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Recruitment, adherence, and retention of endometrial cancer survivors in a behavioural lifestyle programme: the Diet and Exercise in Uterine Cancer Survivors (DEUS) parallel randomised pilot trial

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Abstract

Objective: Healthy eating and physical activity may help endometrial cancer survivors (ECS) improve their quality of life. However, most ECS do not meet the relevant guidelines. This pilot trial aimed to test the study feasibility procedures for a definitive trial of a behavioural lifestyle programme.

Design and setting: This 24-week parallel two-arm randomised pilot trial took place in two hospitals in London, UK (April 2015 - June 2016).

Participants: Sixty disease-free ECS within 3 years of diagnosis

Interventions: Participants were randomised using minimization to receive the intervention or care as usual. The “Shape-Up following cancer treatment” programme used self-monitoring, goal-setting, self-incentives, problem-solving, and group social support for 12 hours over 8 weeks to help survivors improve their eating and physical activity.

Outcome measures: The main outcome measures were recruitment, adherence, and retention rates. Further outcomes included barriers to participation and feedback on programme satisfaction.

Results: Of the 296 potentially eligible ECS, 20% (n=60) were randomly allocated to the active intervention (n=29) or control group (n=31). Three participants in each arm were deemed ineligible after randomisation and excluded from analysis. Twenty participants (77%; 95% CI: 61%-93%) adhered to the intervention and provided generally favourable feedback. At 24 weeks, 25/26 (96%; 95% CI: 89%-100%) intervention and 24/28 (86%; 95% CI: 73%-99%) control participants completed their assessment. No intervention-related adverse events were reported. Among eligible survivors who declined study participation (n=83), inconvenience (78%; 95% CI: 69%-87%) was the most common barrier.

Conclusions: The trial was feasible to deliver based on the a priori feasibility criteria. Enhancing recruitment and adherence in a definitive trial will require designs that promote convenience and consider ECS-reported barriers.

Trial Registration: ClinicalTrials.gov identifier: NCT02433080, 20 April 2015

Trial funding: University College London, St. Bartholomew's Hospital Nurses League, and NIHR University College London Hospitals Biomedical Research Centre

Keywords

Endometrial cancer, survivorship, behaviour change, healthy eating, physical activity, intervention

Strengths and limitations of this study

- This trial tested the feasibility of a standardised theory-based behavioural lifestyle programme for endometrial cancer survivors using a robust randomised parallel design.
- Barriers to participation were systematically assessed.
- The study aimed to minimise these barriers by recruiting survivors within the "teachable moment" period and capitalizing on the endorsement of the study from their clinicians.
- The small sample size and recruitment from London-based hospitals limit the generalisability of the outcomes.

Introduction

Endometrial cancer is the most common gynaecological cancer with about 455,000 incident cases worldwide in 2015. It affects mostly women in developed countries[1] and about 75% women will live for more than 10 years after diagnosis.[2] They are the cancer group with the highest comorbidity burden among survivors[3] and are most likely to die from cardiovascular disease.[4] Furthermore, the prevalence of obesity and suboptimal lifestyle behaviours is high, both of which are associated with lower health-related quality of life.[5] Although most survivors do not spontaneously adopt health-protective behaviours[6] post-diagnosis, they do report trying to make lifestyle changes. However they experience cancer-specific barriers, such as fatigue and bowel issues, and feel there is a lack of guidance.[7]

Behavioural lifestyle interventions improve patient-reported outcomes, such as health-related quality of life, in other cancer survivor groups.[8-10] Randomised controlled trials (RCTs) in endometrial cancer survivors have also shown that health behaviour change is feasible for these patients.[11 12] However, the programmes tested to date have been resource-intensive rendering their widespread dissemination challenging. There is, therefore, a need for effective lifestyle behaviour change interventions that can be adopted within the cancer care pathway. We have adapted an existing evidence-based lifestyle intervention,[13] which is already running within the health care system, to try and facilitate this process.[14] The intervention was adapted to the particular needs and preferences of endometrial cancer survivors, with patient input and utilizing the intervention mapping approach. A definitive RCT will indicate whether this intervention is effective in promoting long-term behaviour change and improving survivors' quality of life. This pilot study was conducted to test the feasibility of the planned RCT's procedures.

The primary objective of the pilot trial was therefore to calculate recruitment, adherence, and retention rates. Secondary outcomes included willingness of clinical staff to recruit

participants, potential adverse events, barriers to participation, reasons for attrition, and participants' study experience [15].

Methods

Study design and participants

The trial protocol has been published.[15] The DEUS (Diet and Exercise in Uterine Cancer Survivors) pilot trial was an eight-week, two-arm, parallel, controlled pilot trial with 1:1 randomisation comparing the use of the "Shape-Up following cancer treatment" programme to care as usual.

Women aged ≥18 years who had been diagnosed with endometrial cancer (ICD C54.1) within the previous 36 months were eligible to take part in the study. Women were excluded if (a) they were diagnosed with stage IVB cancer; (b) they were on active anti-cancer, and/or palliative treatment; (c) they had a second primary cancer; (d) they lacked mental capacity to decide to take part in the study and to participate in it; (e) they had severe depression; (f) they were unavailable for longitudinal follow-up assessments; (g) they had participated in a professionally delivered weight loss or exercise programme during the previous 6 months; (h) their performance score was 3-4[16] (i) or they were unable to understand spoken and written English.

At the 5th week of recruitment, the inclusion criterion "women willing to attend all sessions" was removed given the subjective nature of its interpretation and the exclusion criterion "women with secondary cancer" was added to ensure homogeneity.

Recruitment

Potential participants were recruited from the gynaecology outpatient clinics at University College London Hospitals (UCLH) and Barts Health. Interested and potentially eligible participants were introduced to the study by clinicians and researchers attending the clinics as previously described.[15]

The clinicians at UCLH also identified potential participants that had been treated there but followed up at local sites. Following GP's verification that the patients were alive, invitation letters signed by the consultant were sent to these women together with the participant information sheet, an opt-in form, a barriers to participation survey, and a business reply envelope.

Randomisation and blinding

Consented participants were randomised with a 1:1 allocation to receive either the intervention or usual care through minimization using age and BMI as stratified variables. The process has been previously described in detail.[15] The researcher assessing the 8-week outcomes (MM) was blinded to intervention allocation and participants were requested prior to the assessment not to disclose their allocation.

Shape-Up following cancer treatment intervention

In addition to usual care, intervention arm participants received the "Shape-Up following cancer treatment" manual and were assigned to groups of three to eight, although the initial plan was that they would be assigned in groups of eight. The allocation to groups was on a first-come first-served basis to avoid delays in delivering the intervention to randomised participants and aimed to match participant preferences for dates and times of the group meetings. The five groups met weekly for eight weeks at UCLH. Each session lasted approximately 90 minutes. The theory-based intervention has been previously described.[15] In brief, it included advice on healthy eating, physical activity, management of triggers of unhealthy behaviours, and behavioural relapse prevention. A dietitian (DAK) trained on the programme facilitated the group sessions following a standardized and scripted protocol. An extra trained provider (psychologist or dietitian) attended the meetings of the four groups to aid with facilitation but did not participate in the discussion. DAK was the only facilitator in the last group because of last minute cancellations. The participants in the fourth and final round of randomisation were split into two small intervention groups for convenience

purposes. A participant from the control group that had completed the study was invited to participate in the last group (final n=4 in group 5) to enhance the group experience but was not included in the analysis. There were no other modifications. The completed CONSORT[17] and TIDieR checklists[18] are available in Supplementary appendix S1 and S2, respectively.

Care as usual

Participants in the control arm were offered usual care. After the final follow-up, they received a booklet with healthy lifestyle advice for cancer survivors.[19]

Outcomes

Recruitment rates were calculated separately for each strategy and site. We adapted an existing framework of hierarchical recruitment barriers (availability by disease characteristics, eligibility, physician triage, trial discussion, interest, consent, and enrolment)[20] to describe the recruitment process. In contrast with the original framework, the category “interest” preceded that of “trial discussed” to fit the current recruitment process. Participants who were introduced to the study and decided not to enrol completed a 25-item investigator-designed survey[21] about barriers to participation. UCLH clinicians were interviewed about their views on study recruitment using a semi-structured protocol by phone or face to face (Supplementary appendix S3).

All intervention sessions were audiotaped. RJB attended one intervention session and one study assessment and scored them against a predefined checklist. Engaged intervention-arm participants completed and posted an 18-item programme evaluation questionnaire.[22] Only two follow-up qualitative interviews with intervention participants were performed at study completion, as the data from the open-ended feedback questionnaire were deemed sufficient.

Statistical and qualitative analysis

Despite the pilot nature of the study, a sample size of 32 participants per arm was estimated for examining recruitment, adherence, and retention rates. The study would be deemed feasible if the lower 95% confidence limits for recruitment, adherence, and retention rates were at least 15%, 60%, and 60%, respectively.[15]

Primary outcomes are reported in proportions with 95% confidence intervals (CIs). Descriptive statistics are reported for continuous variables. Categorical variables are summarized using frequencies and percentages. The interviews with clinicians lasted 10 minutes on average, were digitally recorded, transcribed verbatim by a professional company, and checked for accuracy. Given the structured interview and short replies, data were analysed with content analysis using NVivo version 10 (QSR International Pty Ltd, 2014) software. The open-ended questions were analysed using manifest content analysis[23] in Microsoft Office Excel 2011.

