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ENhAncing Lifestyle Behaviors in EndometriaL CancEr (ENABLE): A Pilot Randomized Controlled Trial

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Abstract

Purpose: Endometrial cancer is associated with the highest comorbid disease burden of any cancer. The aim of this trial was to assess the feasibility and safety of an allied health intervention during adjuvant treatment. **Methods:** A mixed-methods pilot randomized (2:1) controlled trial with concealed allocation and assessor-blinding. Eligibility criteria: adjuvant endometrial cancer treatment scheduled, disease stage I-IIIC1, ECOG 0-2 and able to perform unsupervised physical activity (PA). Participants received usual care and 8 sessions of weekly, individualized, lifestyle education (diet and PA) with behavior change and social support (intervention group), delivered predominantly by telehealth, or usual care alone. Feasibility outcomes: recruitment and consent rates, decline reasons, program acceptability, intervention adherence and retention. **Results:** 22/44 eligible patients (50%, 95%CI: 36%, 64%) were recruited over 10 months (14 intervention, 8 usual care). The recruitment rate was 2.2 patients/month (95%CI: 1.4, 3.3). Patients who declined had too much going on (7/22, 32%) or were not interested (6/22, 27%). Mean (SD) age and BMI were 63.2 years (6.8) and 31.9 kg/m^2 (6.7). A majority were FIGO stage 1 (15/22, 68%) and received vaginal brachytherapy (14/22, 64%). Adherence was high, 11/14 (79%, 95%CI: 52%, 92%) participants attended >70% of scheduled sessions. Retention was 100% (95%CI: 85%, 100%) at 9 weeks, however completion of objective measures was impacted by COVID-19 restrictions. Telehealth and online questionnaires enabled participation. No serious adverse events occurred. **Conclusion:** The intervention was acceptable to participants with high levels of adherence and retention. Trial findings will be used to design a future RCT.
Trial registration: The trial was registered on www.anzctr.org.au (ACTRN12619000631101) 29/04/2019.

Keywords

endometrial cancer, physical activity, nutrition, telehealth

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Introduction

Globally in 2018 there were over 380 000 endometrial cancer cases, making it the most common gynecological cancer[1] and disease prevalence and survival are rising.[2] Endometrial cancer is associated with the highest burden of comorbid disease of any form of cancer.[3] Common co-morbidities include hypertension and osteoarthritis.[3] Obesity and poor nutrition are common[4] and are associated with mortality from obesity-related cardiovascular disease.[5] Data from the SEER Program database, of over 40 000 participants, indicate that cardiovascular disease was the leading cause of death in those with endometrial cancer[5] and higher body mass index (BMI, 35+ vs <25) in endometrial cancer survivors is significantly associated with increased mortality (hazard ratio [95%CI] 2.14 [1.08-4.24]).[6]

Despite guidelines for nutrition and exercise for people with cancer[7,8] and well-established benefits of pre and

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Table 1. Trial Eligibility Criteria.

Inclusion criteria	Exclusion criteria
Histologically confirmed diagnosis of endometrial cancer managed surgically	Concurrent, actively treated other malignancy or history of other malignancy treated within the past year
Scheduled to receive or recently commenced (≤2 weeks prior) adjuvant therapy (brachytherapy, radiotherapy, chemotherapy, or any combination of radiotherapy and chemotherapy)	Unstable psychiatric, cognitive, or substance abuse disorders
Age ≥ 18 years	Comorbidities preventing participation in an unsupervised PA program
Able to read and write English	Stage 4 or recurrent disease
ECOG performance status 0 to 2	Met aerobic PA guidelines for the past month (150 minutes of moderate-intensity exercise weekly)
Life expectancy >3 months	
Able to access telehealth (phone or videoconference) for intervention	

Abbreviations: ECOG, Eastern Cooperative Oncology Group; PA, physical activity.

post-diagnosis physical activity (PA) including improvements in cardiovascular health, health-related quality of life (HRQoL),[9,10] fatigue,[11] and survival,[12,13]; few endometrial cancer patients meet the recommendations (27% nutrition and 12% exercise).[4,14] Endometrial cancer survivors report that specific PA and nutrition recommendations were rarely made by oncologists.[15] Participants expressed a desire for monitoring and the need for external motivation to change health behaviors successfully. Identified barriers to successful health behavior change for PA included a lack of motivation, costs associated with gym visits, the weather and emotional eating.[15]

There is great potential for low-cost allied health behavior change interventions to improve outcomes which are important in endometrial cancer. Predominantly observational studies demonstrate positive associations between participants who were meeting PA guidelines and HRQoL.[4,16] Significant associations are reported between PA, body weight and HRQoL[4] and cancer-related fatigue.[17] Few high-quality studies have assessed the impact of multidisciplinary allied health interventions in this population and most have been conducted post-treatment completion.[14,17-25] Further trials across the treatment continuum are required to strengthen existing evidence.[23]

The primary aim of this pilot randomized controlled trial (RCT) was to determine the feasibility, acceptability and safety of a telehealth allied health intervention involving nutrition and physical activity education combined with behavior change and social support, during adjuvant treatment for endometrial cancer.

Methods

Conduct and reporting conform to the CONSORT extension guidelines for randomized pilot and feasibility trials.[26] The intervention components of this trial were reported following the Template for Intervention Description and Replication (TIDiER) guidelines.[27]

Trial Population and Recruitment

Eligibility criteria are provided in Table 1. Hospital outpatient clinic lists were screened and eligible patients were provided with a flier regarding the trial from a member of the treating team (medical or radiation oncologist or nurse consultant) during their appointment. Details of patients who expressed an interest in participation were sent by the treating team to the trial staff who subsequently contacted the patient by telephone and provided them with the trial plain language statement and consent forms either by email or mail. Written, informed consent was obtained from all individual participants included in the trial at the start of the baseline assessment appointment. The study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Peter MacCallum Cancer Centre Human Research Ethics Committee on 14th March 2019 (HREC/48033/PMCC-2019).

