At 4 and 8 months (if applicable), the 8-item Client Satisfaction Questionnaire (CSQ-8)[2] will be administered to measure general treatment satisfaction, perceived quality of treatment, and willingness to recommend the treatment. Additionally, at 4 and 8 months (if applicable), participants will complete Likert ratings and answer open-ended questions on their satisfaction with the intervention components (e.g., values clarification exercises) and recommendations for intervention improvement. Responses to all acceptability measures will be used to refine the protocol across cohorts.

***Qualitative Interviews:*** To obtain more in-depth perspectives, study PIs will conduct qualitative interviews with a portion of participants who have completed the intervention. Interviews will either occur in person or on HIPAA-compliant Zoom with only audio activated (no video). From our total sample we will purposefully sample for participants who achieved a reduction in pain impact and weight and from those who did not see a reduction in pain impact and/or weight. We will interview a minimum of 12 participants but will continue interviews if we do not reach thematic saturation. The structured interview will include questions about participant perceptions of the intervention modality and structure, group and individual session content, and barriers to engagement in pleasant activities. These will be conducted around the Month 4 timepoint if participants complete only the 8 core intervention sessions, and will occur aroung the Month 8 timepoint if all 16 intervention sessions are completed. Directed content analysis will be used to analyze the data.[28]

***Treatment Outcome and Mediator Measures:*** We will conduct study assessments at baseline and at the 4- (mid-intervention) and 8-month time-point (end of intervention. Participants who attend only the core 8 sessions will be asked to attend the 8-month assessment to be able to compare effects across those who do and do not attend optional sessions, and to examine durability of effects. These assessments serve two purposes: (1) evaluate our ability to obtain outcome measures in this population (and to adjust retention strategies over the course of the pilot, if needed) and (2) evaluate the potential of the intervention to produce a meaningful effect of the intervention on pain impact. ***Pain Impact*** will be assessed by a combination of 9-items from the PROMIS Short Form assessing pain intensity, pain interference with normal activities, and physical function (see below PROMIS measures for a description). Impact stratification scores range from 8 (mild impact) to 50 (severe impact).[13] Several measures from the ***PROMIS–Short Form***[1, 13] will be administered to assess self-reported pain intensity, pain interference, depression, and physical function. The Short Physical Performance Battery (SPPB) consists of three measures of lower-extremity function: standing balance, 4-meter walking speed, and ability to rise from a chair. These measures have been standardized and are widely used in older populations as measures of lower extremity function. The SPPB will be completed at Month 0 and Month 4. The Graded Chronic Pain Scale is a 7-item scale that evaluates global pain severity and pain-related interference over the past 6 months.. The GCPS yields a "Characteristic Pain Intensity" score and an overall "Disability" score. The ***Community Health Activities Model Program for Seniors***

(CHAMPS)[54] assesses weekly frequency and duration of a variety of lifestyle physical activities for seniors. Food intake will be assessed via the ***NCI Automated Self-Administered 24-hour Dietary Assessment Tool*** (ASA24).[56] Over a one-week period at baseline and 4 months, participants will complete ASA food recalls on three days (2 weekdays and 1 weekend), with the specific days not known to participants in advance. To assess ***Pleasant Activity Engagement***, participants will complete standardized self-report questions at each intervention phone call on their weekly engagement in pleasant activities, duration of engagement (in minutes), and the level of enjoyment for each activity (completed on a numerical rating scale [NRS] ranging from 0 "none" to 100 "extremely"). The ***Meaningful Activity Participation Assessment*** (MAPA)[16] is a 28-item checklist reflecting common activities that are meaningful to older adults. Items are rated both for how much time is spent and how meaningful the activities are perceived to be. The ***Positive and Negative Affect Schedule*** (PANAS)[63] is a 20-item scale assessing positive affect (PA) and negative affect (NA). The ***Food Pain Coping Questionnaire*** is a 2-item scale assessing food use as a coping mechanism for chronic pain. The ***World Health Organization Quality of Life–Brief*** (WHOQol-Bref) [52] scale consists of 26 items assessing quality of life over the past week in four domains: physical health, psychological health, social relationships, and environment.