Results

Recruitment

Recruitment took place over a period of 27 and 18 weeks (April 2015 – December 2015) at UCLH and Barts Health, respectively (Figure S1, Supplementary appendix S3). The difference in recruitment period between sites was primarily explained by substantial delay of NHS Research and Development (R&D) management approval at Barts Health. Among the first 64 eligible participants approached, 20 consented to participate, leading to rejection of the null hypothesis that recruitment would be ≤15%. Therefore, recruitment continued for enrolling the projected sample of 64 participants but stopped after enrolling 60 participants due to resource constraints. Out of 296 potentially eligible participants, 20.3% (95% CI: 15.7, 24.9) enrolled in the study. Among screened participants, rates of consent were similar for the face-to-face recruitment at the two recruitment sites but lower for the mail out (Table S1 and Table S2).

Reasons for non-participation were documented for 36.7% (n=83) of those who were potentially eligible but did not consent and 90.2% of those that were approached. Inconvenience to everyday life (78%) and transport to trial site (63%) were the main barriers to participation, with further barriers detailed in Figure 1. The CONSORT flow diagram shows the progress through the trial stages (Figure 2).

Clinicians' views on recruitment

Clinicians were supportive of the study and did not have particular concerns about introducing the study to patients. They felt the study might be beneficial to patients, but they believed travelling and commitment would be the main barriers for recruitment.

They deemed the recruitment strategy highly effective, with potentially eligible patients being flagged prior to the clinic, researchers being present and reminding them about approaching patients, and through the existence of a separate space for study recruitment in the clinic. These strategies minimized additional clinician workload.

Clinicians did not anticipate adverse events from the intervention or changes in their relationship with the patients. The framing and content of such an intervention was also highlighted as a potential barrier to recruitment. In particular, approaching patients in a non-discriminatory way was deemed to enhance recruitment. Furthermore, framing of its content as a lifestyle programme was thought to be superior to a weight loss programme, strict diet regime, or educational programme.

Sample characteristics

Participant characteristics at baseline are shown in Table 1. Women were on average (±SD) 62.1 ± 8.3 years old, White (67%), married (53%), 1.2 ± 1.0 years from diagnosis, with a BMI of 28.0 ± 6.3kg/m^2. They were diagnosed mostly with stage IA (49%), type 1 (82%) endometrial cancer.

Adherence

Out of 26 participants in the intervention arm, 21 (81%; 95% CI: 66%-96%) engaged and 20 (77%; 95% CI: 61%-93%) adhered to the intervention, based on our pre-determined criteria [15]. The lower confidence limit was above 60% indicating feasibility.

The percentage of participants who attended zero, five, six, seven, and eight (all) sessions was 15%, 8%, 12%, 35%, 15%, respectively. The mean overall attendance of sessions was 63% (95% CI: 49%, 77%). The mean attendance rates of those who engaged and those who adhered were 79% (95% CI: 70%, 88%) and 82% (95% CI: 74%, 89%), respectively. Reasons for non-adherence were mostly of practical nature, with details available in Supplementary appendix S3.

Programme satisfaction

Eighteen participants randomised to the intervention group who adhered provided feedback for the programme. They scored the programme highly with 44% and 39% reporting that it met or exceeded their expectations, respectively. All aspects of the programme were scored highly (Figure 3). Additionally, most participants ranked self-monitoring, setting SMART (specific, measureable, achievable, relevant, and time-specific) goals, and social support as either very or somewhat helpful in making dietary and physical activity changes (Figure 4). In contrast, the responses for self-incentives were mixed with 28% of participants rating this technique as unhelpful.

A range of topics were regarded as most useful (Figure S2). Among them, most participants agreed that the sections about keeping an eye on portion sizes, food labelling, and internal triggers were the most useful. Others mentioned self-incentives, internal and external triggers, and getting a healthier balance of foods to be the least useful topics (Figure S3). For example, one participant mentioned:

> *I also did not understand the concept of the rewards - better health should be its own reward (Participant in group 4).*

Suggestions for additions to the programme were primarily focused on physical activity, such as provision of relevant DVDs, physical activity during the programme sessions, and diaries to report physical activity and sedentary behaviour in more detail. Most participants did not consider that topics should be eliminated from the programme. Similar feedback was provided for the booklet; most participants did not suggest changes while a few suggested design changes. Further suggestions included the addition of follow-up support and a preference for a larger group (mentioned by participants in smaller groups) to boost the peer-education component.

Peer support of the group, both the focus of the programme and their own interest in health promotion, the feeling of giving back to the care system, the facilitators, and the doctor's referral to the programme facilitated study participation. In contrast, most did not report factors discouraging them to participate but some mentioned inconvenience to everyday life, self-monitoring and identification as a cancer survivor.

Regarding the trial procedures, two participants mentioned their difficulty recalling and quantifying their diet and physical activity. Excellent fidelity to the protocol for both the group sessions (85%) and the assessments (100%) was demonstrated in the study auditing.

Retention

Retention rate was 92% (95% CI: 85%, 100%), with 24/28 (86%; 95% CI: 73%-99%) and 25/26 (96%; 95% CI: 89%-100%) eligible participants in the control and intervention arm completing all assessments, respectively (P=0.61 for difference between proportions). This indicated an absence of attrition bias and the rejection of the null hypothesis that retention rate would be less than 60%.

Adverse events and control arm contamination

No intervention-related adverse events or unintended consequences were reported. Adverse events unrelated to the intervention and reasons for control arm contamination are detailed in the Supplementary appendix S3.

Discussion

This is the first pilot study of a health behaviour change intervention in endometrial cancer survivors in the UK to demonstrate feasibility in terms of recruitment, adherence, and retention. The collaboration of the clinical and research team led to an efficient recruitment process. Participants rated the programme highly and provided rich feedback for refinement. Consistent with the literature[24] and the qualitative findings,[7] the DEUS pilot study aimed to minimize accrual barriers by enrolling survivors within the "teachable moment" period, capitalizing on the endorsement of the study from survivors' clinicians, utilizing a strong behaviour theory-based design, and ensuring standardized delivery of the intervention. These study strengths were also reflected in the reported factors associated with programme involvement. Furthermore, the frameworks for reporting barriers to participation[20 21] provided a comprehensive understanding of these barriers and can be a valuable resource to understand barriers in for future trials.[25] Limitations of the study include the small sample size, recruitment from only two London-based sites, generalizability of the recruited sample, as socio-demographic data from decliners were missing. The relatively low median BMI of participants compared to epidemiological studies[26] indicates healthy volunteer effect biases. The wide socio-economic and demographic differences of the population pools of the two hospitals[27] and the similar recruitment rates at both sites were reassuring and suggest these factors should not impact recruitment and retention.

The focus of the study on healthy lifestyle changes rather than weight loss was postulated to increase uptake and acceptability of the programme.[7] The overall recruitment estimate was similar or somewhat higher than that in other lifestyle intervention trials, although differences in recruitment strategies, eligibility criteria, cancer site, programme length and intensity do

not allow for direct comparisons. The group-based, six-month SUCCEED intervention had a 19% recruitment rate using mail-out.[12] A 12-week group-based physical activity intervention recruited 20% of the eligible endometrial cancer survivors through fliers and telephone recruitment.[28] Similar to DEUS, a more intensive lifestyle intervention in UK breast cancer survivors had a mail-out rate of 17%.[29] While removing the transport and time barriers would theoretically improve recruitment rates, USA home-based lifestyle interventions recruiting cancer survivors from registries have shown much smaller recruitment rates (5.7%) with women, younger, White survivors and those closer to their cancer diagnosis more likely to enrol.[30]

The observed adherence was lower compared with the weight loss SUCCEED intervention (84.1%) comprising of 16 group sessions[12] but similar to that of a group-based 12-week physical activity intervention.[28] While this might indicate that survivors are more committed in weight loss programmes compared to healthy lifestyle programmes, the main reported reasons regarding non-attendance in the current study were around practicalities and life commitments rather than disengagement with the programme. Sending a standardized e-mail to non-attendees about topics covered in the missed session and preparation for the next session helped maintain their engagement.

Having a specific research room and two committed researchers in clinic facilitated recruitment. Screening participants using electronic forms and implementing further pre-randomisation eligibility checks from medical notes could minimize randomisation of ineligible participants. The recruitment rate, while similar between the two sites, was lower in the clinician-endorsed mail-out, indicating the higher effectiveness of the first approach that needs to be balanced with its higher resource requirements in larger trials. Practical reasons rendered intervention adherence acceptable but not optimal. The difficulty of trying to arrange a weekly group meeting with approximately eight people was evident, although a range of potential times was offered to participants and involved working around the logistics to find the most convenient date. Given the wide variability of participants' availability,

simultaneous offers of a group on a weekday early evening or Saturday morning facilitated engagement in Groups 2 and 3. In future studies, larger groups will be possible by un-blinding investigators after enough participants are allocated to each trial arm to run two groups.

Opting for the group-based and face-to-face design aimed to meet survivors' preferences[7] but was in contrast with some previous studies reporting proximity as a particular barrier in this population.[24] The lack of dropouts after the second group session indicated the overall acceptability of the intervention and the favourable rating of most programme aspects provides confidence that only minor content adaptations are needed before testing the study in a large trial. As multiple facilitators will deliver the intervention in a pragmatic setting, future large-scale trials should also measure differences in intervention delivery between various facilitators. Inconvenience and transport were the main barriers to accrual in the current study. Increasing reach might be more feasible with blended designs of group meetings and remote intervention delivery, especially as home-based interventions have typically experienced much lower recruitment rates compared with group-based interventions. In the current programme, even those who adhered mentioned convenience reasons as discouraging participation but the peer support as encouraging. This might suggest delivering some sessions in person and others remotely, potentially through web or mobile technology. A pilot weight loss study with endometrial and breast cancer survivors delivered via a mobile application has shown promising results in a pre-post design.[31] However, further research on mobile applications for weight management is needed, as most lack evidence-based behaviour change techniques, involvement of health care professionals and scientific evaluation.[32]

In conclusion, this self-help lifestyle intervention trial was feasible in terms of recruitment, adherence, and retention. Scaling the trial will require close monitoring of recruitment and attempts should be made to reduce the burden on participants. Further qualitative work could inform a blended in-person and remote design to enhance adherence while retaining

the valued peer support. This should be considered before proceeding to a definitive trial. Overall, the lessons learnt from this pilot should inform the design of future studies in this area.