Study Design

Using a mixed-methods, pilot, parallel group, randomized controlled trial with concealed allocation and assessor blinding, participants were randomized (2 [intervention group]:1[usual care group] allocation) to receive either usual care plus the intervention or usual care alone. The randomization schedule was generated by an independent statistician using permuted random blocks with stratification by adjuvant therapy type (vaginal brachytherapy, pelvic radiotherapy alone, concurrent pelvic radiotherapy and chemotherapy or concurrent pelvic radiotherapy and chemotherapy followed by adjuvant chemotherapy). Randomization was implemented and concealed through the trial database, with an independent database administrator uploading the randomization schedule.

Trial Intervention

Usual care at the trial site did not routinely involve referral to physiotherapy, exercise physiology, nutrition, or social

work services during the recruitment period. Participants in each group received usual care support, with no measures taken to control for these services in the usual care group. Nurse consultant usual care includes routine referral to social work or psychology support where indicated, but no access to routine support for weight management or exercise support. In addition to usual care, participants randomized to the intervention group received 8 weeks of weekly individualized PA and nutrition education with behavior change and social support. All intervention sessions were scripted to ensure standardized content. The initial multidisciplinary session was primarily conducted face-to-face at the hospital, with weekly follow-up conducted via telehealth (video or telephone). The social work assessment was standardized using the Cancer Rehabilitation Evaluation System questionnaire and included screening for social support and social networks.[28] Social work intervention was individualized according to identified needs and referral to support services was made as necessary. In a combined consultation, the dietitian and physiotherapist provided individualized education informed by baseline assessment findings and patient preferences. Education included discussion of the potential consequences of an inadequate diet and inactivity following a diagnosis of endometrial cancer. Recommended nutrition, weight management, PA and associated benefits for people with endometrial cancer were discussed and standard written educational material provided. Participants worked with the health professionals to establish a home-based PA program and develop individualized, patient-centered nutrition and PA-related goals. Participants were educated regarding the benefits of performing PA at a moderate-intensity and guided to use the Borg[29] scale to monitor intensity.

Behavior change strategies to increase and sustain dietary and PA behaviors, based on HealthChange® methodologies, included action plan development, goal setting, and identification of barriers and enablers.[30] Participants were given the option of using a pedometer and a diary to record PA and nutrition details. Participants were also given the option of receiving personalized nutrition and PA motivational text messages. The physiotherapy, nutrition and social work interventionists had 5, 6, and 13 years of oncology rehabilitation experience respectively. Further details, reported according to the TIDiER guidelines, are provided in the Supplemental File (Table S1).

Measures

Assessments were completed for both groups at baseline, 9 weeks and 3 months by 2 research assistants who received a 30-minute training session. Demographic and clinical participant characteristics were collected at baseline. Objective measures were completed in the hospital setting with accelerometers mailed to participants at follow-up assessments. Patient-reported questionnaires were completed in the hospital setting at baseline and electronically via an email survey link or in hard-copy at follow-up. Figure 1 provides an overview of trial assessments.

Primary outcomes. Feasibility was assessed as a composite outcome. The primary feasibility outcomes were recruitment (rate) and reasons for ineligibility. Additional feasibility outcomes included the proportion of eligible patients who provided consent, reasons for declining participation, retention at trial follow-up appointments, the number of complete assessments and acceptability to participants. Adherence to the intervention (number of scheduled appointments attended), the delivery mode and the number of external referrals made for social support were also recorded for intervention participants. A priori rates of recruitment, retention and intervention adherence indicating acceptable feasibility were defined as 7 participants/month, $<15\%$ loss to follow-up at 9-weeks and $\geq 70\%$ attendance, respectively. Acceptability to participants was assessed by inviting all participants to complete an individual semi-structured interview by telephone at 3 months. A purpose-designed interview schedule was developed by the research team to gain a deeper understanding of participants' trial experiences, including completion and delivery format of trial questionnaires and their recommendations for future trials. Intervention participants were additionally asked about their experiences with the various intervention components, including the trial resources and telehealth options.

Safety was assessed by patient-report and medical records and was reported as the number of adverse events occurring related to the trial intervention or assessments. Serious adverse events were defined as those that resulted in death, required hospitalization or prolongation of existing hospitalization, were life threatening or resulted in disability or incapacity.

Secondary effectiveness outcomes

Objective outcomes. Nutrition and physical activity outcomes were assessed objectively. The Patient Generated-Subjective Global Assessment (PG-SGA) includes a subjective assessment of weight-loss, nutritional symptoms, food intake and activity levels and an objective assessment of body composition (fat, muscle stores, and fluid status, scored as "0"=no deficit, "1"=mild deficit, "2"=moderate and "3"=severe). Each component of the PG-SGA is scored between 0 and 4 to provide an overall score (typical scores range from 0 to 35) and category of nutritional status (well-nourished, moderately/suspected malnutrition, and severe malnutrition).[31] Bioelectrical impedance, measured by body composition analysis scales (Tanita Inc., Tokyo, Japan, model T1 SC 330S) was used to calculate fat-free mass index. PA levels were measured by seven-days of accelerometry (Sensewear™ armbands) following each assessment.[32]