**Table 2.** Study Measures

| | | Time-Point (Month) | | |
|---|---|---|---|---|
| **Variable** | **Measure** | **0** | **4** | **8** |
| Participant Engagement | Treatment Engagement Ques. | Every session | | |
| Treatment Credibility | Credibility/Expectancy Scale | X | | |
| Treatment Satisfaction | CSQ-8 | | X | X |
| Qualitative Evaluation | Qualitative Interview | | | X |
| Pain Impact | RTF Impact Stratification | X | X | X |
| Body Weight | By Digital Scale | X | X | X |
| Intensity, Interference, Phys. Function | PROMIS Pain Measures | X | X | X |
| Functional Performance | BPS | X | | X |
| Back-Related Disability | RMDQ | X | X | X |
| Physical Activity | IPAQ | X | X | X |
| Pleasant Activity Engagement | Self-Reported Engagement | X | X | X |
| Reward from Activities | MAPA | X | X | X |
| Positive Affect | PANAS | X | X | X |
| EMA of Pain Intensity | Smartwatch Ratings | X | | X |
| EMA of Mood and Physical Activity | Smartwatch Ratings | X | | X |
| Quality of Life | WHOQoL Bref | X | X | X |

***Note:*** Ques=Questionnaire; Phys=Physical. *See text for a full description of abbreviations for study questionnaires.*

To measure ***Ecological Momentary Assessment (EMA) of Pain, Mood, and Physical Activity***, the smartwatch app ROAMM will be installed on commercially-purchased smartwatches (i.e., Apple Watch) to obtain real-time measures of pain intensity, mood, and physical activity.[36] Participants will be asked to wear a smartwatch for 7 days at baseline and 7 days at the 4-month time-point, during which they will receive three daily prompts (morning, afternoon, evening) to complete measures of current pain intensity (0 to 10 NRS ranging from none to worst possible) and mood (0 to 10 NRS ranging from extremely negative to extremely positive mood). Participants will also complete nightly prompts as to whether they engaged in a 1) social activity, 2) mind-enriching activity, and 3) exercise (yes or no response). Assessment ratings will be entered by rotating a bezel on the watch interface. Continuous accelerometry data will be collected as a measurement of physical activity (average minutes spent per day; collected at 15 Hz).

**Statistical Methods.** To account for variability and imprecision in sample estimates that often accompany smaller pilot studies, we will create 95% confidence intervals (CIs) around all feasibility and acceptability outcomes and consider the data supportive of progression to a full trial if these confidence intervals include our metric for success.

Specific Aim 1: *Evaluate the acceptability of the EMPOWER intervention, as indicated by treatment engagement and participant reported treatment credibility and satisfaction, and potential for treatment efficacy.* We will examine treatment engagement at each session and will measure

several aspects of global acceptability at baseline and at the 4- (mid-intervention) and 8-month (end of intervention) assessment period.

Session-level Engagement. Treatment engagement will assess participants' effort exerted during group activities/phone calls (using a 9-point Likert rating scale), completion of homework (yes/no), and engagement in group and individual discussions (using a 9-point Likert rating scale). Responses will be examined after sessions and after all four cohorts are complete (considering the mean and range of Likert ratings for each questionnaire item). We will also develop a 95% CI around the Likert ratings and examine if our metric for success falls within that interval (i.e., ≥6 on a 9-point Likert scale).

Global Treatment Engagement. The mean portion of group and phone sessions attended will be examined across the entire sample, as well as trends in the portion of sessions attended across the four cohorts. We will determine if our metric for success falls within a 95% CI around our identified threshold for success. The percentage of participants who complete ≥80% of group and phone sessions combined will also be measured, as well as the portion who complete ≥70% of group sessions and ≥70% of phone sessions (considered separately).

Global Treatment Satisfaction and Credibility. On the Client Satisfaction Questionnaire-8 (CSQ-8) and on the adapted Treatment Credibility and Expectancy Scale, we will present the mean (sd) and range as well as develop a 95% CI around questionnaire ratings to examine in relation to our metric for success (i.e., treatment satisfaction: ≥3 on a 4-point Likert scale; treatment credibility: ≥7 on a 11-point Likert scale).

