Title: Narrative Visualization for Breast Cancer Survivors' Physical Activity

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1. SUMMARY

Women breast cancer survivors are at increased risk for several negative health outcomes. Physical activity can reduce these risks, but activity levels in this population are low. Standard interventions that use self-regulation techniques (goal setting, self-monitoring, and feedback) are successful in the short term but do not produce the long-term activity maintenance needed for optimal health benefits. Their effectiveness might be improved by better connecting activity feedback to individuals' real-life experiences and values. Integrated regulation is a form of motivation related to personal values and identity and is strongly related to physical activity over time. Increasing this form of motivation could improve upon current intervention strategies, particularly in this population. Narrative visualization uses photographic, visual, and text annotation to tell a meaningful story with a data chart. This form of visualization can increase reflection, which in turn can predict integrated regulation and physical activity. We hypothesize that an intervention that encourages participants to create narrative visualizations from their step self-monitoring data will produce greater increases in physical activity than a self-regulation intervention. To test this hypothesis, we must first investigate the feasibility and acceptability of the narrative visualization intervention in a pilot randomized controlled trial. We will recruit 60 women breast cancer survivors (aged 55 – 79, < 150 minutes of physical activity per week) in two phases. In Phase I, 20 women will use prototype materials for one week and undergo cognitive interviewing to investigate feasibly and acceptability. Materials will be revised based on responses for use in the subsequent trial. In Phase II, we will randomize 40 participants to receive either the narrative visualization intervention or a standard self-regulation intervention for 12 weeks (with 12 weeks of no-intervention follow-up). Both groups will receive a wearable activity monitor and feedback app for use during the intervention period as well as an initial orientation/goal setting meeting and workbook. In the self-regulation group, participants will receive a workbook in which they will write and log their weekly goals. The narrative visualization group will also receive extended workbook content, a photo printer, and art supplies. The expanded workbooks will include spaces for posting daily photos and drawing explanations of step charts as well as reflection prompts relating the photos and charts to personal values and identity. Participants will be assessed at baseline, 12 weeks, and 24 weeks on changes to their activity, reflection, and integrated regulation. Feasibility indicators will include wear of the monitor and usage of the workbooks. Results from this study will be used to refine the intervention and to develop a follow-up study powered to investigate the relationships between reflection, motivation, and activity. Our overarching goal is to reduce the burden of cancer and improve quality of life among breast cancer survivors. This project represents a critical step towards this goal. Insights from the study will impact research and practice by testing a highly novel, scalable, and motivating intervention in a population at unique risk.

2. BACKGROUND AND RATIONALE

Breast cancer survivors are at risk for negative health outcomes related to both cancer and its treatment.[1,2] Sustained habitual physical activity (PA) can reduce these risks,[3,4] but PA levels are low in this population.[5,6] Self-regulation interventions that use techniques such as goal setting, self-monitoring, and feedback can produce short-term PA increases[7] but have rarely demonstrated long-term behavior change.[8]

A major limitation of self-regulation interventions is the lack of focus on motivation related to personal values and identity, which is called integrated regulation.[9] Increasing evidence suggests that integrated regulation is strongly associated with PA over time.[10,11] Individuals who self-monitor PA have reported that their adherence decreases over time because the feedback they are provided is inadequate: without an emotional connection to their values and everyday experiences, individuals are unsure of how to use and interpret reports of their step progress.[12,13] Older breast cancer survivors in particular face issues related to the impact of treatment on their identities[14,15] and desire their step goals and progress to be placed in the context of their broader values.[16]

Thus, a method for connecting step data to values, identity, and real-life experiences is needed. Reflection is the process of transforming experience into meaning.[17] Brief experiments have found that self-monitoring alone did not produce reflection,[18] and adding reflection prompts to self-regulatory PA programs increased PA.[19] Using visuals to prompt reflection may be even more successful than written prompts.[20] Narrative visualization consists of using drawings, photographs, and text to annotate data charts to better tell a compelling personal story.[21,22] This procedure could address limitations of current step self-regulation interventions and promote reflection and integrated regulation.

3. SPECIFIC AIMS AND OUTCOMES

3.1. SPECIFIC AIMS

Aim 1. Develop and refine reflection materials among a sample of sedentary breast cancer survivors.

Aim 2. Conduct a pilot randomized controlled trial comparing the self-monitoring + narrative visualization intervention to standard self-monitoring.

- **2a.** Determine the feasibility and acceptability of intervention procedures and materials.
- **2b.** Compare the effects of the interventions on objectively-assessed PA and psychological outcomes at 12 and 24 weeks.

3.2. Primary outcomes will be feasibility and acceptability. Specifically, indicators of feasibility and acceptability will include:

- **Attrition** per intervention condition as measured by study records
- **Adherence** to wear of the activity monitor as measured by daily step information in the Fitbit app
- **Adherence** to use of the workbook as measured by observation of photographs of each workbook page (number of photographs taken for values clarification activity, completion of written portion of values clarification activity, number of days with written entries, number of days with graphic entries, photos pasted into workbook, number of stickers pasted into workbook, number of additional drawings, number of "tag" annotations added to graphs, coded level of reflection of written entries)
- **Dose delivered** as measured by study logs of materials provision
- **Dose received** as measured by self-report
- **Adverse events** as measured by self-report and study records
- **Acceptability** will be measured using quantitative items in the 12 week and 24 week questionnaires as well as in the brief interview during the 12 week assessment

3.3. Secondary outcomes

- **Steps.** PA will be measured objectively using Actigraph wGT3X BT monitors. Wear time will be seven days at each assessment point. Because continuous measurement is not feasible, a week-long sample will be taken at the three assessment periods. Estimates will be valid if the monitor is worn ≥ 10 hours per day on ≥ 4 days. Non-wear time will be determined by 60 or more of consecutive minutes of zero activity counts. Because the emphasis of the intervention content is on walking, steps will be the primary measure of PA. We will also investigate minutes of moderate-vigorous intensity PA. Based on criteria used for the NHANES surveys, epoch length will be one minute, and activity counts over 2020 per minute will be considered moderate-vigorous intensity.[23]
- **Anthropometric measurements** will include height (SECA stadiometer; baseline only), weight (Tanita research-grade scale), and waist circumference.
- **Additional psychological variables.** Table 1 shows the variables to be included in questionnaires at each time point.