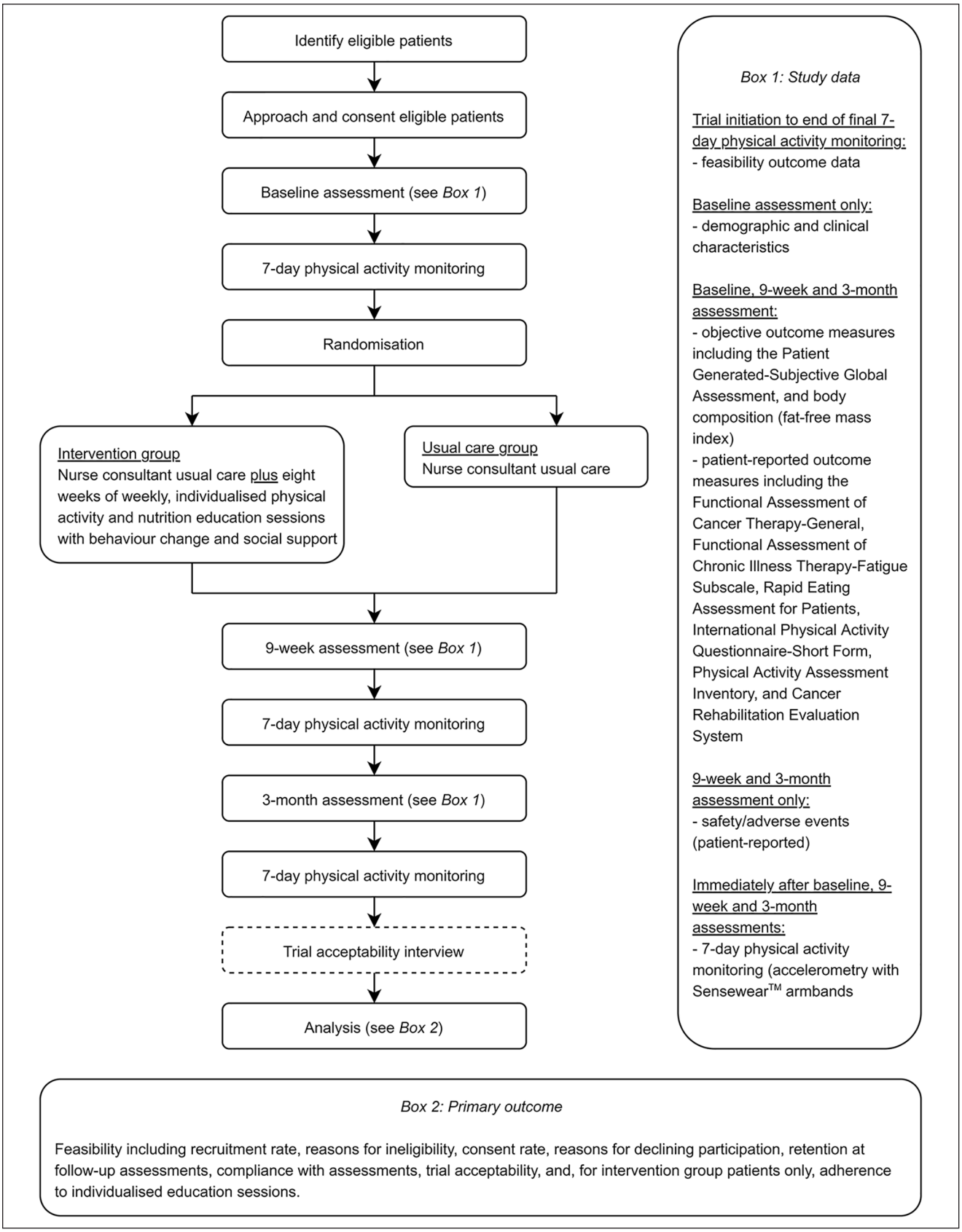

Figure 1. Trial objective and patient-reported outcomes.

Patient-reported outcomes. Health-related quality of life (HRQoL) and fatigue were measured using the Functional Assessment of Cancer Therapy-General (FACT-G) and the Functional Assessment of Chronic Illness Therapy—Fatigue Subscale respectively. Dietary behaviors were assessed with the Rapid Eating Assessment for Patients (REAP) questionnaire. PA levels and self-efficacy were reported using the International Physical Activity Questionnaire-Short form (IPAQ-SF)[33] and the Physical Activity Assessment Inventory (PAAI) respectively. The Cancer Rehabilitation Evaluation System (CARES) questionnaire was used to measure the impact of cancer and associated treatments on day-to-day living and patient needs. Further details of the secondary effectiveness outcomes are provided in the Supplementary file.

Statistical Methods

This was a pilot study with a pragmatic sample size and was not powered to assess efficacy. Descriptive statistics (including counts and percentages for nominal and ordinal variables; and means and standard deviations or medians and interquartile ranges for continuous variables) were used to summarize patient demographic, clinical characteristics, secondary outcomes, adverse events, and operational data (eg, number of intervention sessions). Recruitment data were summarized using a rate (95%CI) (Poisson distribution). Compliance with assessments, as well as adherence and retention data were summarized using a proportion (95%CI); the latter estimated using the Wilson method.[34] All quantitative analyses were conducted in R (reference index version 3.5.1).[35]

Semi-structured interviews were audio-recorded, transcribed verbatim and analyzed by 2 researchers who independently coded sub-sets of the data and performed an inter-rater process on 10% of the overall data to check consistency of coding and ensure consensus on the initial codes generated. Data were entered and managed using Microsoft Excel for Mac version 16.43. Interpretive description was used as a recommended inductive analysis method for exploring clinical phenomena through patient-based interviews.[36] Data were interpreted in a constant comparative manner to explore emerging concepts and patterns,[37] to generate categories describing participants' study experiences.