Potential for Efficacy. To evaluate the potential for intervention efficacy on pain impact, weight, and key putative mediators, we will determine the mean, standard deviation, and range associated with treatment-related changes in these outcomes. We will also develop 95% CIs around the observed mean and examine whether a pre-determined minimal change score is within these CIs. For pain impact, the minimally important change score will be 30% of the baseline score as this number has been previously defined as a clinically meaningful reduction in pain.[19] For weight, the minimal important change score is a 5% reduction in body weight, given that this value is well-established to result in clinically important changes in health parameters.[31]

Specific Aim 2: *Determine trial feasibility, including the ability to meet pre-specified recruitment and retention metrics.*

Recruitment. We will present the rate of recruitment in units of participants/week (only including weeks of active recruitment). We will also report the portion of participants contacted and screened, including those who were enrolled and reasons for ineligibility. We will develop 95% CIs around the recruitment rate and determine if our metric for success is within that confidence interval (i.e., ≥2.5 participants enrolled per week during active recruitment; ≥90% of those who enroll commence treatment).

Retention. We will present the portion of participants who attend the 4- and 8-month assessment sessions, by cohort and the total sample. We will determine if our metric for successful retention (≥80% who enroll complete the 8-month assessment, among the final two cohorts) falls within a 95% CI of our obtained retention.

**Data and Safety Monitoring.** The proposed trial presents minimal risk to participants. The study PIs, Drs. Bartley and McVay, while be responsible for data and safety monitoring with oversight from an external Safety Officer, David Edelman, MD (Duke University). Dr. Edelman will review the study protocol, Manual of Procedures, and Data and Safety Monitoring Plan prior to enrolling

patients, and will be provided data on certain safety issues that arise during the study and given a summary of all adverse events and at a meeting one year after the start of enrollment. At each in-person group session and assessment period, we will inquire whether any adverse events or unanticipated problems occurred. Additionally, if participants disclose adverse events or unanticipated problems between group sessions (e.g., during phone sessions) they will be systematically recorded on the "Adverse Event and Unanticipated Problems form" developed by the University of Florida's Institutional Review Board. All serious and unexpected adverse events will be reported to the University of Florida IRB (within 5 working days), the Safety Officer, and the study's sponsor. Other types of adverse events will be monitored and reported to the University of Florida IRB in the study's annual progress review. Any adverse events or unanticipated problems reported will be followed until resolution, stabilization, or until it is determined that the study participation is not the cause. The study investigators will review reported adverse events every three months to minimize the risk to study subjects. The principal investigators, Drs. Bartley and McVay, will be responsible for the timely execution of this plan.

Electronic data from the smartwatches will be stored on password protected, secure and encrypted Amazon AWS servers according to UF policy. The collected data includes raw accelerometer data (acceleration values in three x, y, and z direction and timestamp), heart rate (per minute), GPS readings (latitude, longitude), mood, pain, activity type, and timestamps. The smartwatch does not collect restricted data – it does not collect health information and it is not connected to identifiable information. Therefore, the data collected on the device is exempt from encryption standards set forth by the UF Information Security Policies and Standards. All devices will be clearly marked as not for use with restricted data and will have a durable physical or electronic label with contact information sufficient to facilitate an expedient return to study staff if a lost device is found. Each device is coded with a number that is assigned to a participant. This assignment document is housed under a secure local server per UF Information Technology Security Charter and managed by the study staff. Data from the smart-watch is temporarily stored, remotely sent to secure servers and then erased from the local disc. Therefore, data on the smartwatch is "not" stored locally — it is permanently erased after uploading it to the Amazon AWS server. Data sent to the server is protected in locked and secure lab with strong password protection and full disk encryption.

**Confidentiality.** All trained personnel assisting with the study will be instructed on the importance of protecting participants' confidentiality and will have successfully completed the required education on protection of human research participants. All paper and computer records will be identified only by subject number rather than by name. All study records will be stored in locked file cabinets and will only be available to the PI or other project staff. Computer data files (without subject identifiers) will be stored on computer servers with secure passwords and electronic storage devices will be encrypted. All study records will be stored in locked file cabinets and will only be available to the PI or other project staff. Study staff will be instructed to not record any information (e.g., responses to pain criteria) obtained during the phone screen.