Table 1. Measures

Variable	Measure	Sub-scales	Alpha	References
Motivation	Behavioral Regulation in Exercise Questionnaire-3	Intrinsic motivation, amotivation, and integrated, identified, introjected, and external regulation	0.73 to 0.86	24,25
Self-reflection	Self Reflection and Insight Scale	Engaging in self-reflection, need for self-reflection, insight	0.71 – 0.91	26
Engaged living	Engaged Living Scale	Valued living, life fulfillment	0.78 – 0.88	27
Values	Chronic Pain Values Inventory	Family, intimate relations, friends, work, health, growth	0.82	28
Basic psychological needs	Basic Psychological Needs in Exercise questionnaire	Autonomy, competence, relatedness	0.75 to 0.86	29
Exercise identity	Exercise Identity Scale	Exercise role identity, exercise beliefs	0.94	30
Body image	Body Image Scale	N/A	0.86+	31
Quality of life	Functional Assessment of Cancer Therapy – Breast	Physical, social, breast, functional ,emotional	0.90	32

4. STUDY DESIGN

This study will combine an initial formative, qualitative study with a pilot randomized controlled trial. The target population is breast cancer survivors aged 55 – 79 who are sedentary (< 150 minutes of physical activity per week), and who completed their primary cancer treatments at least 6 months prior to enrollment. This trial corresponds approximately to phases Ib (formative research to refine the intervention) and IIb (pilot randomized controlled trial to investigate feasibility and effect sizes) in the ORBIT model of behavioral intervention development. The trial itself will occur at a single center, but recruitment will occur at both UTMB and MD Anderson.

We anticipate that the duration of the Aim 1 phase will be approximately four months. From the beginning of recruitment to the final data collection point, we expect the trial to take one year to complete. The trial will consist of two arms: the narrative visualization intervention condition and an attention control intervention that includes only standard self-monitoring.

5. Study enrollment and withdrawal

5.1. Inclusion criteria for Aim 1

1. Age between 55 and 79
2. Female
3. Self-reported diagnosis of breast cancer
4. Participant is inactive (reports less than 150 minutes of moderate-vigorous intensity activity per week)
5. Able to read and understand English
6. Daily access to a smartphone or similar device compatible with Garmin or Fitbit app

5.2. Exclusion criteria for Aim 1

No exclusion criteria for the Aim 1 study will be used.

5.3. Inclusion criteria for RCT

1. Age between 55 and 79
2. Female
3. Self-reported diagnosis of breast cancer
4. BMI is between 18 kg/m^2 and 40 kg/m^2
5. Willingness to be randomized to any condition
6. Participant is able to walk for exercise
7. Able to read and understand English
8. Daily access to a smartphone or similar device compatible with Fitbit app
9. PAR-Q+ indicates that physical activity would be safe (with note from physician required if any heart-related questions are endorsed)

During the COVID-19 pandemic, the following inclusion criteria will be implemented

10. Must have access to teleconference capability from home (i.e. Skype, FaceTime, Zoom or other teleconference programs with smart phone or webcam technology).

5.4. Exclusion criteria for RCT

1. Participant is active (150 or more minutes of moderate-vigorous intensity activity per week)
2. Major health interventions such as surgery, radiation, or chemotherapy within the past 6 months (adjuvant treatments such as tamoxifen are okay)
3. Stroke, hip fracture, hip or knee replacement, or spinal surgery in the past 6 months
4. Report a history of orthopedic complications that would prevent optimal participation in the physical activities prescribed (e.g., heel spurs, severe arthritis)
5. Current evidence of cancer
6. Self-reported smoker
7. Participant reports psychological issues that would interfere with study completion. Examples will be provided to illustrate potential psychological issues, such as dementia or schizophrenia.
8. Participant reports hospitalization within the past year due to psychiatric problem(s)
9. Clinical judgment concerning safety
10. Currently participating in an organized commercial or research exercise program
11. Another member of the household is a participant or staff member on this trial
12. Current use of a wearable activity monitor

5.5. Rationale for inclusion/exclusion criteria

We will not recruit individuals who cannot speak English due to the need to understand the app, which is in English.

Participants will likely be moderate risk as designated by the American College of Sports Medicine, and thus we want to be conservative in our eligibility criteria. If participants endorse any question on the PAR-Q+, they will automatically be ineligible due to unacceptably high risk unless they produce a note from their physician clearing them for participation.

We will focus specifically on cancer survivors who are at least six months post major treatment to ensure that complications do not impact the safety of exercises.

Other exclusion criteria exist to exclude variables that could potentially affect participation in the trial. We will also exclude those with a BMI indicating that they are underweight as we are interested in adults of normal weight, overweight, and obese status. Underweight may indicate other health problems that could compromise participant safety. We will include obese adults up to a BMI of 40, but those over 40 are likely to be substantially different from our target population and will require independent study in the future.

Other health exclusions are for the purposes of safety and unbiased data (e.g., substance use disorder).

No exclusion criteria or quotas will be related to race, ethnicity, or gender.