Full protocol availability

The full protocol of the study has been previously published[15] and it can also be found in the Supplementary Appendix S4.

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Competing interests' statement

DAK and RJB are volunteers for the charity Weight Concern, which developed the original Shape-Up programme for the general population. All other authors have no conflicts of interest to declare.

Contribution to Authorship

The authors' contributions were as follows. Anne Lanceley (AL) and M. Tish Knobf (MTK) conceived the study and were the grant holders. AL and Ranjit Manchanda (RM) were the site investigators for University College London Hospitals and Barts Health, respectively. Dimitrios A. Koutoukidis (DAK), AL, Rebecca J Beeken (RJB) and MTK initiated the study design, and RM helped with protocol development and implementation. DAK and Moscho Michalopoulou (MM) recruited the study participants. RJB was responsible for randomisation and auditing. DAK was the trial manager, ran the group sessions, and conducted the baseline and 24-week follow-up assessments. MM conducted the 8-week follow-up assessments. Matthew Burnell (MB) provided the statistical support, and DAK conducted the statistical analysis. DAK drafted the manuscript, which was amended following comments

from all other authors. All authors read and approved the submitted manuscript. All listed authors meet the criteria for authorship and no individual meeting these criteria has been omitted.

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Ethical approval

The study protocol and documents have been reviewed and approved by the relevant sponsor and National Research Ethics Service Committee London - City Road and Hampstead (Reference: 15/LO/0154).

Availability of data and materials

The materials and datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

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List of legends

Table 1 DEUS pilot trial baseline participant characteristics

Figure 1 Percentage of each barrier to participation with SE

Figure 2 CONSORT diagram of the trial with framework on barriers to participation in the exclusion box

Figure 3 Percentage programme satisfaction (n=18)

Figure 4 Helpfulness of the main behaviour change techniques for dietary and physical activity changes (n=18)

Table 1 DEUS pilot trial baseline participant characteristics

Characteristic	Shape-Up (n=25)	Care as usual (n=24)	Total
Age, mean (SD)	62.6 (9.0)	61.5 (7.7)	62.1 (8.3)
Race			
White	17 (68)	16 (67)	33 (67)
Asian	4 (16)	5 (21)	9 (18)
Black	3 (12)	1 (4)	4 (8)
Mixed / Other	1 (4)	2 (8)	3 (6)
Living arrangement			
Own outright	12 (48)	10 (42)	22 (45)
Own mortgage	5 (20)	5 (21)	10 (20)
Rent from local authority	6 (24)	5 (21)	11 (22)
Rent privately	2 (8)	4 (17)	6 (12)
Marital status			
Married / living with partner	12 (48)	14 (58)	26 (53)
Married / separated	4 (16)	1 (4)	5 (10)
Divorced	3 (12)	2 (8)	5 (10)
Widowed	2 (8)	4 (17)	6 (12)
Civil partnership	0 (0)	1 (4)	1 (2)
Single	4 (16)	2 (8)	6 (12)
Education			
Degree or higher degree	9 (36)	9 (38)	18 (37)
Higher education below degree level	2 (8)	3 (13)	5 (10)
Secondary education	11 (44)	10 (42)	21 (42)
No formal qualifications	3 (12)	2 (8)	5 (10)
Employment			
Full time / self-employed	9 (36)	11 (46)	20 (41)
Part time	3 (12)	1 (4)	4 (8)
Retired	10 (40)	11 (46)	21 (43)
Other	3 (12)	1 (4)	4 (8)
Smoking			
Current	2 (8)	2 (8)	4 (8)
Former	4 (16)	5 (21)	9 (18)
IMD (quintile)			
1 – most deprived	5 (20)	4 (17)	9 (18)

Characteristic	Shape-Up (n=25)	Care as usual (n=24)	Total
2	9 (36)	6 (25)	15 (31)
3	4 (16)	7 (29)	11 (22)
4	3 (12)	3 (13)	6 (12)
5 – least deprived	4 (16)	4 (17)	8 (16)
Time since diagnosis in months, mean (SD)	19.2 (11.2)	21.4 (11.3)	20.3 (11.2)
Time since completion of primary treatment in months, mean (SD)	17.1 (11.2)	18.5 (11.7)	17.8 (11.3)
Surgery	25 (100)	24 (100)	49 (100)
Chemotherapy treatment	3 (12)	5 (21)	8 (16)
External beam radiotherapy	6 (24)	12 (50)	18 (37)
Brachytherapy	11 (44)	13 (54)	24 (49)
Cancer stage			
IA	11 (44)	13 (54)	24 (49)
IB	11 (44)	6 (25)	17 (35)
II	2 (8)	3 (13)	5 (10)
IIIA	1 (4)	2 (8)	3 (6)
Cancer grade			
1	6 (24)	7 (29)	13 (27)
2	13 (52)	9 (38)	22 (45)
3	6 (24)	8 (33)	14 (29)
Histology			
Endometrioid adenocarcinoma	21 (84)	19 (79)	40 (82)
Serous carcinoma	1 (4)	3 (13)	4 (8)
Mixed carcinoma	1 (4)	0 (0)	1 (2)
Serous surface papillary carcinoma	0 (0)	1 (4)	1 (2)
Carcinosarcoma	2 (8)	0 (0)	2 (4)
Adenosquamous carcinoma	0 (0)	1 (4)	1 (2)
Histological type			
Type I	21 (84)	19 (79)	40 (82)
Type II	4 (16)	5 (21)	9 (18)
Charlson Comorbidity Index			
2	18 (75)	21 (84)	39 (80)

Characteristic	Shape-Up (n=25)	Care as usual (n=24)	Total
3	6 (25)	4 (16)	10 (20)
WHO performance status			
0	20 (83)	20 (80)	40 (82)
1	3 (13)	5 (20)	8 (16)
2	1 (4)	0 (0)	1 (2)
Selected comorbidities			
Diabetes	3 (12)	4 (17)	7 (14)
Hypertension	6 (24)	7 (29)	13 (27)
Dyslipidaemia	3 (12)	3 (13)	6 (12)
Asthma	1 (4)	2 (8)	3 (6)
Osteoporosis	2 (8)	4 (17)	6 (12)
Weight, mean (SD)	69.8 (14.8)	71.9 (15.2)	70.9 (14.9)
BMI, mean (SD)	27.3 (6.5)	28.8 (6.1)	28.0 (6.3)
BMI, median (IQR)	26.2 (24.3)	26.9 (8.6)	26.8 (6l.4)
% Fat, mean (SD)	35.3 (7.7)	36.9 (6.3)	36.1 (7.0)

Percentages might not add to 100 due to rounding
IMD: Index of multiple deprivation, IQR: Interquartile range
Data are presented as n (%) unless otherwise specified
Body composition data for usual care n=23