Each intervention session will be audio-recorded for the evaluation of therapist adherence to the protocol, and a random selection of 25% of all sessions conducted will be reviewed by the study PIs. Given that Zoom group sessions will be video-recorded (in order to obtain the audio recording), all video recordings will be destroyed immediately after each session. Additionally, we will conduct individual interviews with participants at the end of the study to evaluate their perceptions of the program. No identifying information will be transcribed as the purpose of this digital recording is to assess treatment integrity. Once the group session audio recordings are reviewed and adherence is discussed with the study interventionist, the recordings will be destroyed. For the individual interviews, we will transcribe all recordings and destroy the audio after transcription. Prior to destruction, the recordings will be kept in a locked filing cabinet in the laboratory of the PIs. Data obtained during audio-recorded qualitative interviews with patients may

be used in future publications but will not be linked with names or identifying information. The audio file will be downloaded from Zoom (or via audio recorder if conducted in person), saved on a password protected computer in our University office, and transcribed for responses to the questions. No names will be included on the typed files. If any personal information comes up during the interview, the information will be redacted from the transcript. Quotes from the interview may be used in future publications but will not be linked with names or identifying information. All audio recordings will be deleted from the network drive where it will be stored, with assistance from the IT department once they have been de-identified and transcribed, no later than 12 months after they are recorded.

7. **Possible Discomforts and Risks:** The risks for this study are minimal and appropriate safeguards are planned and in place to handle risks in a timely and appropriate manner. One area of risk of this study is loss of privacy. There are two ways that privacy is at risk: (a) through data collected and stored by the study team at UF, and (b) by data collected and stored by Apple through participants' use of the Apple Watch. With regard to study team collected data, we cannot guarantee that data will not be unlawfully obtained. The steps described above in "Confidentiality" section will decrease the chances of this. With regard to data collected by Apple, any data the patients share with Apple is subject to the privacy terms of Apple. Patients will be informed during the consent process that the data they share with Apple is not protected by the University. Further, it is generally unsafe for women who are pregnant to engage in weight loss efforts, and it is an exclusion criterion in our study. As such, participants will be withdrawn from the study if they become pregnant.

   **Protection against potential risks.** Participants will fill out several questionnaires about themselves. While these generally carry no associated risks, it is possible that participants might experience some distress from completing these questionnaires due to the sensitive nature of the items. We will take all necessary steps to minimize discomfort and participants will be free to omit any questions that they do not wish to answer. The procedures and activities included in the EMPOWER intervention involve minimal risk. Participants will be informed that they can discontinue study procedures at any time, and they will not be penalized for doing so. The activity tests for the Back Performance Scale may produce discomfort and participants can stop these procedures at any time. An extensive literature on behavioral weight loss interventions suggests that there is very limited risk, particularly if patients are prescribed a calorie goal of greater than 1,000 kcals/day. Participants will be encouraged to maintain a calorie intake within a safe range of 1,200-1,800 kcals per day. With any program that promotes physical activity, there is a small increased risk of musculoskeletal injury; however, the physical activity-focused portion of this intervention will emphasize finding safe activity and approaching it at a safe pace. The PI is a psychologist and is trained to deal with depression. Any participants whose responses during the group sessions or on the PROMIS Depression Short Form (raw score $\geq$33) indicate severe psychological distress (such as severe depression) will be interviewed by the site PI or other appropriately trained professionals for suicide risk and risk of harm to self and others. Participants will be assisted to the emergency room if danger is imminent or referred to either their physician or a mental health professional if necessary.

8. **Potential Benefits to Participants:** Participation in this research will provide the participant with a first-hand look at research and provide them with the opportunity to participate in a new self-management treatment for chronic musculoskeletal pain and overweight/obesity. Participants who complete the EMPOWER intervention may show improvement in pain and weight management. Ultimately, such knowledge may enhance quality of life and reduce pain in the targeted population, as well as lead to advances in the treatment of pain and excess weight in adults. Given the minimal risks associated with the study procedures, the risks are considered reasonable in relation to the potential benefits.