Results

Primary Outcome

Feasibility. Recruitment occurred between May 2019 and March 2020. The flow of participants through the trial is provided in Figure 2. Two-hundred and twelve patients were screened and 44 (21%) were eligible. Key reasons for ineligibility included patients who were not newly diagnosed and were attending the outpatient clinic for follow-up (n = 126, 59%) or those who had stage IV or recurrent disease (n = 30, 14%). Twenty-two of the 44 eligible patients (50%, 95%CI: 36%, 64%) provided informed consent and were recruited to the trial over 10 months (14 intervention group, 8 usual care). The recruitment rate was 2.2 patients/month (95%CI: 1.4, 3.3). Most patients who declined had too much going on (7/22, 32%) or were not interested (6/22, 27%). Table 2 provides baseline participant demographic and clinical characteristics. Descriptive statistics for baseline measures are presented in Table 3. Mean participant age and BMI were 63.2 years (SD = 6.8 years) and 31.9 kg/m^2 (SD = 6.7 kg/m^2), respectively. The majority of participants were International Federation of Gynecology and Obstetrics (FIGO) stage I (15/22, 68%) and received vaginal brachytherapy alone (14/22, 64%). Retention was 100% (95%CI: 85%, 100%) at 9 weeks and 91% (20/22) at 3 months, however completion of objective nutrition follow-up measures was impacted by COVID-19 government restrictions on face-to-face research assessments at the time. Adherence to the intervention was high with 11/14 (79%, 95%CI: 52%, 92%) participants attending ≥70% of scheduled weekly sessions. Of 14 initial sessions, 7 were conducted via telehealth (2 videoconferencing and 5 telephone) and 7 at the hospital. Eleven intervention group participants (79%) agreed to use the trial pedometer or had their own device to track their physical activity levels throughout the 8-week intervention. Of follow-up sessions 13/88 (15%) were conducted face-to-face at the hospital and 75/88 (85%) by telehealth (61 (81%) telephone, 14 (19%) videoconferencing). Seven participants (50%) returned the trial diary which they had used to record weekly nutrition and physical activity behaviors and goals set. Participants reported being well supported with 3/14 (21%) requiring social work support following initial assessment.

Safety. There were no serious adverse events. One minor adverse event related to trial assessment occurred (skin irritation following accelerometer wear). One intervention participant reported an increase in chronic low back pain as a result of increasing PA intensity. This participant was advised by the trial physiotherapist to continue the PA program but at a lower intensity. Both events resolved without requiring additional management.

Acceptability to participants. Telephone interviews were conducted with 18 participants (12 intervention, 6 usual care) and lasted between 6 and 32 minutes. Six categories were generated describing aspects of participants' trial experiences (Table 4). From these, 4 themes emerged, which are presented here, and which capture the issues participants consistently and centrally reflected on.

Theme 1. Accessibility enables participation and enhances the study experience.

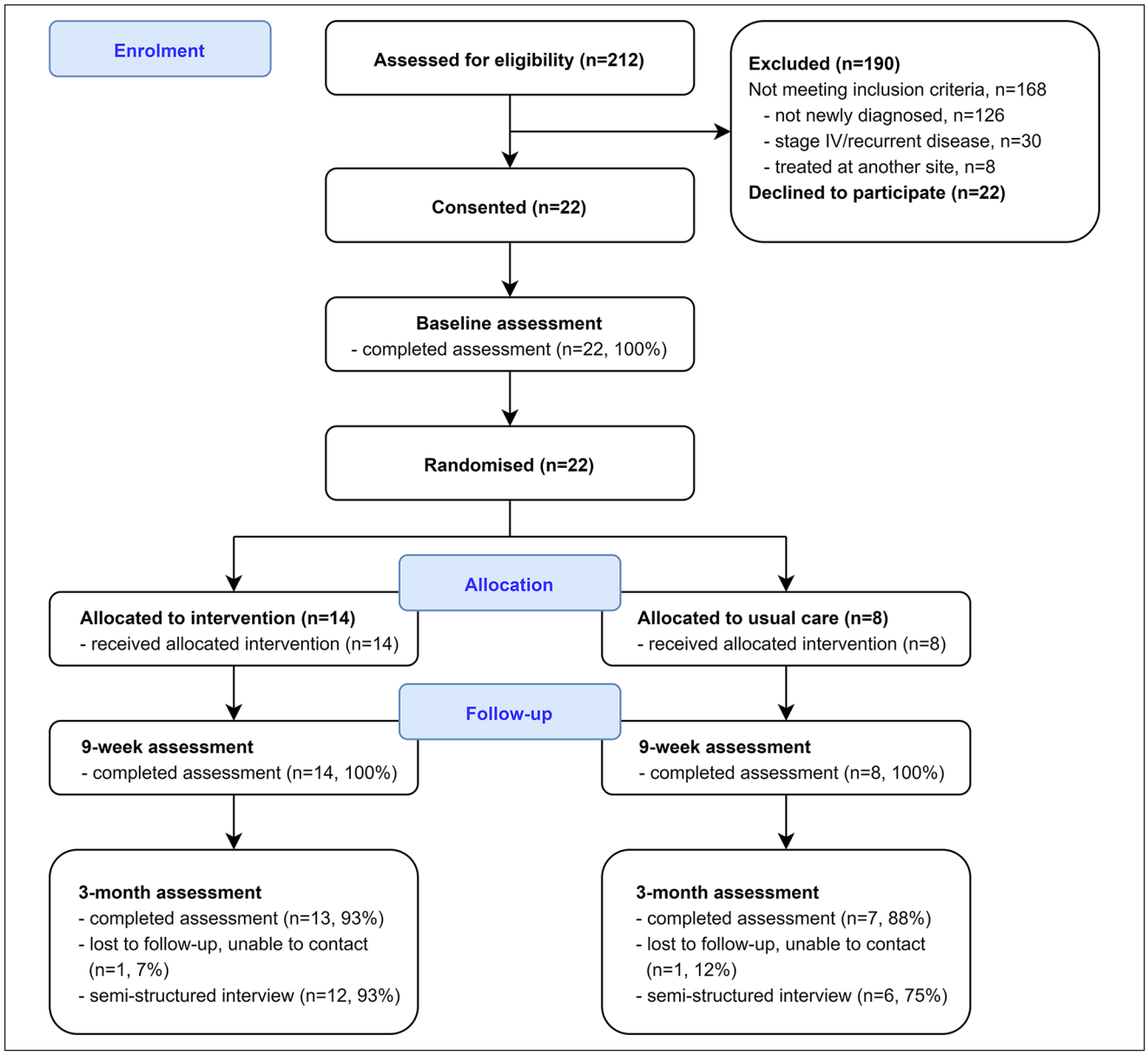

Figure 2. Participant flow through the trial.