5.6. Recruitment strategies

Participants will be recruited using several methods:

1. In-person recruitment at UTMB and MD Anderson clinics
2. Phone and email screening of eligible patients at MD Anderson clinics
3. Referrals from practitioners at both institutions
4. Flyers and brochures available in treatment and waiting areas of both institutions, community clinics in Galveston and surrounding areas.
5. Mailed letters and emails to members of research and cancer registries at both institutions
6. Targeted Facebook advertisements
7. Emails to local organization listservs (each institution, local cancer support groups, etc.)
8. Presentations at local cancer and wellness events
9. As necessary, newspaper and radio advertisement

Specifically, recruitment of MD Anderson patients may occur by flyer, in-person, by email, or by phone. Study staff at MD Anderson will review upcoming patient appointments in the clinic via EPIC. Participants who look to be eligible will be called over the phone to explain to them the study procedures and see if they are interested in participating. This procedure is regularly used successfully by our collaborators at MD Anderson. Whereas at UTMB we must obtain practitioner permission to approach patients, all MD Anderson patients have provided consent to be approached by research-related phone calls. Reciprocal approval of all screening materials, protocols, etc by the MD Anderson IRB will be obtained prior to any recruitment. Participants will also be screened at that time to ensure that they are eligible to participate in the study. If the patient is interested and eligible, UTMB study staff will call to set up an appointment for informed consent, baseline assessment, and randomization/study orientation. MD Anderson staff will assist with this pre-screening but will not be involved in intervention or assessment procedures. MD Anderson clinics will be a recruitment site only, not an intervention site (i.e., UTMB consent forms will be used, MD Anderson personnel will not have access to any non-screening-related study data, etc.).

5.7. Randomization

A random number generator will be used to create a list of group assignments by ID number. Sheets containing group assignments (intervention or comparison group) will be placed in envelopes that are labeled with the corresponding ID number. The envelopes will be opaque, and foil will be placed inside to ensure that the randomizer cannot see inside. Carbon paper will also be included to provide an audit trail. ID numbers will be assigned in the order participants arrive to their randomization visit. Upon opening the envelope, the staff member undertaking the randomization will sign and write the date on the envelope. The inner paper that lists the group assignment, with the ID, signature, and date written on it via carbon paper, will be kept in the participant's file.

5.8. Blinding

Because of the nature of this behavioral study, participants and interventionists cannot be blinded to their group assignment.

5.9. Participant withdrawal

Participants may withdraw from the study at any time. Withdrawal prior to the end of the study will not affect the safety of participants. The consent form lists the following potential reasons that participants may be removed by the investigators:

- The researchers believe that participation in the research is no longer safe for you.
- The researchers believe that other treatment may be more helpful.
- The sponsor stops the research for the safety of the participants.
- The sponsor cancels the research.
- You are unable to keep appointments or to follow the researcher's instructions.

5.10. Premature termination or suspension of study

There is no reason to believe that the proposed intervention would produce increased risk as compared to standard self-monitoring. Because anticipated risks and benefits to individual participants are small, we do not anticipate early termination of the study due to excessive risk or differences in anticipated benefits.

5.11. Participant remuneration

For the initial formative study, participants (n = 20) will receive $50 for their participation. Participants in this study do not get to keep any of the study materials. For the RCT, participants will receive $50 incentive for attending assessments ($25 at 12 weeks and $25 at 24 weeks) and will be able to keep the activity monitors and other supplies provided. Parking will also be provided.

6. INTERVENTIONS

6.1. Description of the active control group intervention

This group will receive only a wearable activity monitor, app, and workbook. We will use Fitbit. The workbook will contain a weekly calendar with prompts to write in that week's goal and whether each daily goal was achieved. Basic pen supplies will be provided for writing in the workbook. At orientation, instruction will be provided on the use of the materials, and participants will set long-term (24 weeks) goals and their goals for the first week. Goals are based on estimates of appropriate step counts for older adults with chronic illness.[33] Goals will be negotiated with each participant, based on their baseline totals. The suggested progression will be from 2 days per week at 8,000 steps (week 1) to 5 days per week at 8,000 or more steps (from week 6 on). Negotiated goals are critical in an autonomy-promoting study, to ensure that participants do not feel controlled. The standard protocol will include daily reminders to log progress in the workbook negotiated with participants and expected to occur via automated phone reminders set to occur every day at a time they choose). After their final assessment, participants in this condition will receive the additional supplies given to the narrative visualization intervention participants.

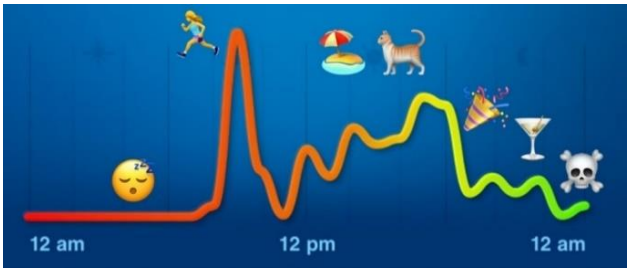
In summary, the active control group will receive an activity monitor, mobile app, and a workbook. This workbook will include simple diary-like calendar pages. Participants will be instructed to enter their step count into these calendars every night.

6.2. Description of the narrative visualization intervention

This intervention builds upon the standard intervention by expanding the workbook and providing art supplies and an instant camera for more detailed reflection activities. The orientation meeting will include extended instructions on using the additional materials as well as tips and examples for creating narrative visualizations.

The workbook will include two pages for each calendar day. One page will include a blank chart for drawing their interpretation of their step chart for the day. Ample space will be provided for writing, drawing, and placing stickers or photos at various points in the chart to represent things that happened that day. The workbooks will have sufficient pages for 12 weeks of entries. **Figure C.1.** shows an example of narrative visualization, though participants will be encouraged to be creative in how they annotate their charts.

Figure C.1. Example narrative visualization



In this very simple example, a standard step chart (taken from the Nike Fuelband app) was annotated with emojis to show what was going on that day. Without the annotations, the user would know that she met her step goal, but would not know why PA dropped off late in the day. Here, it is clear that a planned running bout and a trip to the beach to play with the wharf cats were the causes of the early activity. The lack of activity at the end of the day coincided with attending a party, drinking too much, and getting sick. This narrative clearly offers a starting point for reflection: perhaps in the future, more pleasant trips to do fun things could be planned, and the participant could limit drinking at parties. These visuals also relate the steps to personal values, such as spending time outdoors and socializing. Visual triggers provide a foundation for figuring out how to interpret PA data and what to do to change behavior in the context of one's values and identity.

