Title: FitEx for Endometrial Cancer Survivors: Initial Efficacy

NCT trial number: NCT05737745

November 22, 2024

Study Protocol:

Overview:

This study targets 30 endometrial cancer survivors (ECS) and 2-5 support team members per ECS enrolled in intervention groups. We will use a 3-group design [FitEx (intervention 1) versus FitEx+yoga (intervention 2) versus standard-of-care (control)] with 3 assessments (pre, post [after 8-week program], and follow-up [6-month]). All participants will be given the option to receive a Fitbit Charge 5™ to objectively measure moderate-vigorous physical activity. ECS randomized to either intervention arm will participate in the 8-week FitEx program with their support team members which includes goal setting, self-monitoring, and weekly 30-minute synchronous sessions via Zoom. ECS in the control group will receive a one-time educational newsletter and will not recruit support team members. This protocol will be completed twice, once in 2023 and once in 2024.

OBJECTIVES:

- Aim 1: Among ECS, compare changes in objective MVPA between intervention groups and usual care (FitEx vs. control and FitEx+yoga vs. control) at 8 weeks.
- Aim 2: Among ECS, compare secondary efficacy outcomes and maintenance.
    - Aim 2a: Examine changes in secondary efficacy outcomes [e.g., quality of life (QOL), self-compassion, flourishing, self-efficacy, social support, habituation of exercise, and fruit/vegetable consumption] between intervention and usual care conditions (FitEx versus control and FitEx+yoga versus control) at 8 weeks.
    - Aim 2b: Explore maintenance of MPVA and secondary outcomes between intervention versus usual care (FitEx vs. control and FitEx+yoga vs. control) at 6 months.
- Aim 3: Among support team members, compare changes in MVPA and secondary outcomes (listed above) between intervention groups (FitEx vs. FitEx+yoga) at 8 weeks and 6 months.

RECRUITMENT:

Eligible ECS will be recruited via word-of-mouth, emails, phone calls, and flyers. An informational video on the research project will also be used for recruitment purposes (e.g., linked in emails). The first person to contact a potential participant will always be a Carilion Clinic affiliate on this research study such as Dr. Armbruster or gynecologic oncology clinicians and staff or a clinical research coordinator. The person contacting the participant afterward may be any IRB-approved research personnel on this study. Carilion Clinic affiliates may CC other research study personnel onto email correspondence or reference other research study personnel on phone calls so that other research study personnel may take over the screening or consenting process after the first instance of contact.

ECS who are randomized in either of the intervention groups may recruit up to 5 friends, family members, loved ones, or any support system members to join them as “support team members” within the study. ECS in the intervention groups will identify individuals they wish to be on their intervention team and share relevant contact information (phone number and/or email address of the potential support team members). ECS will be instructed to obtain verbal confirmation of interest from potential support team members before sharing information with research study personnel (ECS confirmation of support team member verbalizing interest in being contacted about the study will be tracked in REDCap). Research study personnel will then contact potential support team members to describe that they received their contact information from the enrolled ECS and to discuss the study and enrollment.

Recruitment will be limited to 3 phone calls and 2 email attempts per participant.

SCREENING & CONSENT

If an ECS is interested in participating, research study personnel will conduct a screening assessment and informed consent process either in-person or virtually. If conducted in-person, the informed consent process documents will be stored in the study coordinator’s office at Carilion Clinic. If conducted virtually, the informed consent process will be documented within REDCap. Participants may be consented on REDCap either over the phone or via teleconference depending on their preference. Consents conducted via teleconference will use secure, password protected Microsoft Teams or WebEx platforms. Zoom will not be used to consent participants. Support team members will undergo the same consent process as ECS after follow-up call and screening. All participants will be provided ample time to decide if they would like to join the study. There will be multiple opportunities for the participant to opt out before enrollment. Prior to consent, all potential participants will be sent a copy of the consent form for their review. A phone call or secure, web-based teleconference will be scheduled for interested participants to fill out the econsent via REDCap.