The opportunity for remote participation was appreciated, which reduced travel burden and made participation more accessible and stress-free. The telehealth and phone consultation options were described as streamlined and easy to navigate. Most participants preferred the opportunity to complete trial questionnaires online, in their own home and at their own pace and time. Participants appreciated the opportunity to coordinate trial appointments with other clinical appointments.

> *"having the questionnaire when I could do it, when I wanted to do it, you know, I wasn't told you must do it at x time, you know, so yeah, that to me was . . . I guess it's the flexibility of the study which was really easy."* (P07)

> *"Well telehealth is telehealth isn't it and for someone who lives in the country the way I do, three-hour drive from Melbourne, we really want this to work."* (P22)

Theme 2. Participation offers opportunities for receiving and contributing value.

Participants derived value from their participation and reported appreciating the opportunity to contribute value to others. The trial resources such as the diary and activity trackers provided motivation and accountability to stay on track with goals. Participants felt supported and encouraged to solidify existing goals or set new goals. Contact with the trial team provided ongoing support, a sense of caring and being listened to, motivation and encouragement, direction

Table 2. Participant Demographic and Clinical Characteristics.

	Intervention (n = 14)	Usual care (n = 8)
Age (years), mean (SD)	65 (7)	60 (6)
Social situation		
Home alone, independent	6 (43)	1 (13)
Home with family	8 (57)	7 (88)
Employment		
Working full time	2 (14)	2 (25)
Working part time	1 (7)	1 (13)
Sick leave/leave of absence	0	1 (13)
Retired	9 (64)	3 (38)
Home duties	1 (7)	1 (13)
Studying	1 (7)	0
Highest education		
Some secondary school	2 (15)	2 (29)
Completed secondary school	3 (23)	3 (43)
Some trade, community, or TAFE	2 (15)	0
Completed trade, community, or TAFE	3 (23)	0
Some university	0	1 (14)
Completed bachelor's degree	2 (15)	2 (29)
Other	1 (8)	0
Missing	[1]	[1]
BMI, mean (SD)	31 (7)	34 (6)
Colinet comorbidity score, median (range)	6.5 (0 to 14)	2 (1 to 13)
FIGO stage		
I	1 (7)	0
IA	5 (36)	1 (13)
IB	3 (21)	5 (63)
II	2 (14)	1 (13)
IIIA	1 (7)	1 (13)
IIIC1	2 (14)	0
Treatment		
Brachytherapy	9 (64)	5 (63)
Pelvic radiotherapy alone	3 (21)	2 (25)
Concurrent pelvic radiotherapy and chemotherapy followed by adjuvant chemotherapy	2 (15)	1 (13)

[a]Values are n (%) unless specified.
Abbreviations: BMI, body mass index; FIGO, International Federation of Gynecology and Obstetrics;TAFE, technical and further education.

and assistance/advice for questions around diet and exercise and an added sense of accountability and feeling included in something. Many participants reported their motivations for participating in the trial as altruistic and desired to contribute to research and the development of new and improved information and resource.

> *"And I found the support from [physiotherapist] and from [dietitian] to be invaluable. They were approachable, they obviously had great knowledge in their areas, they always answered the questions I had."* (P22)

> *"I found it was beneficial for me, so therefore I feel it should help many women. I felt encouraged, supported, and above all I participated because I do support this sort of thing and I just hope that it helps other women . . .."* (P04)

Theme 3. Encountering study-related and personal health challenges.

While telehealth participation was reported as the preferred option by most, some felt the technology required involved a steep learning curve. Participants had mixed experiences using the 2 physical activity monitors provided for the study (accelerometers for 1-week assessments and pedometers for motivation throughout intervention). A proportion felt uncertain about the function of the accelerometer and how to use it, and some struggled with unclear instructions for the pedometer and described that it recorded steps inconsistently. The COVID-19 pandemic was reported to impact on trial participation. Usual physical activity routines were disrupted, and pandemic related anxiety and stressors impacted their overall state and wellbeing. A proportion of participants reported

Table 3. Baseline Patient-reported and Objective Measures.

	Intervention		Usual care	
Patient-reported measures				
FACT-G	n	Mean (SD)	n	Mean (SD)
Physical wellbeing	14	24 (3)	8	23 (5)
Social wellbeing	13	24 (4)	8	22 (5)
Emotional wellbeing	14	19 (3)	8	21 (3)
Functional wellbeing	14	19 (6)	8	21 (4)
Total score	13	87 (14)	8	87 (13)
FACIT-Fatigue total score	14	13 (10)	8	14 (8)
CARES severity (*t*-score)				
Physical	12	50 (6)	7	45 (2)
Medical interaction	6	56 (0)	4	57 (1)
Psychosocial	13	46 (5)	8	48 (3)
Sexual	6	62 (14)	7	60 (14)
Marital	6	53 (2)	6	56 (6)
Total number of problems endorsed*	14	29 (14-26)[a]	8	49 (24-52)[a]
REAP total score	14	2.3 (0.2)	8	2.3 (0.2)
PAAI total score	14	47 (14)	8	59 (25)
Distress thermometer total score	14	3.4 (2.9)	7	3.3 (2.2)
International Physical Activity Questionnaire-Short Form				
MET-minutes per week	14	693 (495-915.8)[a]	8	425.3 (204.8-1421.4)[a]
Meeting PA guidelines n (%)	14	9 (64)	8	3 (38)
Objective measures				
Accelerometry	n	Mean (SD)	n	Mean (SD)
Steps per day	14	4902.4 (3219.8-6008.1)[a]	8	5858.2 (4167.6-15799.4)[a]
MVPA, hours per day	14	0.4 (0.1-0.5)[a]	8	0.3 (0.06-1.4)[a]
PG-SGA				
Score	13	4.5 (2.7)	8	4.1 (1.6)
Category n (%)	13	10 (77) A, 3 (23) B	8	8 (100) A
FFM (kg)	13	46.4 (4.1)	8	48.3 (5.6)
FFMI (FFM (kg)/height $(m)^2$	13	17.6 (2.1)	8	19.2 (2.5)