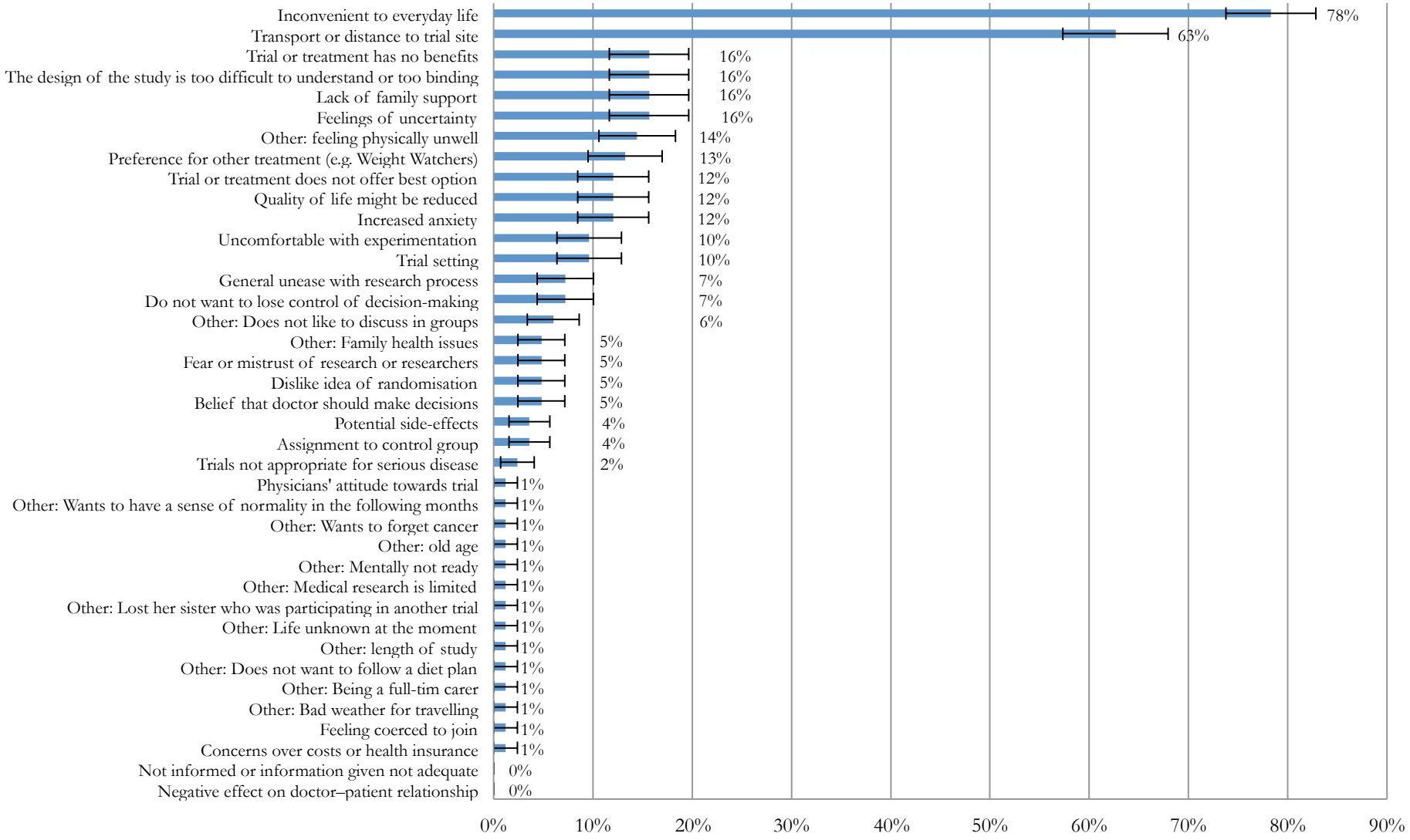
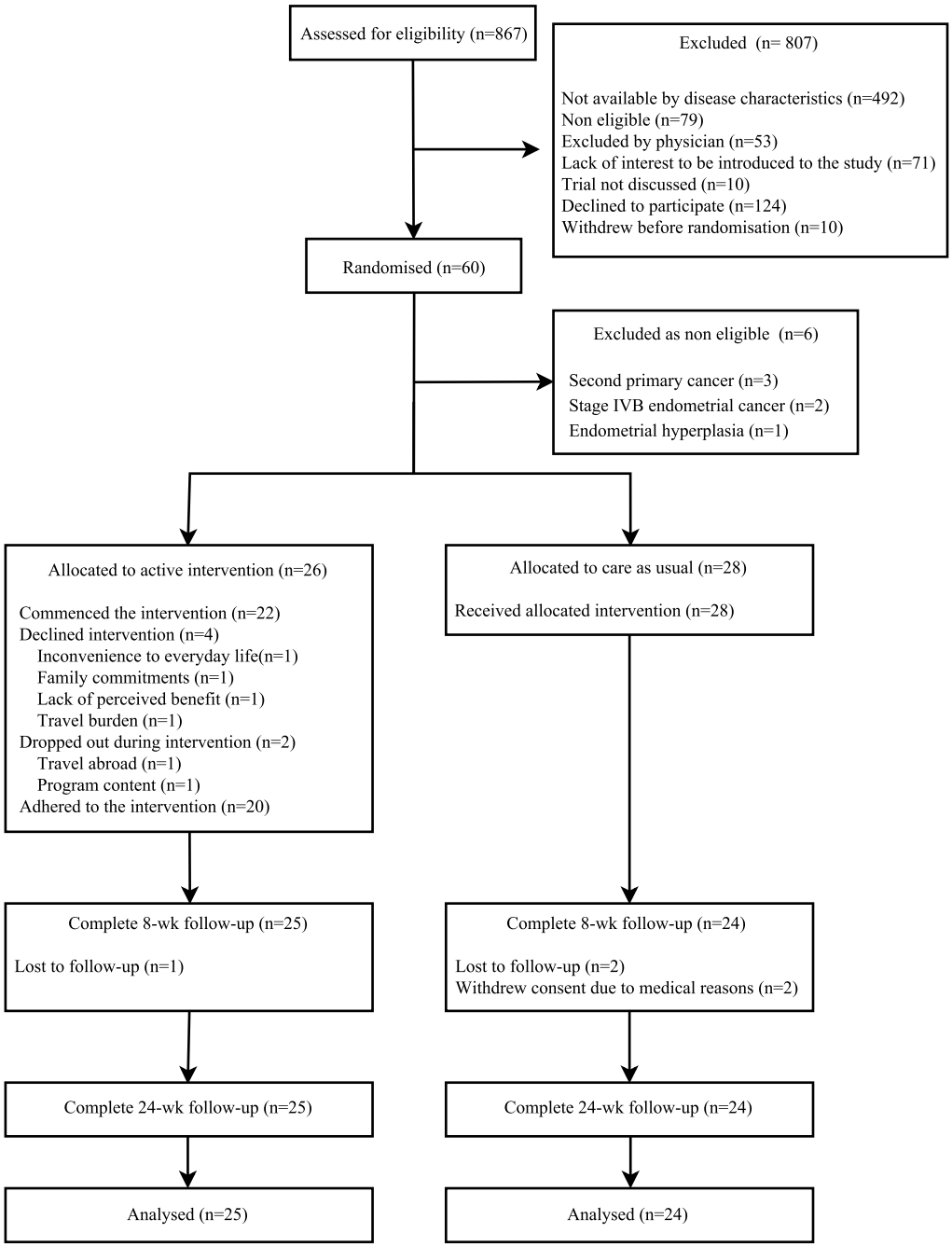


Figure 1 Percentage of each barrier to participation with SE (n=83)


Assessed for eligibility (n=867)
Excluded (n= 807)
Not available by disease characteristics (n=492)
Non eligible (n=79)
Excluded by physician (n=53)
Lack of interest to be introduced to the study (n=71)
Trial not discussed (n=10)
Declined to participate (n=124)
Withdrew before randomisation (n=10)
Randomised (n=60)
Excluded as non eligible (n=6)
Second primary cancer (n=3)
Stage IVB endometrial cancer (n=2)
Endometrial hyperplasia (n=1)
Allocated to active intervention (n=26)
Commenced the intervention (n=22)
Declined intervention (n=4)
Inconvenience to everyday life(n=1)
Family commitments (n=1)
Lack of perceived benefit (n=1)
Travel burden (n=1)
Dropped out during intervention (n=2)
Travel abroad (n=1)
Program content (n=1)
Adhered to the intervention (n=20)
Allocated to care as usual (n=28)
Received allocated intervention (n=28)
Complete 8-wk follow-up (n=25)
Lost to follow-up (n=1)
Complete 8-wk follow-up (n=24)
Lost to follow-up (n=2)
Withdrew consent due to medical reasons (n=2)
Complete 24-wk follow-up (n=25)
Complete 24-wk follow-up (n=24)
Analysed (n=25)
Analysed (n=24)

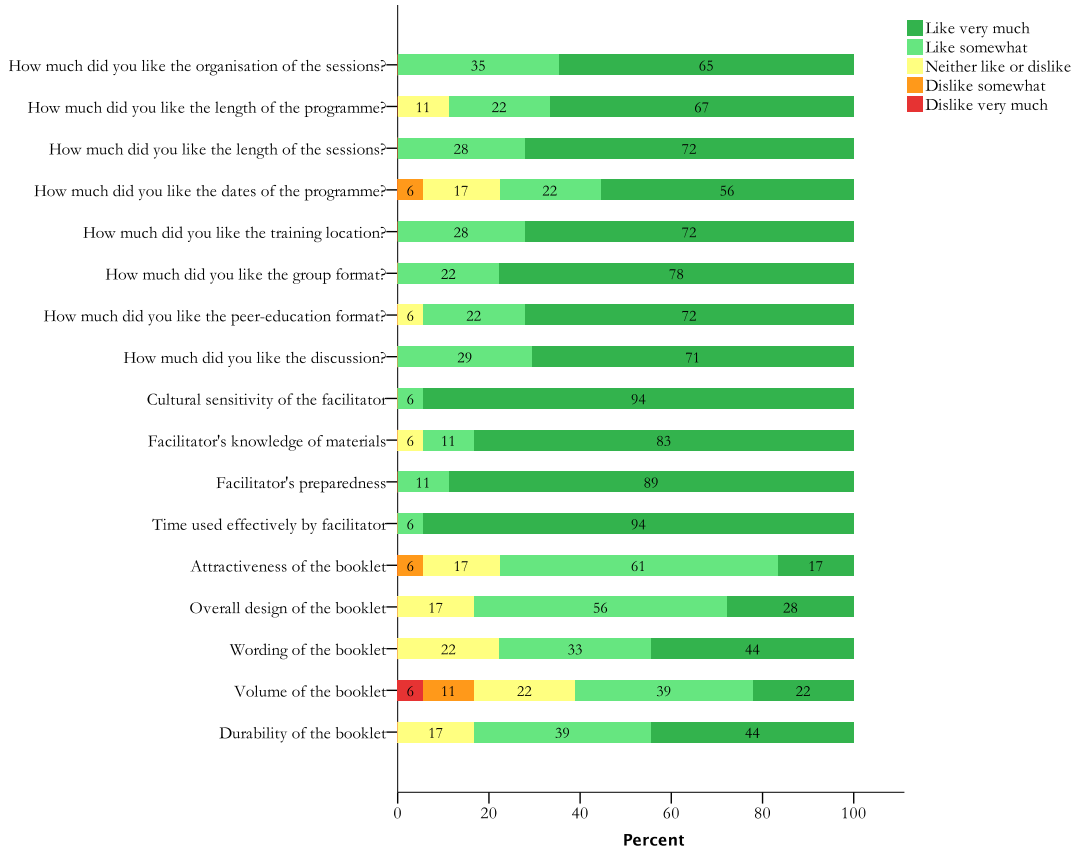


Figure 3 Percentage program satisfaction (n=18)