**Importance of the Knowledge to Be Gained.** Chronic musculoskeletalpain and overweight/obesity result in significant impairments, as well as tremendous individual and societal burden. The data obtained from the current study has the potential to advance treatment strategies for pain and weight management among middle-aged and older adults and may have broader implications for other medical populations likely to suffer from chronic pain and obesity. Moreover, our findings will enhance the understanding of underlying mechanisms contributing to treatment-related effects in pain impact and weight loss.

**Inclusion of Women and Minorities.** Given sex-specific prevalence of musculoskeletal pain and obesity,[18, 61] both male and female subjects will be recruited with the goal of equal gender distribution. It is planned that adult minorities (45-80 years) will be included in the study sample in proportion to census levels in the Gainesville, Florida (Alachua County) community including: 69.9% White, 20.6% Black/African-American, 6.3% Asian, 10.3% Hispanic or Latino, and 2.9% More than One Race. To ensure that the study sample includes census levels of minorities, we will assess their representation periodically over the course of the study and adjust recruitment or over-sample as needed.

9. **Conflict of Interest:** There is no conflict of interest involved with this study beyond the professional benefit from academic publication or presentation of the results.

**References**


1. Amtmann D, Cook KF, Jensen MP, Chen WH, Choi S, Revicki D, Cella D, Rothrock N, Keefe F, Callahan L, Lai JS. Development of a PROMIS item bank to measure pain interference. *Pain.* 150:173-182, 2010
2. Attkisson CC, Zwick R. The client satisfaction questionnaire. Psychometric properties and correlations with service utilization and psychotherapy outcome. *Evaluation and program planning.* 5:233-237, 1982
3. Bartley EJ, Hossain NI, Gravlee CC, Sibille KT, Terry EL, Vaughn IA, Cardoso JS, Booker SQ, Glover TL, Goodin BR, Sotolongo A, Thompson KA, Bulls HW, Staud R, Edberg JC, Bradley LA, Fillingim RB. Race/ethnicity moderates the association between psychosocial resilience and movement-evoked pain in knee osteoarthritis. *ACR Open Rheumatology.* 1:16-25, 2019
4. Bartley EJ, Palit S, Fillingim RB, Robinson ME. Multisystem resiliency as a predictor of physical and psychological functioning in older adults with chronic low back pain. *Front Psychol.* 10:1932-1932, 2019
5. Borkovec TD, Nau SD. Credibility of analogue therapy rationales. *Journal of Behavior Therapy and Experimental Psychiatry.* 3:257-260, 1972
6. Bruehl S, Chung OY, Jirjis JN, Biridepalli S. Prevalence of clinical hypertension in patients with chronic pain compared to nonpain general medical patients. *The Clinical journal of pain.* 21:147-153, 2005
7. Carvalho J, Trent LR, Hopko DR. The impact of decreased environmental reward in predicting depression severity: support for behavioral theories of depression. *Psychopathology.* 44:242-252, 2011
8. Centers for Disease Control and Prevention. Prevalence of disabilities and associated health conditions among adults—United States, 1999. *JAMA.* 285:1571-1000, 2001
9. Collins FS, Koroshetz WJ, Volkow ND. Helping to end addiction over the long-term: The research plan for the NIH HEAL Initiative. *JAMA.* 320:129-130, 2018
10. Crombez G, Eccleston C, Van Damme S, Vlaeyen JW, Karoly P. Fear-avoidance model of chronic pain: the next generation. *The Clinical journal of pain.* 28:475-483, 2012
11. Dahlhamer J, Lucas J, Zelaya C, Nahin R, Mackey S, DeBar L, Kerns R, Von Korff M, Porter L, Helmick C. Prevalence of chronic pain and high-impact chronic pain among adults - United States, 2016. *Morbitiy and Mortality Weekly Report.* 67:1001-1006, 2018
12. de Wit LM, Fokkema M, van Straten A, Lamers F, Cuijpers P, Penninx BWJH. Depressive and anxiety disorders and the association with obesity, physical, and social activities. *Depression and Anxiety.* 27:1057-1065, 2010
13. Deyo RA, Dworkin SF, Amtmann D, Andersson G, Borenstein D, Carragee E, Carrino J, Chou R, Cook K, Delitto A, Goertz C, Khalsa P, Loeser J, Mackey S, Panagis J, Rainville J, Tosteson T, Turk D, Von Korff M, Weiner DK. Report of the NIH Task Force on research standards for chronic low back pain. *Physical therapy.* 95:e1-e18, 2015
14. Diabetes Prevention Program Research Group. The Diabetes Prevention Program (DPP): description of lifestyle intervention. *Diabetes Care.* 25:2165-2171, 2002
15. Dong HJ, Larsson B, Levin LA, Bernfort L, Gerdle B. Is excess weight a burden for older adults who suffer chronic pain? *BMC geriatrics.* 18:270, 2018
16. Eakman AM, Carlson ME, Clark FA. The Meaningful Activity Participation Assessment: a measure of engagement in personally valued activities. *International journal of aging & human development.* 70:299-317, 2010
17. Epstein LH, Salvy SJ, Carr KA, Dearing KK, Bickel WK. Food reinforcement, delay discounting and obesity. *Physiology & Behavior.* 100:438-445, 2010
18. Fakhouri THI, Ogden CL, Carroll MD, Kit BK, Flegal KM: Prevalence of obesity among older adults in the United States, 2007-2010. In: NCHS Data Brief. Vol 106, 2012.