[a]Median (interquartile range).
Abbreviations: FFM, fat-free mass; FFMI, fat-free mass index; MET, metabolic equivalent of task; MVPA, moderate-vigorous physical activity; PA, physical activity; PAAI, physical activity assessment inventory; PG-SGA, patient-generated subjective global assessment; REAP, rapid eating assessment profile.

having to additionally navigate fluctuating mental health and side effects of their cancer treatments, such as treatment-related fatigue, feeling ill after treatment, rise and fall of energy levels due to steroid medication, mobility and balance issues and variable physical strength.

> *"that [study assessment] was a little at times inconvenient because of with workload and just meetings and things that I had for work so, yeah. So I found it a little bit hard at times but most of the time it was OK."* (P06)

> *"when it says what's your stress levels and that, it's, and it's also you've got pandemic of COVID.. so it's an unusual time and, you know," (P21)*

Theme 4. Recommendations.

Participants reported several ways in which the trial could be improved in the future:

(1) Nutrition and exercise: providing recipes for healthy meals and snacks, incorporating mindfulness and relaxation exercises, structured group exercise opportunities with preference for community-based settings close to home;
(2) Participation support: additional social components to increase motivation and accountability;
(3) Trial tools and information capture: more accurate pedometers and tools for capturing information and advice received;
(4) Trial recruitment, information and communication: attention around appropriate timing of recruitment; providing early and comprehensive trial information and additional research staff contacts.

> *"some kind of guide or even a few little recipes, sort of simple ones . . . just simple healthy alternatives"* (P11)

Table 4. Participant Quotes.

Category	Sub-category	Illustrative quotes
1. Study experience		
1.1.	Participation experience	"For me it was quite seamless. I mean I appreciated you, um, linking up with me at the same as another appointment so it made use of my trip to Melbourne rather than making special visits so that was good." (P18) "I live about hundred odd ks away from the hospital so I didn't know whether that would be demanding on my time as well to try and get in there for interviews and so forth. But fortunately we could do things over the phone and via the email so that made it a lot simpler." (P19) "that's what I liked, it was the flexibility of you guys around my locked in doctors' appointments or other appointments" (P07)
1.2.	Study assessments and intervention sessions	"following up can be a little bit tricky if it didn't coincide with an appointment that we already had at the . . . I think for travel distance, like going all the way into the city for that appointment and then having radiotherapy, having all the different times um could've been an issue, I did find that a bit tricky at times." (P08) "weighing yourself and, you know, like the measurements and all that kind of stuff, it's done discreetly" (P07) "I find upsetting when I'm read things when I'm right beside the actual person and they're reading to me off a clipboard, I'm capable of reading and um kind of doing that myself" (P11)
1.3.	Treatment side effects	"that was a bit difficult for me, I fluctuated quite a bit. But I was quite conscious of everything. I don't know, I felt a bit spacey toward the end of treatment. I mean, you know, I suppose I didn't lose sight of the goals, it was just hard to . . .hard to complete those," (P09) "you feel like you're getting kicked in the gut all the time you don't feel like standing up straight." (P03) "I did as much as I physically felt able to at the time 'cause I was still recovering from surgery." (P03)
1.4.	Coronavirus	"I think everybody will be a little bit cautious too, I don't know whether I'd be comfortable using a pool with, you know, that there's quite a number of people in it." (P19)
1.5.	Survey completion	"How do you go from say numbers through to number 10? One day you might be feeling number 9 and the next day you're feeling number 2; and because I have pain issues and stuff like that, so then some of them the question was are you in pain, well yes I am, I'm in pain every day but it doesn't really relate to this surgery, right, so how do you answer it?" (P11) "I didn't in any way feel judged or looked down upon Or, um, I actually never felt, and this is the honest truth, I never felt like it was a survey. I felt like I was being supported and that I was getting these calls for these women to support me in what I was going through. . ." (P04) ". . .not that I found it difficult to answer but I didn't feel my answers were relevant to what . . . I don't know, I just didn't like them, I didn't like the way they were worded. . .." (P16) "I think it was quite good, except there were a couple of double-ups but I sort of expect that in surveys that long. Yeah, fairly easy." (P18) "I've sort of done many questionnaires over the years, so, so that's probably the easiest. And, you know, and you have time to think about it a little bit more than when you're, um, I suppose put on the spot a little bit more when it's face to face or via telephone." (P19)
1.6.	Calculating activity time	"Well sometimes more and sometimes less, it gets hard to pick, but when I'm answering the questions on the surveys I'm thinking well crikey that's a long time to be sitting down, surely I don't sit down for that long." (P18) ". . .it was just realistically trying to work out so how long, I might sit down and have a coffee and then [laughs] OK like you just . . . it's just like trying to guess." (P21) "And also the question how many minutes a day do you sit? [laughs] I found that one a bit difficult, I have no idea if I was even close on that. And, you know, I sort of start to think in hours and then I had to change it to minutes and then it seemed like an awful lot and then I thought well that's probably what I do do.]" (P16)

(continued)

Table 4. (continued)