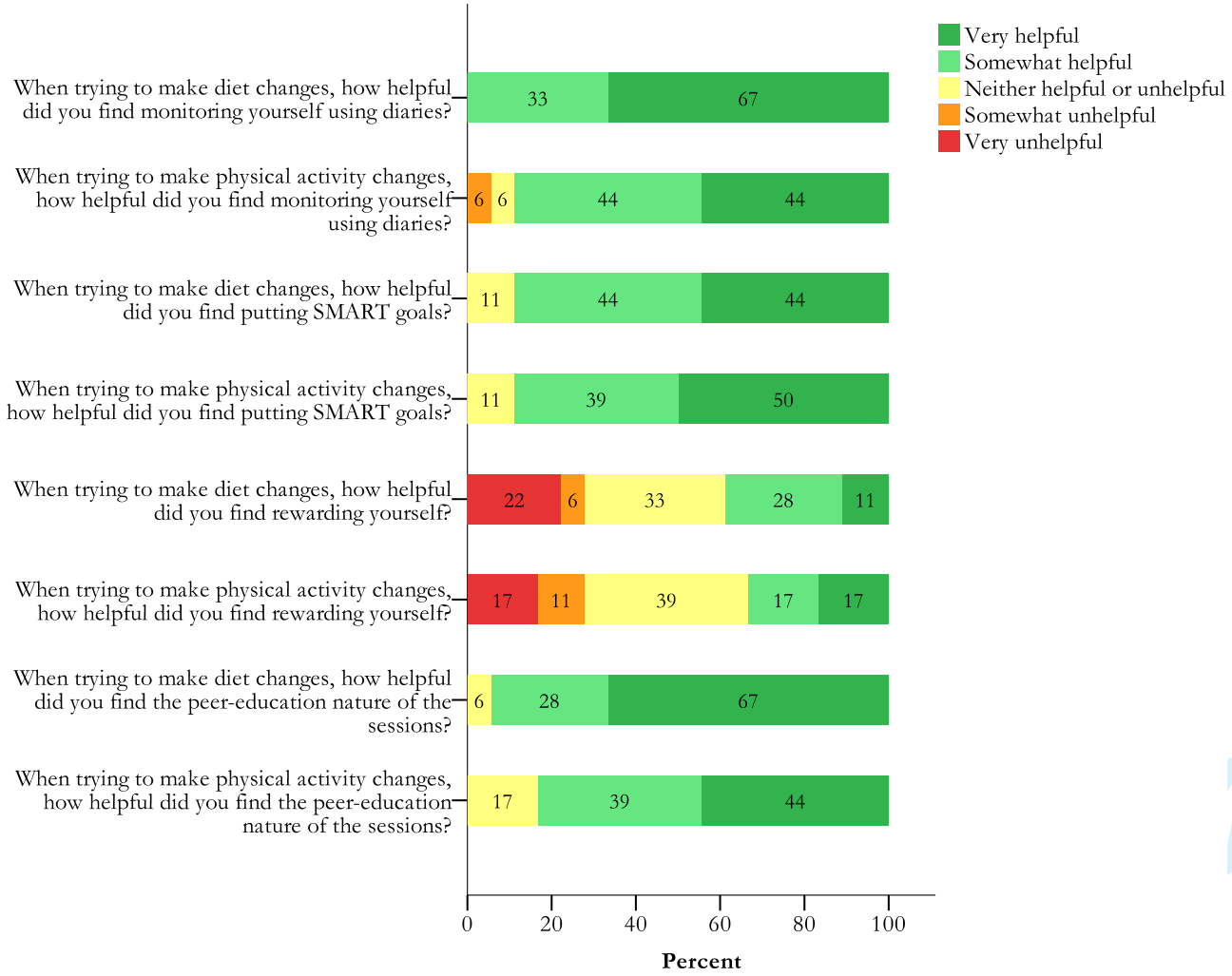


Figure 4 Helpfulness of the main behaviour change techniques for dietary and physical activity changes (n=18)

CONSORT checklist of information to include when reporting a pilot trial*

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
Title and abstract			
1a	Identification as a randomised trial in the title	Identification as a pilot or feasibility randomised trial in the title	1
1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives:			
2a	Scientific background and explanation of rationale	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	4
2b	Specific objectives or hypotheses	Specific objectives or research questions for pilot trial	4-5
Methods			
Trial design:			
3a	Description of trial design (such as parallel, factorial) including allocation ratio	Description of pilot trial design (such as parallel, factorial) including allocation ratio	5
3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	5
Participants:			
4a	Eligibility criteria for participants		5
4b	Settings and locations where the data were collected		5
4c		How participants were identified and consented	5-6 and protocol paper
Interventions:			
5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered		6-7 and protocol paper
Outcomes:			
6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	7 and protocol paper
6b	Any changes to trial outcomes after the trial commenced, with reasons	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	5
6c		If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	n/a

Sample size:			
7a	How sample size was determined	Rationale for numbers in the pilot trial	Protocol paper
7b	When applicable, explanation of any interim analyses and stopping guidelines		n/a
Randomisation:			
Sequence generation:			
8a	Method used to generate the random allocation sequence		6 and protocol paperr
8b	Type of randomisation; details of any restriction (such as blocking and block size)	Type of randomisation(s); details of any restriction (such as blocking and block size)	6 and protocol paper
Allocation concealment mechanism:			
9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned		Protocol paper
Implementation:			
10	Who generated the random allocation sequence, enrolled participants, and assigned participants to interventions		Protocol paper
Blinding:			
11a	If done, who was blinded after assignment to interventions (eg, participants, care providers, those assessing outcomes) and how		6 and protocol paper
11b	If relevant, description of the similarity of interventions		
Analytical methods:			
12a	Statistical methods used to compare groups for primary and secondary outcomes	Methods used to address each pilot trial objective whether qualitative or quantitative	7-8
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Not applicable	n/a
Results			
Participant flow (a diagram is strongly recommended):			
13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	8-9, Figure 2 Table S1
13b	For each group, losses and exclusions after randomisation, together with reasons		Figure 2
Recruitment:			

14a	Dates defining the periods of recruitment and follow-up		8
14b	Why the trial ended or was stopped	Why the pilot trial ended or was stopped	8
Baseline data:			
15	A table showing baseline demographic and clinical characteristics for each group		Table 1
Numbers analysed:			
16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	8-12
Outcomes and estimation:			
17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	8-12
17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable	n/a
Ancillary analyses:			
18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	Results of any other analyses performed that could be used to inform the future definitive trial	n/a
Harms:			
19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)		12 and Suppl. material
19a		If relevant, other important unintended consequences	n/a
Discussion			
Limitations:			
20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	12, 14
Generalisability:			
21	Generalisability (external validity, applicability) of the trial findings	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	12-13
Interpretation:			
22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	12-15
22a		Implications for progression from pilot to future definitive trial, including any proposed amendments	
Other information			

Registration:		
23	Registration number and name of trial registry	Registration number for pilot trial and name of trial registry
Protocol:		
24	Where the full trial protocol can be accessed, if available	Where the pilot trial protocol can be accessed, if available
Funding:		
25	Sources of funding and other support (such as supply of drugs), role of funders	
26		Ethical approval or approval by research review committee, confirmed with reference number

*Here a pilot trial means any randomised study conducted in preparation for a future definitive RCT, where the main objective of the pilot trial is to assess feasibility.

TIDieR Template for Intervention Description and Replication

^^The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (section)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	Abstract	_____
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	Shape-Up following cancer treatment intervention	Protocol paper (see below for reference)_____
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	Shape-Up following cancer treatment intervention	Protocol paper_____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	Shape-Up following cancer treatment intervention	Protocol paper_____
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	Shape-Up following cancer treatment	Protocol paper_____

		intervention	
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Shape-Up following cancer treatment intervention	_____
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	Shape-Up following cancer treatment intervention	_____
	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Shape-Up following cancer treatment intervention	Protocol paper_____
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	Shape-Up following cancer treatment intervention	Protocol paper_____
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	Shape-Up following cancer treatment intervention	_____

	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Outcomes	Protocol paper_____
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Program satisfaction	_____

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

Protocol paper: D.A. Koutoukidis, R.J. Beeken, R. Manchanda, M. Burnell, M.T. Knobf, A. Lanceley, Diet and exercise in uterine cancer survivors (DEUS pilot) - piloting a healthy eating and physical activity program: study protocol for a randomized controlled trial. Trials, 2016. 17(1): p. 130. 10.1186/s13063-016-1260-1.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

Supplementary appendix (S3)

Recruitment, adherence, and retention of endometrial cancer survivors in a behavioral lifestyle program: the Diet and Exercise in Uterine Cancer Survivors (DEUS) parallel randomized pilot trial

Dimitrios A. Koutoukidis, Rebecca J. Beeken, Ranjit Manchanda, Moscho Michalopoulou, Matthew Burnell, M. Tish Knobf, Anne Lanceley

Interview protocol with clinicians

1. What are your views on the trial?
    a. Prompt: effects on clinical practice
    b. Prompt: Benefits to participants
2. What are your views on recruiting participants for the trial?
3. What can make recruitment more difficult?
    a. Prompt: Potential harm to patients
    b. Prompt: Perceived patient barriers
4. What can make recruitment easier?
    a. Prompt: Individual benefits to clinicians
5. Is there anything that can make you think twice about recruiting eligible participants?
6. How can recruitment for this trial affect your relationship with your patient?