**19.** Farrar JT, Young JP, Jr., LaMoreaux L, Werth JL, Poole RM. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. *Pain.* 94:149-158, 2001

**20.** Feinkohl I, Lachmann G, Brockhaus W-R, Borchers F, Piper SK, Ottens TH, Nathoe HM, Sauer A-M, Dieleman JM, Radtke FM, van Dijk D, Pischon T, Spies C. Association of obesity, diabetes and hypertension with cognitive impairment in older age. *Clin Epidemiol.* 10:853-862, 2018

**21.** Field AE, Coakley EH, Must A, Spadano JL, Laird N, Dietz WH, Rimm E, Colditz GA. Impact of overweight on the risk of developing common chronic diseases during a 10-year period. *Archives of internal medicine.* 161:1581-1586, 2001

**22.** GBD 2017 Disease and Injury Incidence and Prevalence Collaborators. Global, regional, and national incidence, prevalence, and years lived with disability for 354 diseases and injuries for 195 countries and territories, 1990-2017: a systematic analysis for the Global Burden of Disease Study 2017. *Lancet (London, England).* 392:1789-1858, 2018

**23.** Gore M, Sadosky A, Stacey BR, Tai KS, Leslie D. The burden of chronic low back pain: clinical comorbidities, treatment patterns, and health care costs in usual care settings. *Spine.* 37:E668-677, 2012

**24.** Hales CM, Carroll MD, Fryar CD, Ogden CL. Prevalence of obesity among adults and youth: United States, 2015-2016. *NCHS data brief.*1-8, 2017

**25.** Hayes SC, Luoma JB, Bond FW, Masuda A, Lillis J. Acceptance and Commitment Therapy: Model, processes and outcomes. *Behaviour Research and Therapy.* 44:1-25, 2006

**26.** Hayes SC, Strosahl KD, Wilson KG: Acceptance and commitment therapy: An experiential approach to behavior change, Guilford Press, New York, NY, US, 1999.

**27.** Herman PM, Broten N, Lavelle TA, Sorbero ME, Coulter ID. Health care costs and opioid use associated with high-impact chronic spinal pain in the United States. *Spine* 44:1154-1161, 2019

**28.** Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. *Qualitative health research.* 15:1277-1288, 2005

**29.** Jacobson NS, Dobson KS, Truax PA, Addis ME, Koerner K, Gollan JK, Gortner E, Prince SE. A component analysis of cognitive-behavioral treatment for depression. *J Consult Clin Psychol.* 64:295-304, 1996

**30.** Janke AE, Kozak AT. "The more pain I have, the more I want to eat": obesity in the context of chronic pain. *Obesity (Silver Spring, Md.).* 20:2027-2034, 2012