Category	Sub-category	Illustrative quotes
1.7.	Goal setting	"I did set goals but I didn't write any of them down. I just basically sort of took it on board to sort of say well yeah I need to have a decent breakfast and, you know, and then I need not to eat after a certain period at night, I think it was 8pm. So, you know, half an hour walk each day. . ." (P19) "I had a few problems um meeting the goals. Um If I was having an off week I did find it hard to get out there and do the walking. . ." (P01)
2. Study resources		
2.1.	Telehealth	"So probably better it was the telehealth than trying to work in a visit to the hospital for myself regarding distance and travel." (P08) ". . .a phone call's just . . . for my age group it's just as easy." (P16) "Well it was preferable for me just because of the distance, you know, so um, and I suppose it was my choice also not to go onto the video conference 'cause my self-esteem's a little bit low at the moment and I really didn't want to be on the video. . ." (P19)
2.2.	Activity monitors	". . .chemo meant that I had a lot of downtime, not knowing how it was going to work for me, so I ended up having quite a few days of not my normal day. So I felt like that was inaccurate on a standard week for me. . ." (P08) ". . .after the first day, the first day you have it on it sort of feels a bit odd but then just, you know, put it on in the morning, take it off when you go to bed and you just forget you've got it on really so that didn't even bother me." (P04) ". . .in the beginning it was like doing only like five thousand steps, so it was like well, you know, then I was like setting eight thousand steps and then now I'm doing ten thousand steps. . ." (P06)
2.3.	Study diary (diet and exercise)	"Having the diary every day was a good, um, kept me on track. I think that's a really good book to, um, a way for people to stay on . . . for me it was anyway, to keep track of what I was doing and to motivate me each day to try and stick to my goals." (P08) ". . .I could see an easy pattern emerging so I sort of didn't bother for the last couple of weeks. But I did it initially to see exactly what it was I was eating and not eating, you know, trying to get it into some focus and the exercise into some focus." (P16) "So I found the diary really good even though I didn't write a lot in it, it did . . . I don't know . . . I would never have been able to keep track of my food if I hadn't written it down." (P22)
3. Communication		
3.1.	Experience with study team	"It ah, was actually good to have contact with somebody else other than my usual contact in the hospital so it was um, ah, it was a good experience for me" (P01) "It's really simple and you can do it when you wanna do it. . .." (P07)
3.2.	Communication, check ins and being listened to	"Well it was nice to know there was someone there that you could actually talk to and ask questions if you felt like you wanted to ask a question or be directed into the right, you know, person. So no I found that very helpful and encouraging." (P14) "I enjoyed the little sms messages I received with the encouragement to do my walks and ahm stuff like that, that was really good." (P17) ". . .as I said I enjoyed the support and the frequent phone calls, I really enjoyed that which means that you people really care." (P17)

(continued)

Table 4. (continued)

Category	Sub-category	Illustrative quotes
4. Nutrition and physical activity		
4.1.	Nutrition habits and dietitian advice	"I thought the biggest benefit for me personally probably was the diet in that um I now include a lot more different colors in my food plate at the same time in most cases" (P07) "Well it was a good, um, thing to be in because it sort of made me think a bit more about what I was actually eating and quantities." (P09) "I was more conscious of my choices of food when I'm shopping and stuff like that. But I must admit I've slipped back into apple pie and whipped cream" (P14) "I guess that's the other reason for the diary, you're watching what you eat to see how it's affecting you. And it's easy to forget what you're eating in a day." (P22) "The dietitian, actually they put me onto a couple of good things that I'd totally forgotten." (P16) "planning snack foods, you know, I'm a bit of a compulsive eater. Yeah so I found all that useful and I'm trying to keep up with it." (P22) "a dietitian would kind of probably know or have something under her belt that she could advise. . . well that kind of thing didn't happen in this study. So that would be very helpful I think for a person like me." (P11) "they did give me some good suggestions, don't get me wrong, but once I'd implemented them there wasn't much else to say if you know what I mean. So, I didn't really feel I needed as much with the dietitian." (P16)
4.2.	Physical activity habits and physiotherapist advice	"And I found the support from [physiotherapist] and from [dietitian] to be invaluable. They were approachable, um, they obviously had great knowledge in their areas, they always answered the questions I had" (P22) "the physio was good to, you know, just to improve upon my exercise that I was probably already doing to make myself accountable." (P08) "I was doing some walking but I wasn't walking as fast, and I hadn't actually realized in a way and then when [physiotherapist] actually challenged me on it I thought yes she's absolutely right. So I started to make a much more conscious decision to walk faster and a little bit further and I've kept that up." (P16) "It was more about the physical activity. So [physiotherapist] encouraged me to do things. So we would set goals, you know, this week we'll do so much and try and reach this and then, you know, depending on how I felt, and um that's what we'd do, week by week we'd set ourselves some sort of um task and try to achieve it," (P04)
5. Feedback and recommendations		
5.1.	Control group	"I just felt ah the control group should've been given something even if it was just a follow up with their local . . . that the doctor would check on them or something like that. But leaving us out there fluttering was a bit of a disappointment." (P03)
5.2.	Recruitment process	"a good way to be involved and it was approached just by a pamphlet initially and then umm following up from there. And so it was purely choice, you didn't feel any pressure in any way" (P08) "nurse explained to me when I first went in what it was about, what they thought they could get out of it. Yeah, no it was fine, it was very clear to me from the beginning what it was about." (P16) "they didn't explain too much about the study, maybe at the first introduction they would talk a bit more about it or something maybe." (P20)

(continued)

Table 4. (continued)

Category	Sub-category	Illustrative quotes
5.3.	Group sessions	"I mean a structured class I would sort of . . . is probably a lot better than you working on your own for sure, unless you're highly motivated." (P11) "group exercise is so much more motivating" (P08) "I suppose if you're doing it in a group and everyone's sort of just doing their very best at what they can do, yeah, I think I would've been interested in that." (P19) "I probably wouldn't have done it. No, I don't like organized . . . that's part of the prob- . . . I mean I've tried going to gyms and I've tried all that stuff, and over years, over years, not recently but over years, and it just doesn't really interest me." (P16)
5.4.	Program duration	"if it was much longer, you know, I suppose not the novelty, you know, as much as you don't get as much out of it than you possibly have in that short eight week spiel." (P19)
6. Participation value		
	Participation value	"I think it could be so beneficial. I'm so eager to see the results when they come out um 'cause I think that, yeah, it could be very positive for people going through cancer" (P02) "I felt very supported through the whole thing, certainly the offer of conversations or visits or phone calls and things like that. So no there was plenty of opportunity to be involved and have support if I needed it." (P08) "It's been encouraging and I've got to meet some lovely people" (P14) "for me personally it's bigger than me, a research project is bigger than just one person so I would've fit in with whatever because um I really want, I really believe the study would be beneficial to so many people. So I was very accommodating" (P02)