Table C.1 shows examples of daily and weekly reflection questions that can be answered with a combination of text and visuals (please note that these prompts may change based on the results of the Aim 1 interviews). We will also include additional one-time prompts to provide context for these reflections. For example, we will ask participants in their first week to take photos that represent how they feel about themselves and photos that represent their values, following the procedures of a published photo values clarification activity.[20]

Table 1. Reflection prompts

Timing	Prompt
Daily	How were you active today?
	Why do you think you were (or were not) active today?
	What impacted your decisions about activity today?
Weekly	Looking back, do you see any patterns in your activity?
	How can you take this knowledge and use it to be more active next week?
	How do you feel about your progress this week? Do you feel closer to your goals?

Art supplies will include adequate film for one photo per day for 12 weeks, decorative tape for pasting photos into the workbook, writing materials, and stickers (e.g., emojis or other potentially explanatory pictures).

In summary, the narrative visualization group will receive an activity monitor, a mobile app, a workbook, and an art supply kit. This art supply kit will include an instant camera, writing materials, stickers, photo paper, and photo corners for pasting photos into the workbook. The workbook will differ from that of the active control group. This workbook will contain a values clarification exercise, which will involve participants taking 10 photos over a period of about one week. These photos will be of things the participant values and will be used as a jumping-off point for connecting personal values to reasons to be physically active. The daily pages for entering steps will also be more elaborate than those of the active control group. These pages will include a blank graph on which participants will draw their step graph and add text, drawing, and sticker annotations that explain what they were doing at different times. There will also be space for including photos of interesting things seen on walks (and sufficient photo paper will be provided for daily photos). Daily and weekly reflection questions will encourage participants to think about why they were active each day and how their behavior changed over time.

Element	Active control	Narrative visualization
Activity monitor	x	x
Mobile app	x	x
Reminders to log steps nightly	x	x
Art supply kit (camera, writing materials, stickers, photo corners, photo paper)		x
Workbook pages:		
Daily diary calendar pages	x	

Values clarification activity		x
Daily blank graphs		x
Daily reflection questions		x
Weekly reflection questions		x

6.3. Administration of intervention

The interventions are primarily self-guided, with minimal personal attention from interventionists. Participant contact with interventionists will occur at the orientation visit only.

Daily texts/emails that serve to remind participants to complete their workbook page that day will be generic and not considered personal intervention.

6.4. Procedures for training interventionists and monitoring intervention fidelity

Interventionists will be trained by the Principal Investigator to conduct the orientation visit. Intervention fidelity is itself an outcome of this study and as such is detailed in the measures and statistical analysis sections of this protocol.

6.5. Assessment of participant compliance with study intervention

Participant compliance is an outcome of this study and as such is detailed in the measures and statistical analysis sections of this protocol.

7. STUDY SCHEDULE – AIM 1 FORMATIVE STUDY

7.1. Screening

We have collaborated with oncologists at various clinics to expand our effort in recruitment. A HIPAA waiver request form has been completed. With the oncologist's approval, we will pre-screen patients via medical records for eligibility. The oncologists will refer their patients. We will not approach patients unless we have oncologist's and patient's permission.

Research staff will use the Aim 1 screening guide, either in person or by phone, to determine eligibility in the study. Should the participant be found eligible, the staff member will schedule an appointment for informed consent and enrollment.

7.2. Enrollment and provision of materials

Research staff will conduct the informed consent interview. Once the interview is complete and participants have asked any questions they may have, the participant and staff member will each sign two copies of the consent form. One copy will be provided to the participant and the other kept for study records.

The staff member will then use the Aim 1 visit 1 checklist to go through study procedures for this visit. S/he will provide participants with materials (activity monitor, workbook, camera, film, writing materials, photo corners, stickers) and go over instructions for their use. At the conclusion of the visit, the staff member will schedule an appointment for the return visit after approximately one week.

- Obtain and document consent from participant on study consent form
- Administer Aim 1 Visit 1 checklist/interview guide
- Provide and document the following materials:
    - Activity monitor
    - Instant camera
    - Workbook (binder with pre-printed instruction pages for 7 days + values activity + troubleshooting guide)
    - Writing materials
    - Stickers
    - Film for camera
    - Photo corners for pasting photos in workbook
    - Bag to hold materials
- Set up activity monitor app on the participants' mobile device & daily reminder

7.3. Cognitive interviewing visit

An interviewer, who will receive training in cognitive interviewing, will guide participants through orientation to the workbook and using the wearable device, mobile app, and photo printer at this initial meeting. Interviews one week later will use a combination of think-aloud and probing procedures from a semi-structured guide, as has been used in development of other behavioral interventions.[34-36]

- Collect and document returned materials
- Prepare audio recorder
- Administer Aim 1 Cognitive Interviewing checklist and guide
- Provide participant gift card and document

8. STUDY SCHEDULE - RCT

During the COVID-19 pandemic, the following consenting/interview methods will be implemented:

In response to the COVID-19 pandemic and related Institutional guidelines, the following modifications are being implemented effective immediately:

All visits will be conducted entirely by teleconference call. Ongoing participants will receive a phone call by study staff to inform the subject of the implemented modifications. We will read the modification letter to the subject over the phone. If the subject agrees with the modifications, we will document the subject verbal response in a note to file. If we are not able to reach the subject, we will mail the subject a letter.

8.1. Screening

We have collaborated with oncologists at various clinics to expand our effort in recruitment. A HIPAA waiver request form has been completed. With the oncologist's approval, we will pre-screen patients via medical records for eligibility. The oncologists will refer their patients. We will not approach UTMB patients unless we have oncologist's and patient's permission.

For patients at MD Anderson clinics, as discussed above in section x, staff will review upcoming patient appointments in the clinic via EPIC and call potentially eligible participants. Whereas at UTMB we must obtain practitioner permission to approach patients, all MD Anderson patients have provided consent to be approached by research-related phone calls and emails. If the patient is interested and eligible, UTMB study staff will later call to set up an appointment for informed consent, baseline assessment, and randomization/study orientation.

Research staff will use the RCT screening guide, either in person or by phone, to determine eligibility in the study. Should the participant be found eligible, the staff member will schedule an appointment for informed consent and enrollment.