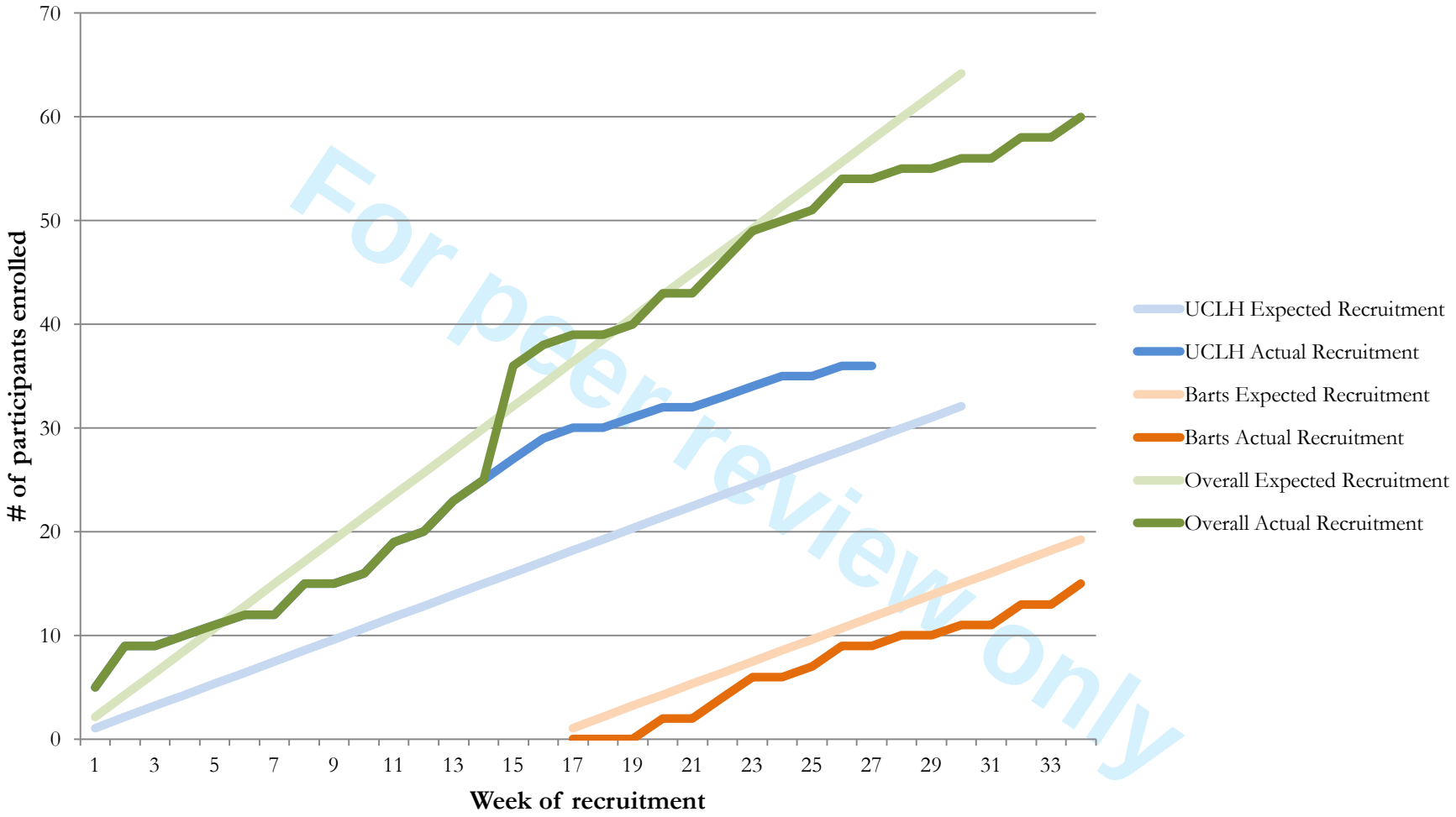


Figure S1 Projected and actual recruitment by site. The sharp spike in week 13 in overall recruitment indicated the recruited participants through mail out.

Table S1 Number of screened participants at each stage of the recruitment process

	UCLH	Barts	Hospitals combined	Mai-out	Total
1. Women in gynecologic oncology clinic	**2305**	**1047**	**3352**	**294**	**3646**
Other cancer site - not endometrial cancer	1638	828	2466	36	2502
Stage IVB (metastatic) endometrial cancer	11	7	18	14	32
Active anti-cancer, and/or palliative treatment	164	47	211	3	214
Endometrial Diagnosed >3years	67	49	116	69	185
Second primary cancer	34	8	42	2	44
Duplicates	168	3	171	106	277
2. Available for trial by disease characteristics	**223**	**88**	**311**	**64**	**375**
Not able to understand spoken and written English	23	13	36	1	37
Lack of mental capacity	3	2	5	-	5
Severe depression	2	-	2	-	2
WHO performance score 3-4	7	3	10	5	15
Unavailable for longitudinal follow-up assessments	4	3	7	2	9
Participated in a professionally delivered weight loss or exercise program during the previous 6 months	8	2	10	1	11
3. Eligible for participation	**176**	**65**	**241**	**55**	**296**
Did not attend clinic	23	13	36	-	36
Too distressed	5	-	5	-	5
Clinician did not introduce her to the study because of the long wait	1	-	1	-	1
Clinician did not introduce her due to confusion about eligibility criteria	-	2	2	-	2
Clinician did not introduce her because she had vision difficulties	1	-	1	-	1
Clinician did not introduce her because she was due for a knee operation	1	-	1	-	1

	UCLH	Barts	Hospitals combined	Mai-out	Total
Discussed with clinician and decide not to take part due to travel	2	-	2	-	2
Not approached by clinical team - medical notes missing / no pink leaflet	1	-	1	-	1
Lost her in clinic - clinician forgot to mention study	1	-	1	-	1
Not introduced to the study because researcher not in clinic	1	1	2	-	2
Pregnant	-	1	1	-	1
4. Physician Triage & introduced to the study	**140**	**48**	**188**	**55**	**243**
Not interested to hear about study	23	9	32	-	32
Long wait / too busy to talk about study	2	-	2	-	2
5. Participants interested	**115**	**39**	**154**	**18**	**172**
Lost in clinic - talking to other eligible participants	1	0	1		
6. Trial discussed	**114**	**39**	**153**	**9**	**162**
Decided not to take part and completed barriers survey	49	13	62	9	71
Decided not to take part, gave reasons, but did not complete barriers survey	6	6	12	-	12
Decided not to take part without giving reasons	1	2	3	-	3
Could not be reached back	11	3	14	-	14
Excluded due to cancer recurrence	1	0	1	-	1
7. Participant consented	**46**	**15**	**61**	**9**	**70**
Dropped out due to family reasons	2	-	2	-	2
Dropped out due to feel of no benefit	1	-	1	-	1
Dropped out due to inconvenience to everyday life	3	1	4	-	4
Dropped out due to health reasons	1	1	2	-	2
Not eligible - second primary cancer	1	-	1	-	1
8. Participant enrolled (randomized)	**38**	**13**	**51**	**9**	**60**

Table S2 Proportions (95% CIs of consented and enrolled participants by recruitment site)

	UCLH	Barts Health	Both hospitals	Mail-out	Total
Consented participants					
% Of eligible	26.1 (19.6, 32.6)	23.1 (12.8, 33.3)	25.3 (19.8 30.8)	16.4 (6.6, 26.1)	23.6 (18.8, 28.5)
% Of physician triage	32.9 (25.9, 39.8)	31.3 (20.0, 42.5)	32.4 (26.5, 38.4)	-	-
% Of interested	40.0 (32.8, 47.2)	38.5 (26.6, 50.3)	39.6 (33.4, 45.8)	-	-
Enrolled participants					
% Of eligible	21.6 (15.5, 27.7)	20.0 (10.3, 29.7)	21.2 (16.0, 26.3)	16.4 (6.6, 26.1)	20.3 (15.7, 24.9)
% Of physician triage	27.1 (20.6, 33.7)	27.1 (16.3, 37.9)	27.1 (21.5, 32.7)	-	-
% Of interested	33.0 (26.1, 40.0)	33.3 (21.9, 44.8)	33.1 (27.2, 39.1)	-	-
% Of consented	82.6 (77.0, 88.2)	86.7 (78.4, 94.9)	83.6 (78.9, 88.3)	100	85.7 (81.7, 89.7)