"group get-togethers or something like that that people . . . I don't know whether they want to talk about their circumstances" (P19)

Secondary Effectiveness Outcomes

Secondary effectiveness outcomes are reported in the Supplemental File (Tables S2 and S3). The trial was not powered to detect between-group differences for these outcomes. Objective follow-up measures of nutrition were available for 8 participants (5 intervention and 3 usual care) at 3-months as a result of government restrictions in place due to the COVID-19 pandemic.

Discussion

This pilot RCT of nutrition and PA education with behavior change and social support demonstrated feasibility through participant retention to the trial and intervention adherence. However, a future definitive RCT would require additional sites for recruitment rates to meet our pre-determined levels of feasibility. The intervention was safe, with no serious adverse events occurring and participants perceived the trial to be acceptable.

Previous multi-disciplinary lifestyle interventions in endometrial cancer have targeted weight loss and increasing PA and have been conducted in the post-treatment phase. Such interventions have been undertaken in both hospital,[14,17,20,23] home,[18,19,22] or mixed[21,24,25,38] settings and demonstrate inconsistent results with respect to changes in PA (often not measured objectively), body weight, dietary intake and HRQoL.[14,17,19-21] Secondary effectiveness outcomes from this trial are presented for completeness only given the trial was not powered to detect differences between groups. Additionally, for both groups the COVID-19 pandemic and restrictions impacted follow-up measure completion, patterns of PA and HRQoL reported by participants. In keeping with findings from this trial, prior studies report an absence of intervention-related adverse events, however safety is commonly not reported.

The trial uptake by eligible patients of 50% was higher than reported in other lifestyle behavior interventions in this population which report rates of between 10% and 25%.[14,17,19-21,25,38] Two single-group trials conducted in the home environment do not report uptake rates.[18,22] There are several possible reasons for the improved uptake to this trial. Firstly, interventions initiated closer to the point of diagnosis, representing a potentially teachable moment,[39] may target a timepoint on the cancer treatment continuum where patients are more receptive to making changes to lifestyle behaviors. Interventions to change behaviors closer to diagnosis have been demonstrated to have significant impact; greater use of active coping strategies at diagnosis is associated with reduced all-cause mortality (HR 0.78, $P = .04$) at 4 to 5 years post endometrial cancer diagnosis.[40] It remains uncertain whether it is best to offer these kinds of interventions during active treatment, or immediately post treatment for treatments given for a limited period of time. Secondly, key medical and nursing staff were actively involved in recruitment. Thirdly, as reported by participants, the use of telehealth and online questionnaires reduced potential barriers to involvement faced by those living a distance from the hospital.

Trial retention was high in contrast to a 6-month single-group trial, which excluded participants receiving active chemotherapy or radiotherapy, in a mixed-cancer sample (n = 99, 58 with endometrial cancer) involving a home-based exercise program for rural participants with a completion rate of only 36%.[22] Similar to our trial where levels of baseline physical activity were high, 68% of participants reported exercising regularly in the past, suggesting selection bias in those who agreed to participate in the trial. Program completion was significantly associated with higher baseline HRQoL and PA levels and findings also suggest that program duration, 6-months compared to the 8-weeks in our trial, may be an important factor impacting on adherence.[22]

The trial findings both extend and align with knowledge in the area regarding endometrial cancer participant experiences of nutrition and PA interventions. The majority of previous work reports participant preferences. Survivors express an interest in exercise and feel able to participate, with walking of moderate-intensity commonly preferred.[41,42] During or 3 to 6 months after treatment are preferred time points for starting a PA program reported by 49% (49/101) of gynecological cancer survivors within 2 years of diagnosis.[42] Future research should be conducted to compare the effects of interventions delivered at differing timepoints on the treatment continuum. Most gynecologic cancer survivors report being receptive to weight management counseling.[19,43] Building on what is known with respect to preferences, participants of this trial reported enablers such as the use of telehealth and online measures, and make key recommendations for modifications in subsequent trials, including group sessions to increase social support.

Several study limitations are worth noting. The generalizability of trial findings is limited given recruitment occurred at a single center. Recruitment bias is likely given few participants required social support and baseline PA levels were relatively high. Participants were excluded from the trial if they had met PA guidelines for aerobic exercise over the preceding 4 weeks at recruitment. Given this time period included post-operative recovery participants were likely to be less active than normal. Future trials should consider excluding participants who report meeting PA aerobic guidelines pre-diagnosis, rather than at recruitment. Stricter eligibility criteria will target the intervention to a

less active population, with the greatest potential to benefit from the intervention. Definitive randomized controlled trials are needed to determine the clinical and cost-effectiveness of models of care which are feasible to implement and scale with existing resources, including group sessions with remote monitoring and continued use of telehealth to reduce barriers to accessing services.

Conclusion

This pilot trial demonstrated intervention safety and participant acceptability. Levels of feasibility were above prespecified thresholds with respect to adherence to the intervention and retention at follow-up outcome assessments. Participant experiences and key recommendations will inform modifications to future intervention design for an appropriately powered RCT with multiple recruitment sites.

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Author Contributions

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Availability of Data and Material

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Consent to Participate

Informed consent was obtained from all individual participants included in the study.

Consent for Publication

Written consent to publish was obtained from all individual participants included in the study.

Ethics Approval

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Peter MacCallum Cancer Centre Human Research Ethics Committee on 14th March 2019 (HREC/48033/PMCC-2019).

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Supplemental Material

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