8.2. Enrollment and provision of accelerometer

Research staff will conduct the informed consent interview. Once the interview is complete and participants have asked any questions they may have, the participant and staff member will each sign two copies of the consent form. One copy will be provided to the participant and the other kept for study records. The staff member will take the participant's height, weight and waist circumference at this visit and ask several demographic questions (age, gender, race) for the purposes of calibrating the accelerometer. Once calibrated and activated, the staff member will provide instructions as to wearing the accelerometer for one week. At the conclusion of this visit, the staff member will schedule a follow-up appointment for approximately one week after the enrollment appointment.

- Obtain and document consent from participant on study consent form
- Obtain height, weight and waist circumference measurements
- Calibrate and activate accelerometer

COVID-19 adjustments for consenting/enrollment:

- The visit will be conducted using teleconference communication (examples: via phone, skype, zoom)
- Consent will be obtained via teleconference call and the study subjects will scan or photograph and transmit the signed consent form to us via email or text.

- Height, weight, and waist measurements- we will obtain self-reported height, weight, and waist measurements. If possible, we will obtain measurements at a future face to face visit if available.
- We will drop off and pick up the activity monitor. For the participant to wear for 7 days, for at least 10 hours per day.
- We will give the option to participants to complete an assessment visit when the recommended guidelines are lifted, and we are able to have a face to face visit.
- We will give participants paper forms of the questionnaires to complete prior to the baseline visit.

8.3. Baseline and orientation visit

Participants will return after approximately one week to engage in baseline assessment, be randomized to a condition, and to begin the intervention. Baseline assessments will include height, weight and waist circumference, collection of the accelerometer and questionnaires. A staff member will randomize the participant and then, based on their condition, provide them with appropriate materials. The staff member will go over these materials in detail, following a specific checklist. S/he will also check off materials provided on a separate log sheet. Participants will engage in a brief goal-setting activity before leaving.

- Collect and document accelerometer
- Check accelerometer data to ensure that they include at least 10 hours on at least 4 days
- *If not enough days are found, request that participant wear an accelerometer for an additional 7 days and return for their randomization afterwards
- Administer questionnaires
- Randomize participant

<u>For the narrative visualization intervention:</u>

- Follow RCT visit 2 checklist to document each step
- Provide activity monitor
- Download activity monitor app onto participant's mobile device and provide orientation
- Provide workbook
- Orient participant to contents of the workbook
- Provide camera, film, writing materials, stickers, photo corners, film, and bag and provide orientation
- Administer goal-setting activity

<u>For the self-monitoring only intervention:</u>

- Follow RCT visit 2 checklist to document each step
- Provide activity monitor
- Download activity monitor app onto participant's mobile device and provide orientation
- Provide workbook
- Orient participant to contents of the workbook
- Provide writing materials
- Administer goal-setting activity

COVID-19 adjustments for baseline/orientation:

- The initial portion of the visit will occur in-person. Study staff will wear personal protective equipment and follow safety precautions, such as sanitizing equipment. The in-person portion will consist of obtaining measurements, retrieving the activity monitor, providing participant materials, and assisting with downloading the Fitbit app onto participant phones.
- The rest of the orientation portion of the visit will be conducted using teleconference communication (examples: via phone, skype, zoom)

8.4. 12 week follow-up

After approximately 10 weeks, a staff member will document and mail the participant a calibrated accelerometer and questionnaires. The staff member will call the participant to ensure receipt and to make sure it is fitted correctly. At approximately 12 weeks, the participant will meet with an assessor to measure height, weight, waist circumference and collect the accelerometer and questionnaires. A brief interview will also occur. Study staff will follow a guide with a checklist to ensure the interview proceeds as planned.

- Mail accelerometer and questionnaires (approximately 2 weeks before), call to inform participant, and document.
- Phone/email/text reminder to bring workbook to appointment (day before)
- Collect accelerometer
- Check accelerometer data to ensure that they include at least 10 hours on at least 4 days
- *If not enough days are found, request that participant wear an accelerometer for an additional 7 days and return it in a provided padded, pre-stamped envelope
- Administer or collect questionnaires
- Make copies/take pictures of workbook pages
- Conduct interview according to RCT interview guide and checklist
- Provide gift card and document

COVID-19 adjustments for consenting/enrollment:

- We will collect the activity monitor and questionnaires during a brief in-person visit. Study staff will wear personal protective equipment and sanitize equipment as needed. The gift card will be provided at the conclusion of this visit.

8.5. 24 week follow-up

After approximately 22 weeks, a staff member will mail the participant a calibrated accelerometer and possibly questionnaires. The staff member will call the participant to ensure receipt and to make sure it is fitted correctly. At approximately 24 weeks, the participant will meet with an assessor to measure height, weight, waist circumference, collect the accelerometer, and administer or collect questionnaires.

- Mail accelerometer and possibly questionnaires (approximately 2 weeks before), call to confirm receipt, and document
- Phone/email/text reminding participant to bring the workbook to appointment (day before)
- Collect accelerometer
- Check accelerometer data to ensure that they include at least 10 hours on at least 4 days
- *If not enough days are found, request that participant wear an accelerometer for an additional 7 days and return it in a provided padded, pre-stamped envelope
- Administer or collect questionnaires
- Make copies/take pictures of workbook pages
- Provide gift card and document

COVID-19 adjustments for consenting/enrollment:

- We will collect the activity monitor and questionnaires during a brief in-person visit. Study staff will wear personal protective equipment and sanitize equipment as needed. The gift card will be provided at the conclusion of this visit.
- While reviewing data in January of 2021, we noticed that many follow-up assessments scheduled after March of 2020 were missing. We suspect many of these missing visits were due to COVID-19 in some form and wish to investigate and gather as much information as possible from these participants. Thus, we are amending our procedures for follow-up to include the possibility of contacting participants more than one month after their indicated follow-up time. These visits will be amended to consist only of questionnaire, interview, and if possible collection/photography of materials. We have added several questions about COVID-19 to our interview guide to find out more about whether or not participants used intervention materials during the pandemic. The consent form has been updated to include these procedures. When we contact participants with no follow-up data, we will conduct a new consent interview and re-consent them using the new form to ensure that they are fully aware of the updated procedures.