RANDOMIZATION & GROUPS

Each ECS who enrolls in the study will be randomized into one of three groups:

1. Standard-of-care (control)
2. FitEx intervention (FitEx-ECS)
3. FitEx intervention with integrated yoga principles (FitEx-ECS+yoga)

Overall, this study targets 10 ECS per group (30 total ECS) with 2-5 support team members per ECS in each intervention group (approximately 30 total support team members in each intervention group) yearly, for 2 years (90 participants per year, 180 participants total). All participants will be given the option to receive a Fitbit Charge 5^{TM} to objectively measure moderate-vigorous physical activity.

Control Group:

ECS in the control group will be given the option to receive a Fitbit and will be sent a one-time educational newsletter about survivorship PA and nutrition recommendations. Control group participants will fill out all questionnaires at baseline, post, and 6-months follow up. Control

group participants will not recruit support team members, fill out FitEx-specific forms, nor participate in weekly Zoom sessions.

Intervention Groups:

ECS randomized to either intervention arm will participate in the 8-week FitEx program adapted for ECS with their support team members. The FitEx-ECS intervention will entail group dynamics, goal setting, self-monitoring (tracking physical activity and fruit and vegetables intake via the FitEx-ECS portal within Fitabase or the FitEx Individual Log form), and feedback on goal attainment. The FitEx-ECS+yoga intervention will entail postures, breathwork, and mindfulness in addition to group dynamics, goal setting, self-monitoring (tracking physical activity and fruits and vegetables intake via the FitEx-ECS portal within Fitabase), and feedback on goal attainment. Each participant of either intervention group will have the option to receive Fitbit Charge 5™s, fill out repeated program forms and questionnaires, and read weekly group-specific newsletters. Participants in either intervention will not have to pay any intervention program-related fees.

Additionally, all participants will be asked to report their weight during the baseline, post-program, and 6-month follow up questionnaires packet (see updated questionnaires document). Participants may also choose to report their weight using the FitEx-ECS portal within Fitabase.

Participants from both intervention groups will also be strongly encouraged to attend weekly group-specific 30-minute synchronous Zoom sessions consisting of virtual physical activity and social support with other teams. Topics for both intervention groups are similar, however the FitEx-ECS+yoga group's newsletter and virtual sessions are guided by yoga principles and mindfulness. Participants in the Zoom sessions will be verbally reminded of the audio recording at the beginning of each session. Participants may choose to turn on or off their cameras according to what is most comfortable.

SMS Reminders to Sync:

Participants in all groups with Fitbit devices who have not synced their Fitbit devices after 6 days will receive up to a maximum of two automated SMS-based reminders per week.

- Prompt: "Please open your Fitbit app and sync this past week's activity."

Automated SMS-based prompts will be set up using the FitEx-ECS portal within Fitabase. Fitabase uses Azure Always Encrypted to encrypt phone numbers at rest and in transit to protect participant personal information.

COMPENSATION

After enrollment: All participants will have the option to receive Fitbit Charge 5™s to track their data over the course of the study and for them to keep after the study. If a participant already owns a Fitbit they wish to use, they will instead be reimbursed $99 for using their personal Fitbit for the study.

Post-intervention: Upon completion of the post-program exit interviews, participants in the intervention groups will receive $10.

At 6-months follow-up: Upon completion of both filling out the program survey and wearing their Fitbit for one week at the 6-months follow-up timepoint, all participants (from any of the three groups) will be compensated $20.

ASSESSMENTS

All participants will be assessed at baseline (week 1), post-program (week 9), and follow-up (6 months).

Pre-program:

At baseline, participants in all three groups will have the option to record Fitbit data for 7 days. Participants in the intervention groups will also be asked to track self-monitored physical activity, track self-monitored fruit and vegetables intake, and fill out the FitEx pre-program form. All participants will receive questionnaires. Questionnaires will be distributed via REDCap at baseline, post, and follow up.