**31.** Jensen MD, Ryan DH, Apovian CM, Ard JD, Comuzzie AG, Donato KA, Hu FB, Hubbard VS, Jakicic JM, Kushner RF, Loria CM, Millen BE, Nonas CA, Pi-Sunyer FX, Stevens J, Stevens VJ, Wadden TA, Wolfe BM, Yanovski SZ. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults. *Circulation.* 129:S102-S138, 2014

**32.** Khan SS, Ning H, Wilkins JT, Allen N, Carnethon M, Berry JD, Sweis RN, Lloyd-Jones DM. Association of Body Mass Index With Lifetime Risk of Cardiovascular Disease and Compression of Morbidity. *JAMA cardiology.* 3:280-287, 2018

**33.** Kim EH, Crouch TB, Olatunji BO. Adaptation of behavioral activation in the treatment of chronic pain. *Psychotherapy* 54:237-244, 2017

**34.** Lauby-Secretan B, Scoccianti C, Loomis D, Grosse Y, Bianchini F, Straif K. Body fatness and cancer--Viewpoint of the IARC working group. *The New England journal of medicine.* 375:794-798, 2016

**35.** Lauder W, Mummery K, Jones M, Caperchione C. A comparison of health behaviours in lonely and non-lonely populations. *Psychology, health & medicine.* 11:233-245, 2006

**36.** Manini TM, Mendoza T, Battula M, Davoudi A, Kheirkhahan M, Young ME, Weber E, Fillingim RB, Rashidi P. Perception of older adults toward smartwatch technology for assessing pain and related patient-reported outcomes: Pilot study. *JMIR Mhealth Uhealth.* 7:e10044-e10044, 2019

**37.** Manos RC, Kanter JW, Busch AM. A critical review of assessment strategies to measure the behavioral activation model of depression. *Clinical Psychology Review.* 30:547-561, 2010

**38.** Mazzucchelli TG, Da Silva M. The potential of behavioural activation for the treatment of chronic pain: An exploratory review. *Clinical Psychologist.* 20:5-16, 2016

**39.** Mehra M, Hill K, Nicholl D, Schadrack J. The burden of chronic low back pain with and without a neuropathic component: a healthcare resource use and cost analysis. *Journal of medical economics.* 15:245-252, 2012

**40.** Molton IR, Terrill AL. Overview of persistent pain in older adults. *The American psychologist.* 69:197-207, 2014

**41.** Nasreddine ZS, Phillips NA, Bédirian V, Charbonneau S, Whitehead V, Collin I, Cummings JL, Chertkow H. The Montreal Cognitive Assessment, MoCA: a brief screening tool for mild cognitive impairment. *J Am Geriatr Soc.* 53:695-699, 2005

**42.** National Institute of Diabetes and Digestive and Kidney Diseases: Overweight and obesity statistics. Available at: https://niddk.nih.gov/health-information/health-statistics/overweight-obesity

**43.** Okifuji A, Hare BD. The association between chronic pain and obesity. *Journal of pain research.* 8:399-408, 2015

**44.** Otis J: Managing chronic pain: A cognitive-behavioral therapy approach, Oxford University Press, 2015.

**45.** Peeters A, Bonneux L, Nusselder WJ, De Laet C, Barendregt JJ. Adult obesity and the burden of disability throughout life. *Obesity research.* 12:1145-1151, 2004

**46.** Pi-Sunyer X. The medical risks of obesity. *Postgrad Med.* 121:21-33, 2009

**47.** Pitcher MH, Von Korff M, Bushnell MC, Porter L. Prevalence and profile of high-impact chronic pain in the United States. *The journal of pain : official journal of the American Pain Society.* 20:146-160, 2019

**48.** Santos MM, Rae JR, Nagy GA, Manbeck KE, Hurtado GD, West P, Santiago-Rivera A, Kanter JW. A client-level session-by-session evaluation of behavioral activation's mechanism of action. *Journal of Behavior Therapy and Experimental Psychiatry.* 54:93-100, 2017

**49.** Schultchen D, Reichenberger J, Mittl T, Weh TRM, Smyth JM, Blechert J, Pollatos O. Bidirectional relationship of stress and affect with physical activity and healthy eating. *British Journal of Health Psychology.* 24:315-333, 2019