8.6. Additional communications with participants by phone, email/text, and in person

Study staff will ensure that participants have contact information for the research team and knows how to call after hours in the case of a question or problem.

Participants will be asked (but may decline) to provide alternative contacts to the study staff. At each study visit, participants will be asked if there have been any changes in their contact information or that of their alternative contacts.

Attempts at contact will be documented in each participants' contact log. Information discussed, provided to, or obtained from the participant will be documented in the log.

Study staff will provide basic technical troubleshooting with study devices (Fitbit monitor, app, camera) during business hours by text or phone. If necessary, we will set up one meeting per participant to replace broken or lost equipment. We will allow one other meeting for technical support of other kinds, if necessary.

Study staff will contact participants by phone, text or email the day before each appointment. If emailed or text regarding the appointment and scheduling, staff will respond. Study staff will also send generic cards at approximately 5 months in to the intervention period to remind the participants of their participation in the study and that they will be contacted to schedule another appointment at a later date.

Prior to determining that a participant is lost to follow up form, we will attempt to contact the participant at least 3 times, attempt contacting the alternative contact(s), and attempt a final contact by mail. A form documenting all mailed correspondence will be stored in the participants' file.

Participants will be notified that study staff may not respond to non-emergency contacts outside of normal business hours.

Additional contact may occur for the purposes of picking up/dropping off accelerometers or questionnaires.

Due to difficulties from COVID19 additional contact may occur for the purpose of collecting final questionnaires, interview, and collection/photography of material. The following steps will take place if we contact a subject for this purpose:

We will ask for their permission to re-consent for the purpose of collection/photography of material, questionnaires, and interview. This visit may be completed by using a teleconference call or in person.

9. ASSESSMENT OF SAFETY

9.1. Plan for monitoring and safety review

The Principal Investigator (PI) will be responsible for monitoring the safety environment of participants and ensuring that appropriate medical care and coverage is provided to all participants if necessary.

The PI is also responsible for monitoring procedures during conduct of the study for each participant, including eligibility, enrollment, data collection, evaluation of study outcomes, problems with informed consent, and subject safety and well-being.

The plan will include:

1. Review of screening results by PI
2. Immediate reporting of adverse events by interventionists to PI
3. Quarterly review of collected data by PI
4. Annual review by PI and UTMB IRB

Screening data will be reviewed during recruitment periods by the PI. Ensuring that any values indicating ineligibility and/or unsafe practices are flagged. Flagged participants may be excused from the study or instructed on safer practices, as needed. These decisions will be made in consultation with Dr. Volpi.

In the case of adverse events, standard protocol for reported adverse events will be used. Study data will be reviewed by the PI or Co-I, as needed. Finally, the UTMB IRB will review study progress yearly.

We do not anticipate a strong ethical imperative to cease one of the arms prior to the planned end of the study, and thus we will not perform full statistical analysis during these periodic reviews. The reviews will focus on indicators of safety for participants, such as large decreases in quality of life or strength, or large weight gains.

We will not convene an external Data Safety and Monitoring Board. Should the NCI request that we do so, we will take advantage of protocols used in the past by investigators associated with the Claude D. Pepper Older

Americans Independence Center at UTMB. The center has previously convened external DSMBs for its investigators from its external advisory board.

Anticipated non-serious adverse events include musculoskeletal pain or mild injuries, other non-serious injuries (e.g., bruises), minor discomfort, cardiac events, fatigue, and possible loss of confidentiality. If an anticipated adverse event occurs, the PI will discuss as soon as possible and determine whether the event requires reporting to the IRB and/or to the NCI. The attribution and impact of each event on the overall project's risk/benefit ratio will then be determined in consultation with the Co-Is.

All unanticipated, serious, fatal, and/or life-threatening adverse events will be immediately reported to the UTMB IRB within 24 hours of occurrence. All serious, fatal, and/or life-threatening adverse events will be reported to the program officer as well. The IRB and PI are responsible for determining if modifications are needed to the consent form and/or protocol based on the event. If a determination is made that participants are exposed to unacceptably high risk in comparison to benefit, the study will be suspended until proper modifications are made for participant safety. Aggregate reports of adverse events will be prepared in consultation with the regulatory key resource of the Institute for Translational Sciences at UTMB and forwarded to the IRB for review.

Should cessation of study activities be required (temporarily or permanently), the program officer will be notified immediately.

9.2. Unexpected problems

Unexpected problems involve risks to participants that meet all of the following criteria:

- Unexpected in terms of nature, severity, or frequency given the nature of the research and population
- Related or possibly related to participation in the study
- Suggests that the research places participants at a greater risk of harm than was previously known or recognized

Incidents that meet these criteria will require documentation in an unanticipated problem report form submitted to the IRB within 1 week. The Principal Investigator will also contact the Program Officer at NCI to determine next steps.

9.3. Expected adverse events

An adverse event is an unfavorable medical occurrence in a human subject. This population consists of women susceptible to adverse events related to age, cancer, cancer treatment, comorbidities, overweight/obesity, and sedentary lifestyle. Based on these factors and adverse events that occurred in previous similar studies, we anticipate the following potential adverse events:

- Acute mild activity-related injuries
- Acute musculoskeletal pain
- Minor discomfort
- Fatigue
- Cardiac events
- Mild, acute illness
- Complications of ongoing chronic illness(es)
- Acute hospitalization for a specific, unrelated illness (e.g., flu)

9.4. Characteristics and severity of an adverse event

- ***Mild*** events include discomfort without disruption of daily activities. No therapy or only symptomatic therapy is required. This level is equivalent to the National Cancer Institute's Common Terminology Criteria for Adverse Events version 4.03 Grade 1 adverse events (mild; asymptomatic or mild symptoms; intervention not indicated).
- ***Moderate*** events include discomfort sufficient to modify daily normal activity. Specific therapy is required. Laboratory test alterations indicate injury without long-term risk. This level is equivalent to NCI Grade 2 (moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate activities of daily living).