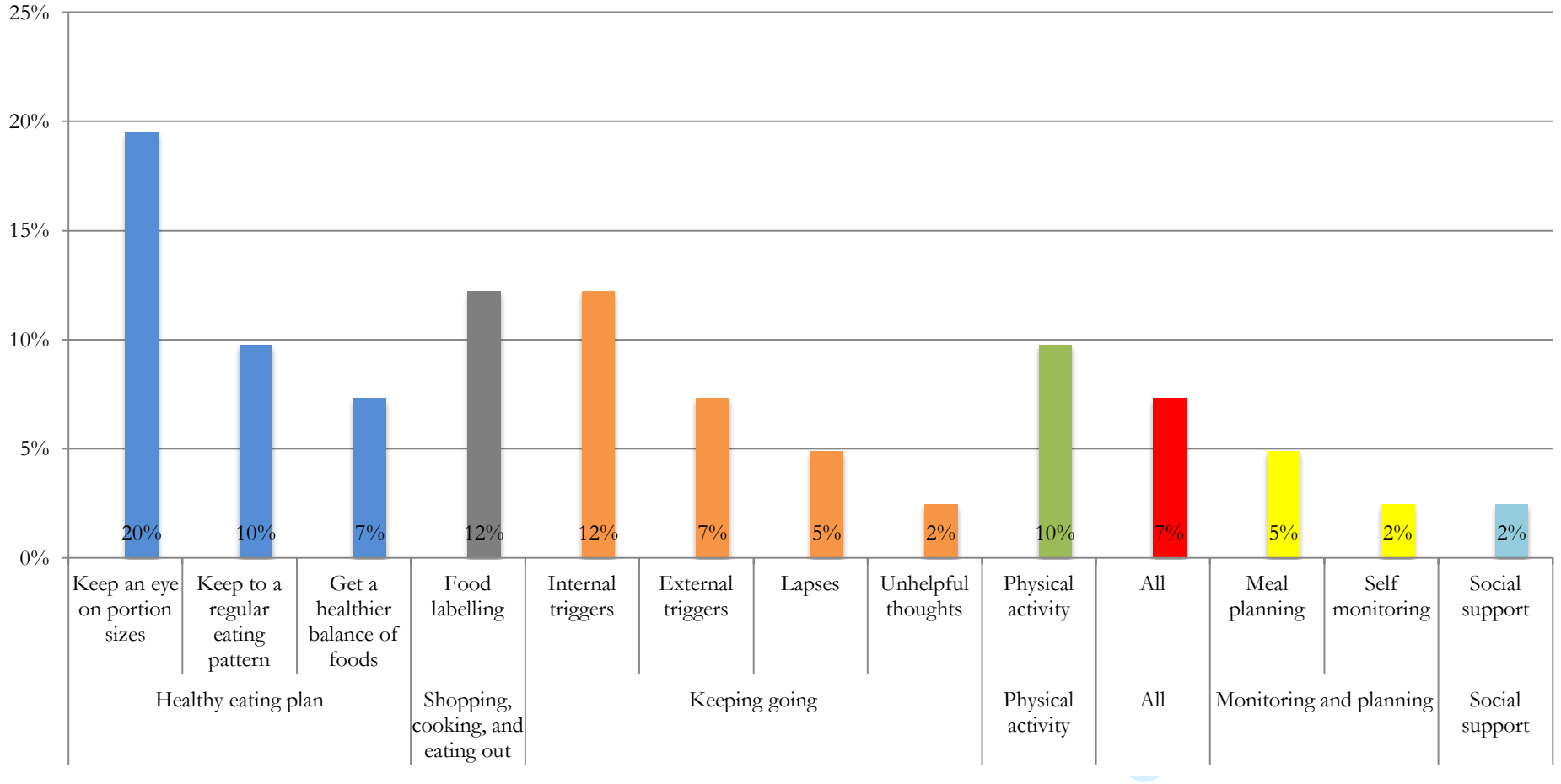


Figure S2 Percentage responses to the question "Which topic of the programme did you find the most useful?" by topic and programme section (in colour)

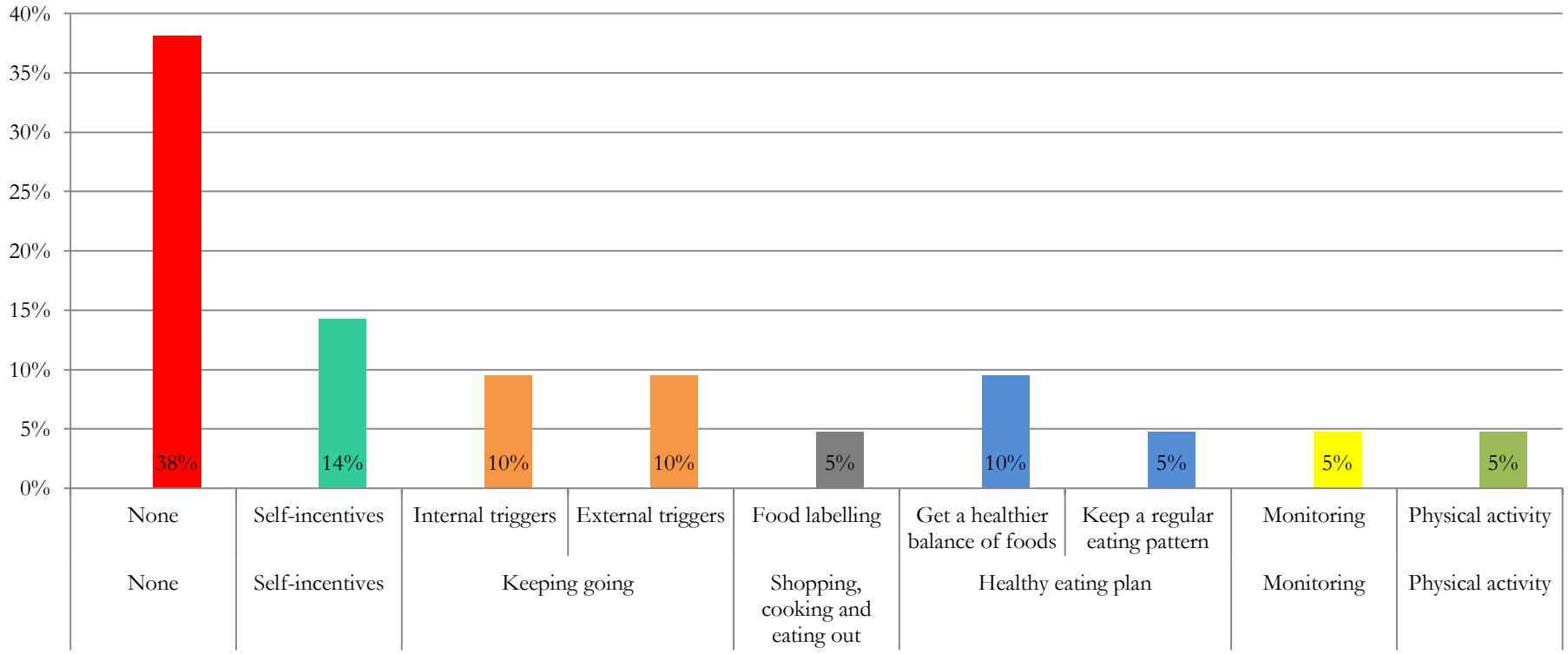


Figure S3 Percentage responses to the question "Which topic of the programme did you find the least useful?" by topic and programme section (in colour)

Reasons for non-adherence to the intervention

Of the six participants that did not adhere (23.1%), four dropped out before the first session. Reasons included inconvenience to everyday life, travel burden, lack of perceived benefit or family commitments. The remaining two dropouts occurred in the first two sessions due to program content and travelling abroad. Of the 32 absences among the adhered participants, eight were work-related, seven were family-related, six were due to seasonal illness, four due to fatigue, three due to holidays, one due to travel disruption, and one due to other commitments.

Adverse events unrelated to the active intervention

In the intervention arm, one participant reported fatigue before and during the intervention and another reported a fractured bone after intervention completion. None were related to the intervention. Five participants in the control arm reported adverse events (ovarian cancer diagnosis, cancer recurrence, bowel obstruction, fractured bone, and swollen ankle). One unrelated severe adverse event (death) occurred to a non-eligible participant randomized to the intervention arm. The direct cause of death was metastatic bronchial carcinoma. Other significant conditions leading to death were obstructive sleep apnea and obesity hypoventilation syndrome. The participant withdrew due to medical reasons before commencement of the group sessions and, thus, the death was unrelated to the intervention. No safety concerns or complaints were reported.

Control arm contamination

Nine control arm participants (37.5%) searched for information on diet or physical activity. Two of them spoke with their GP and one with their nurse. Internet sources of information included the WCRF website (one), CRUK website (one), NHS choices (three), Change4Life (one), and other (two). One participant signed up to aerobic/tai chi classes.

Two joined Slimming World; two weeks and one month before the final study follow-up, respectively, achieving 5% and 7.5% weight loss compared to their 8-week measurements.

BMJ Open

Recruitment, adherence, and retention of endometrial cancer survivors in a behavioural lifestyle programme: the Diet and Exercise in Uterine Cancer Survivors (DEUS) parallel randomised pilot trial

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Manuscript ID	bmjopen-2017-018015.R1
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Date Submitted by the Author:	12-Jul-2017
Complete List of Authors:	Koutoukidis, Dimitrios; University College London, Behavioural Science and Health; University College London, Women's Cancer Beeken, Rebecca; University College London, Behavioural Science and Health; University of Leeds, Institute of Health Sciences Manchanda, Ranjit; Barts Cancer Insitute, Queen Mary University of London, Centre for Experimental Cancer Medicine; University College London, Women's Cancer Michalopoulou, Moscho; University College London, Women's Cancer Burnell, Matthew; University College London, Women's Cancer Knobf, Tish; Yale University, Lanceley, Anne; University College London, Women's Cancer
Primary Subject Heading:	Obstetrics and gynaecology
Secondary Subject Heading:	Nutrition and metabolism
Keywords:	Endometrial cancer, survivorship, behaviour change, healthy eating, physical activity, intervention

Recruitment, adherence, and retention of endometrial cancer survivors in a behavioural lifestyle programme: the Diet and Exercise in Uterine Cancer Survivors (DEUS) parallel randomised pilot trial

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Abstract

Objective: Healthy eating and physical activity may help endometrial cancer survivors (ECS) improve their quality of life. However, most ECS do not meet the relevant guidelines. This pilot trial aimed to test the study feasibility procedures for a definitive trial of a behavioural lifestyle programme.