Program:

During the 8-week duration of intervention program, Fitbit data will be collected from all participants in the control, FitEx-ECS, and FitEx-ECS+yoga groups.

In both intervention groups, self-monitored physical activity and fruit and vegetables intake will be tracked with the FitEx-ECS portal within Fitabase or with the FitEx Individual Log (see attached). Intervention group-specific weekly newsletters and Zoom sessions will occur throughout the duration of the 8 weeks. Intervention participants will be verbally reminded of the audio recording at the beginning of each Zoom session.

Additionally, a video of each session's synchronous movement will be recorded by the instructor only so that participants in either intervention group who were unable to attend can participate in the physical movement when their schedule allows.

Post-program:

After the 8-week program, participants in both intervention groups will fill out the FitEx post-program form and participants in all groups will repeat questionnaires, all distributed via REDCap. For both intervention groups, 30- to 45-minute semi-structured interviews will be scheduled and conducted with ECS survivors and support team members (See "Follow Up Materials" attachment for interview guide.)

Questionnaires & surveys:

Questionnaires for intervention groups include: 1. The Stanford Leisure-Time Activity Categorical Item (L-CAT) 2. 6 items from the validated Behavioral Risk Factor Surveillance System survey (BRFSS F/V), 3. Flourishing Index, 4. Yoga Self-Efficacy Scale (YSES), 5. Social Support for Exercise Survey (SSES), 6. Self-Compassion Scale Short Form (SCS-SF), 7. Self-Reported Behavior Automaticity Index (SRBAI), and 8. The Functional Assessment of Cancer Therapy - Endometrial (FACT-En). Additionally, all participants will be asked to report their weight within the questionnaires packet (see updated questionnaires document). All

questionnaires will be electronically facilitated with REDCap. ECS will be sent all questionnaires to fill out. Support team members will be sent all questionnaires to fill out except the FACT-En.

Electronic questionnaires will be sent in an automated email via REDCap up to two times for each timepoint: baseline (week 1), post-program (week 9), and follow-up (6-months)

6-month follow-up:

All participants will be contacted via their preferred method at follow-up (6 months) to schedule a 7-day long follow-up assessment. All participants will be asked to record Fitbit data for the 7-day duration and fill out questionnaires. Participants in the intervention groups will also self-monitor other physical activity, self-monitor fruits and vegetables intake, and the FitEx follow-up program form. Control group participants will be invited to future iterations of the FitEx interventions.

Zoom:

This research study is using Zoom as the virtual web conferencing platform for weekly meetings. The meetings conducted during this study will be recorded by the researcher using the audio and video recording capabilities available in the Zoom videoconferencing platform.

STATISTICAL ASSESSMENT:

Measures

Due to the small sample size and exploratory nature of this pilot study, statistical analyses will be descriptive rather than inferential. However, we will determine if a signal exists between intervention and control groups regarding participants' physical activity using MET (metabolic equivalents) data from Fitbits. Weekly data will be compared at week-8 (intervention conclusion) to baseline. Data is considered appropriate it was collected from at least 4 days per week. Data from missing days was input at "0". Students T-tests were used to compare means from each intervention group to the control condition for the primary outcome.

Attendance/Retention Measures

Participants who enroll in the study will be asked to attend weekly meetings. The attendance at the meetings will be recorded to assess the percentage of participants who are interested in weekly meetings. The acceptability of FitEx will be assessed in part using meeting attendance. Attendance and retention will be used as measures of intervention acceptability.

The number of support group members who attend each session will also be noted. The ratio of support group members to endometrial cancer survivor participants will also be noted.

We will examine our attrition rate and attendance as noted above. We will also reach out to participants who do not complete our study to determine the reasons for their decisions. Our study will be feasible in its current state if our attrition rate is between 10-27%.