- ***Severe*** events include incapacity, inability to work, inability to perform normal daily activity, hospitalization required, prolonged emergency treatment required, life-threatening events, laboratory tests indicating a serious health threat or permanent injury, and death. This level is equivalent to NCI Grades 3 (severe/medically significant but not immediately life-threatening), 4 (life-threatening, urgent intervention indicated), and 5 (death).

9.4.1. Relationship to study participation

Attribution will be assessed by the PI on a scale used by CRC investigators: 1) not related, 2) possibly related, 3) probably related, and 4) definitely related to the study interventions.

9.4.2. Expectedness

The Principal Investigator will be responsible for determining whether adverse events are expected or unexpected. An adverse event will be considered unexpected if the nature, severity, or frequency of the event is not consistent with risk information previously described. We may use de-identified photographic copies of workbook pages in publications and/or presentations. Photographs including an individual's face will be obscured.

9.5. Reporting

All unanticipated, serious, fatal, and/or life-threatening adverse events will be immediately reported to the UTMB IRB within 24 hours of occurrence. All serious, fatal, and/or life-threatening adverse events will be reported to the program officer as well. The IRB and PI are responsible for determining if modifications are needed to the consent form and/or protocol based on the event. If a determination is made that participants are exposed to unacceptably high risk in comparison to benefit, the study will be suspended until proper modifications are made for participant safety. Aggregate reports of adverse events will be prepared in consultation with the regulatory key resource of the Institute for Translational Sciences at UTMB and forwarded to the IRB for review.

Should cessation of study activities be required (temporarily or permanently), the program officer will be notified immediately.

The PI will hold responsibility for monitoring and reporting adverse events of any kind. We do not anticipate severe adverse events, though mild and moderate events are possible. The scale to be used is the UTMB Clinical Research Center Adverse Event Grading Scale. Examples of each level of adverse event on the scale are provided below.

Table 1. Reporting of adverse events to IRB

NCI Adverse Event Grade	Expected	Unexpected
Grade 1	Reporting not required	Report within 10 days
Grade 2	Reporting not required	Report within 10 days
Grade 3 (UTMB level 3)	Report by phone within 24 hours	Report by phone within 24 hours
Grade 4 (UTMB level 3)	Report by phone within 24 hours	Report by phone within 24 hours
Grade 5 (UTMB level 3)	Report by phone within 24 hours	Report by phone within 24 hours

The PI will follow the reporting requirements for serious and unexpected adverse events outlined in the UTMB IRB Adverse Event Policy. All unanticipated, serious, fatal, and/or life-threatening adverse events will be reported to the UTMB IRB within 24 hours of occurrence or recognition. Aggregate reports of adverse events will be prepared on an annual basis and forwarded to the IRB at annual review.

10. STATISTICAL CONSIDERATIONS

10.1. Study hypotheses

Aim 1. Participants will…

- Complete >80% of values clarification activities
- Complete >80% of daily workbook entries
- Participants will wear the activity monitor <80% of days
- Report no serious adverse events related to the study

Aim 2. The narrative visualization intervention will produce, as compared to the self-monitoring intervention at 12 weeks…

- Greater physical activity
- Greater intrinsic motivation for activity
- Greater integrated regulation for activity
- Greater perceived autonomy
- Greater perceived competence
- Greater engagement in self-reflection
- Greater insight
- Greater need for self-reflection
- Greater perceived valued living
- Greater perceived life fulfillment
- Greater exercise role identity
- Greater exercise beliefs
- Greater physical quality of life
- Greater social quality of life
- Greater functional quality of life
- Greater emotional quality of life

Aim 2 feasibility and acceptability hypotheses:

- Participants will complete >80% of values clarification activities
- Participants will complete >80% of daily workbook entries
- Participants will wear the activity monitor <80% of days
- Participants will report no serious adverse events related to the study
- Study records will indicate attrition did not differ by group assignment
- Study records will indicate that all intervention materials were provided as intended
- Study records will indicate that >90% of intervention materials were reported received as intended
- Participants will rate intervention materials >4 out of 5

10.2. Sample size considerations

As a Phase Ia evidentiary study, hypothesis tests are not powered to detect statistical significance. A study of 40 individuals would have 80% power to detect a large effect size of approximately F = 0.45 for an ANCOVA model, but we will not interpret statistical significance. Rather, we have set a priori cut points for effect sizes to which we will compare our outcomes. These effect sizes represent points at which we can conclude that the intervention components adequately impact psychosocial and behavioral outcomes to proceed to further testing. For the comparison to the standard group, the intervention group must produce at least a small effect size difference in integrated regulation to allow us to proceed to Phase Ib.

10.3. Final analysis plan

10.3.1. Qualitative analyses

Qualitative investigations of interview transcripts and workbook content will be performed using NVivo. We will use thematic analysis to create codes to better understand how participants reacted to specific aspects of the intervention.[37]

Interviews will be recorded and transcribed with interviewer field notes, then the investigators will refine any materials or procedures that were flagged by participants. Once the investigators have come to a consensus, we will apply insights from this sub-study to orientation procedures and intervention materials as needed.

We will use Fleck's procedures for coding reflection levels in the workbook text.[38] These procedures involve creating "chunks" of content surrounding a particular theme, then rating these chunks against a framework of reflection levels. We will count the number of instances of each level of reflection within the text workbook responses. Artistic content will be analyzed using standard thematic analysis, as Fleck's procedures investigate reflective text or verbal responses to art rather than reflection in the art itself.

10.3.2. Quantitative

All quantitative analyses will be performed by the study statistician, who will be blinded to group allocation. For tests of feasibility and acceptability, we will use descriptive statistics only.

A priori benchmark indicators will be used from a variety of similar studies (e.g., 80% completion, no serious related adverse events) to indicate whether feasibility or acceptability were achieved.

For quantitative hypotheses, we will use analyses of covariance, controlling for baseline values of the dependent variable as well as time since diagnosis. We will follow the intent to treat principle, and imputation methods will be used as necessary to account for missing data. As indicated above, these outcomes will be used primarily for the purposes of shaping a fully powered follow-up study.