**50.** Shiri R, Karppinen J, Leino-Arjas P, Solovieva S, Viikari-Juntura E. The association between obesity and low back pain: a meta-analysis. *American journal of epidemiology.* 171:135-154, 2010

**51.** Shmagel A, Foley R, Ibrahim H. Epidemiology of chronic low back pain in US adults: Data from the 2009-2010 National Health and Nutrition Examination Survey. *Arthritis care & research.* 68:1688-1694, 2016

**52.** Skevington SM, Lotfy M, O'Connell KA. The World Health Organization's WHOQOL-BREF quality of life assessment: Psychometric properties and results of the international field trial. A Report from the WHOQOL Group. *Quality of Life Research.* 13:299-310, 2004

**53.** Smith D, Wilkie R, Croft P, McBeth J. Pain and mortality in older adults: The influence of pain phenotype. *Arthritis Care Res* 70:236-243, 2018

**54.** Stewart AL, Mills KM, King AC, Haskell WL, Gillis D, Ritter PL. CHAMPS physical activity questionnaire for older adults: outcomes for interventions. *Med Sci Sports Exerc.* 33:1126-1141, 2001

**55.** Stokes A, Berry KM, Collins JM, Hsiao CW, Waggoner JR, Johnston SS, Ammann EM, Scamuffa RF, Lee S, Lundberg DJ, Solomon DH, Felson DT, Neogi T, Manson JE. The contribution of obesity to prescription opioid use in the United States. *Pain.* 160:2255-2262, 2019

**56.** Subar AF, Kirkpatrick SI, Mittl B, Zimmerman TP, Thompson FE, Bingley C, Willis G, Islam NG, Baranowski T, McNutt S, Potischman N. The Automated Self-Administered 24-hour dietary recall (ASA24): a resource for researchers, clinicians, and educators from the

National Cancer Institute. *Journal of the Academy of Nutrition and Dietetics.* 112:1134-1137, 2012

**57.** Takagaki K, Okamoto Y, Jinnin R, Mori A, Nishiyama Y, Yamamura T, Yokoyama S, Shiota S, Okamoto Y, Miyake Y, Ogata A, Shimoda H, Kawakami N, Furukawa TA, Yamawaki S. Mechanisms of behavioral activation for late adolescents: Positive reinforcement mediate the relationship between activation and depressive symptoms from pre-treatment to post-treatment. *Journal of Affective Disorders.* 204:70-73, 2016

**58.** Thorn BE: Cognitive Therapy for Chronic Pain: A Step-by-Step Guide, The Guilford Press, New York, NY, US, 2004.

**59.** Vincent HK, Heywood K, Connelly J, Hurley RW. Obesity and weight loss in the treatment and prevention of osteoarthritis. *PM R.* 4:S59-S67, 2012

**60.** Vlaeyen JW, Crombez G. Fear of movement/(re)injury, avoidance and pain disability in chronic low back pain patients. *Manual therapy.* 4:187-195, 1999

**61.** Von Korff M, Dworkin SF, Le Resche L, Kruger A. An epidemiologic comparison of pain complaints. *Pain.* 32:173-183, 1988

**62.** Wang C, Chan JSY, Ren L, Yan JH. Obesity reduces cognitive and motor functions across the lifespan. *Neural Plast.* 2016:2473081-2473081, 2016

**63.** Watson D, Clark LA, Tellegen A. Development and validation of brief measures of positive and negative affect: the PANAS scales. *Journal of personality and social psychology.* 54:1063-1070, 1988

**64.** Zabatiero J, Smith A, Hill K, Hamdorf JM, Taylor SF, Hagger MS, Gucciardi DF. Do factors related to participation in physical activity change following restrictive bariatric surgery? A qualitative study. *Obesity Research & Clinical Practice.* 12:307-316, 2018

**65.** Zhang TT, Liu Z, Liu YL, Zhao JJ, Liu DW, Tian QB. Obesity as a risk factor for low back pain: A meta-analysis. *Clinical spine surgery.* 31:22-27, 2018