11. ETHICS AND PROTECTION OF HUMAN SUBJECTS

11.1. Institutional Review Board and ethical standard

The protocol, informed consent forms, recruitment materials, screening materials, and copies of all written or spoken materials/communication provided to participants will be submitted to the UTMB IRB for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before any changes are implemented.

The investigator will ensure that this study is conducted in full conformity with the principles set forth in the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects Research, as drafted by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 18, 1979) and codified in 45 CFR Part 46 and/or the ICH E6.

11.2. Informed consent process

All study personnel have attended required courses on human subject protection and HIPAA regulations, and certificates of Institutional Review Board training completion are on file at UTMB. Participants that are eligible based on initial telephone screening will be invited to attend an initial session. They will be given an individual orientation to the study, including information on all aspects of the study. They will be able to ask questions at any time. Following this explanation, potential participants will be given informed consent information and forms to sign. Only then will participants engage in assessments, be randomized to a group, and proceed with orientation to their study group.

11.3. Exclusion of women, minorities, children, and vulnerable populations

We will not recruit children, pregnant women, or prisoners for this study.

11.4. Participant risks

Risks in this study are moderate and include breaches of confidentiality, minor injuries, and safety. The steps taken to reduce these risks include surveillance of exercise patterns (by “friending” participants on the apps they are using and reviewing their activity patterns weekly). We acknowledge that, in addition to these related risks, many unrelated and/or random adverse events may occur during the study period. Participants may catch colds, flu, or other similar sicknesses and may be injured in ways unrelated to exercise.

All known related risks will be described in the protocol and consent form.

Confidentiality could be breached, as is a risk in all human subjects research. Sensitive personal health information or other sensitive information could be divulged inappropriately to outside sources.

Injury, pain, fatigue. Participants may experience joint discomfort, muscle soreness, or other minor injuries due to increased physical activity. There is a low risk of cardiac events during exercise among deconditioned adults, particularly those who are overweight/obese and/or older.

Psychological stress. Participants may feel uncomfortable due to some of the questions included in the questionnaires.

There is no reason to believe that the proposed intervention would produce increased risk as compared to standard self-monitoring. Because anticipated risks and benefits to individual participants are small, we do not anticipate early termination of the study due to excessive risk or differences in anticipated benefits.

11.5. Protection against risks

General. Inclusion/exclusion criteria will allow us to exclude from the study anyone who is potentially at higher risk for developing complications due to research procedures. Participants will be able to withdraw from the study at any time if study procedures are upsetting or painful for them. We will closely monitor all participants for adverse events (see data safety and monitoring plan below).

Confidentiality. All data collected will be confidential. The risk of breached confidentiality of potentially sensitive data is minimal and comparable to the risk inherent in any human subjects research project. We will take standard precautions to ensure that personal health information is not identifiable, including:

- Paper copies of questionnaires and screening forms will be kept in a locked file cabinet in the research coordinator's locked office. ID numbers will be used on these forms to match them to individual participants. The database matching ID numbers to identifying information will be individually password-protected and kept separately on the password-protected server. We will abstract wear and step data from their Fitbit app accounts weekly into a database kept on this server, but we will not otherwise collect data from the app.
- Data collected on measurement equipment will be uploaded to the server as soon as possible after collection. Then, it will be erased from the equipment. ID numbers will be used for participant identification on all physiologic measurement equipment as an added layer of protection. No identifying data will be kept on measurement equipment or on portable data storage devices such as laptops or USB drives.
- Transcripts and scans of workbook pages will be saved by ID number, with any identifying information redacted. These files will be kept on a password-protected server.

Injury, pain, fatigue. Exercise may produce minor injuries or, much less likely, adverse cardiac events. Though starting an exercise program can be minimally to moderately risky, depending on the individual, when participants are properly screened the benefits outweigh the risks. Exercise can improve fitness, quality of life, cardiometabolic indicators of health, mood, fatigue, and a number of other outcomes (see research plan for references). The goals that we will suggest will increase slowly to ensure safety. Dr. Volpi is a physician. She will review all adverse events and data abstracted from the apps that indicate potentially dangerous activities.

Psychological stress. Participants may refuse to answer any of the questions, take a break, or stop their participation.

11.5. Potential benefits

Participants may experience improvements in mood and energy levels due to increased physical activity.

11.6 Future used of stored identifiable data

No identifiable data will be stored for future research use.

12. DATA HANDLING AND RECORD KEEPING

12.1. Data management responsibilities

The PI is responsible for collection and storage of data on paper, in pdfs of workbook scans, and saved in recording equipment. All data of interest will be abstracted into a computer database located on a secure UTMB server. Data saved in recording equipment will be erased after transfer to the server.

Questionnaire data will not be personally identifiable. All questionnaires will use ID numbers for identification purposes, and the correspondence of ID numbers to names will be kept in a password-protected file on a password-protected, secure server. Databases will use ID numbers for identification of data and will also be stored on the secure, password-protected server.

For non-UTMB study personnel we will use UTMB SharePoint link to provide de-identified information.

The PI is responsible for collection and storage of all data on paper questionnaires as well as in subsequent computer databases.

12.2. Sources of data

Participants will provide verbal and written data specifically for research purposes. We will also scan their narrative visualizations and reflections in their workbooks for analysis. Research-grade measurement equipment (activity monitors, etc.) will capture physiological data. The wearable devices and mobile apps will

collect limited data on physical activity as well as manually entered data by the participant. Procedures for ensuring the confidentiality and anonymity of these data are discussed below. Only trained study staff will have access to written study data. These data will be confidential.

12.3. Study records retention

Study documents will be retained for a minimum of 3 years from the date of the final financial report is sent to the NCI. No records will be destroyed without written consent of the sponsor, if applicable.

12.4. Protocol deviations

A protocol deviation will be considered any noncompliance with the clinical study protocol or good clinical practice requirements. The noncompliance may be on the part of the participant, the investigator, or study staff. Deviations will be reported to the IRB and corrective actions will be taken and documented as necessary.

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