Design and setting: This 24-week parallel two-arm randomised pilot trial took place in two hospitals in London, UK (April 2015 - June 2016).

Participants: Sixty disease-free ECS within 3 years of diagnosis

Interventions: Participants were randomised using minimization to receive the intervention or care as usual. The “Shape-Up following cancer treatment” programme used self-monitoring, goal-setting, self-incentives, problem-solving, and group social support for 12 hours over 8 weeks to help survivors improve their eating and physical activity.

Outcome measures: The main outcome measures were recruitment, adherence, and retention rates. Further outcomes included barriers to participation and feedback on programme satisfaction.

Results: Of the 296 potentially eligible ECS, 20% (n=60) were randomly allocated to the active intervention (n=29) or control group (n=31). Three participants in each arm were deemed ineligible after randomisation and excluded from analysis. Twenty participants (77%; 95% CI: 61%, 93%) adhered to the intervention and provided generally favourable feedback. At 24 weeks, 25/26 (96%; 95% CI: 89%, 100%) intervention and 24/28 (86%; 95% CI: 73%, 99%) control participants completed their assessment. No intervention-related adverse events were reported. Among eligible survivors who declined study participation (n=83), inconvenience (78%; 95% CI: 69%, 87%) was the most common barrier.

Conclusions: The trial was feasible to deliver based on the a priori feasibility criteria. Enhancing recruitment and adherence in a definitive trial will require designs that promote convenience and consider ECS-reported barriers.

Trial Registration: ClinicalTrials.gov identifier: NCT02433080, 20 April 2015

Trial funding: University College London, St. Bartholomew's Hospital Nurses League, and NIHR University College London Hospitals Biomedical Research Centre

Keywords

Endometrial cancer, survivorship, behaviour change, healthy eating, physical activity, intervention

Strengths and limitations of this study

- This trial tested the feasibility of a standardised theory-based behavioural lifestyle programme for endometrial cancer survivors using a robust randomised parallel design.
- Barriers to participation were systematically assessed.
- The study aimed to minimise these barriers by recruiting survivors within the "teachable moment" period and capitalizing on the endorsement of the study from their clinicians.
- The small sample size and recruitment from London-based hospitals limit the generalisability of the outcomes.

Introduction

Endometrial cancer is the most common gynaecological cancer with about 455,000 incident cases worldwide in 2015. It affects mostly women in developed countries[1] and about 75% women will live for more than 10 years after diagnosis.[2] They are the cancer group with the highest comorbidity burden among survivors[3] and are most likely to die from cardiovascular disease.[4] Furthermore, the prevalence of obesity and suboptimal lifestyle behaviours is high, both of which are associated with lower health-related quality of life.[5] Although most survivors do not spontaneously adopt health-protective behaviours[6] post-diagnosis, they do report trying to make lifestyle changes. However they experience cancer-specific barriers, such as fatigue and bowel issues, and feel there is a lack of guidance.[7]

Behavioural lifestyle interventions improve patient-reported outcomes, such as health-related quality of life, in other cancer survivor groups.[8-10] Randomised controlled trials (RCTs) in endometrial cancer survivors have also shown that health behaviour change is feasible for these patients.[11 12] However, the programmes tested to date have been resource-intensive rendering their widespread dissemination challenging. There is, therefore, a need for effective lifestyle behaviour change interventions that can be adopted within the cancer care pathway. We have adapted an existing evidence-based lifestyle intervention,[13] which is already running within the health care system, to try and facilitate this process.[14] The intervention was adapted to the particular needs and preferences of endometrial cancer survivors, with patient input and utilizing the intervention mapping approach. A definitive RCT will indicate whether this intervention is effective in promoting long-term behaviour change and improving survivors' quality of life. This pilot study was conducted to test the feasibility of the planned RCT's procedures.

The primary objective of the pilot trial was therefore to calculate recruitment, adherence, and retention rates. Secondary outcomes included willingness of clinical staff to recruit

participants, potential adverse events, barriers to participation, reasons for attrition, and participants' study experience [15].

Methods

Study design and participants

The trial protocol has been published.[15] The DEUS (Diet and Exercise in Uterine Cancer Survivors) pilot trial was an eight-week, two-arm, parallel, controlled pilot trial with 1:1 randomisation comparing the use of the "Shape-Up following cancer treatment" programme to care as usual.

Women aged ≥18 years who had been diagnosed with endometrial cancer (ICD C54.1) within the previous 36 months were eligible to take part in the study. Women were excluded if (a) they were diagnosed with stage IVB cancer; (b) they were on active anti-cancer, and/or palliative treatment; (c) they had a second primary cancer; (d) they lacked mental capacity to decide to take part in the study and to participate in it; (e) they had severe depression; (f) they were unavailable for longitudinal follow-up assessments; (g) they had participated in a professionally delivered weight loss or exercise programme during the previous 6 months; (h) their performance score was 3-4[16] (i) or they were unable to understand spoken and written English.

At the 5th week of recruitment, the inclusion criterion "women willing to attend all sessions" was removed given the subjective nature of its interpretation and the exclusion criterion "women with secondary cancer" was added to ensure homogeneity.

Recruitment

Potential participants were recruited from the gynaecology outpatient clinics at University College London Hospitals (UCLH) and Barts Health. Interested and potentially eligible participants were introduced to the study by clinicians and researchers attending the clinics as previously described.[15]

The clinicians at UCLH also identified potential participants that had been treated there but followed up at local sites. Following GP's verification that the patients were alive, invitation letters signed by the consultant were sent to these women together with the participant information sheet, an opt-in form, a barriers to participation survey, and a business reply envelope.

Randomisation and blinding

Consented participants were randomised with a 1:1 allocation to receive either the intervention or usual care through minimization using age and BMI as stratified variables. The process has been previously described in detail.[15] The researcher assessing the 8-week outcomes (MM) was blinded to intervention allocation and participants were requested prior to the assessment not to disclose their allocation.

Shape-Up following cancer treatment intervention

In addition to usual care, intervention arm participants received the "Shape-Up following cancer treatment" manual and were assigned to groups of three to eight, although the initial plan was that they would be assigned in groups of eight. The allocation to groups was on a first-come first-served basis to avoid delays in delivering the intervention to randomised participants and aimed to match participant preferences for dates and times of the group meetings. The five groups met weekly for eight weeks at UCLH. Each session lasted approximately 90 minutes. The theory-based intervention has been previously described.[15] In brief, it included advice on healthy eating, physical activity, management of triggers of unhealthy behaviours, and behavioural relapse prevention. A dietitian (DAK) trained on the programme facilitated the group sessions following a standardized and scripted protocol. An extra trained provider (psychologist or dietitian) attended the meetings of the four groups to aid with facilitation but did not participate in the discussion. DAK was the only facilitator in the last group because of last minute cancellations. The participants in the fourth and final round of randomisation were split into two small intervention groups for convenience

purposes. A participant from the control group that had completed the study was invited to participate in the last group (final n=4 in group 5) to enhance the group experience but was not included in the analysis. There were no other modifications. The completed CONSORT[17] and TIDieR checklists[18] are available in Supplementary appendix S1 and S2, respectively.

Care as usual

Participants in the control arm were offered usual care. After the final follow-up, they received a booklet with healthy lifestyle advice for cancer survivors.[19]

Outcomes

Recruitment rates were calculated separately for each strategy and site. We adapted an existing framework of hierarchical recruitment barriers (availability by disease characteristics, eligibility, physician triage, trial discussion, interest, consent, and enrolment)[20] to describe the recruitment process. In contrast with the original framework, the category “interest” preceded that of “trial discussed” to fit the current recruitment process. Participants who were introduced to the study and decided not to enrol completed a 25-item investigator-designed survey[21] about barriers to participation. Eight UCLH clinicians were interviewed about their views on study recruitment using a semi-structured protocol by phone or face to face (Supplementary appendix S3).

Participants attended a 90-minute baseline site visit with a trained researcher (DAK) to complete their measurements and questionnaires. The visit was repeated at 8- and 24-weeks with MM and DAK, respectively. All intervention sessions were audiotaped. RJB attended one intervention session and one study assessment and scored them against a predefined checklist. Engaged intervention-arm participants completed and posted an 18-item programme evaluation questionnaire.[22] Only two follow-up qualitative interviews with intervention participants were performed at study completion, as the data from the open-ended feedback questionnaire were deemed sufficient.

Statistical and qualitative analysis

Despite the pilot nature of the study, a sample size of 32 participants per arm was estimated for examining recruitment, adherence, and retention rates. The study would be deemed feasible if the lower 95% confidence limits for recruitment, adherence, and retention rates were at least 15%, 60%, and 60%, respectively.[15]

Primary outcomes are reported in proportions with 95% confidence intervals (CIs). Descriptive statistics are reported for continuous variables. Categorical variables are summarized using frequencies and percentages. The interviews with clinicians lasted 10 minutes on average, were digitally recorded, transcribed verbatim by a professional company, and checked for accuracy. Given the structured interview and short replies, data were analysed with content analysis using NVivo version 10 (QSR International Pty Ltd, 2014) software. The open-ended questions were analysed using manifest content analysis[23] in Microsoft Office Excel 2011. This process involved determining the frequency of words and content in the text.

Results

Recruitment

Recruitment took place over a period of 27 and 18 weeks (April 2015 – December 2015) at UCLH and Barts Health, respectively (Figure S1, Supplementary appendix S3). The difference in recruitment period between sites was primarily explained by substantial delay of NHS Research and Development (R&D) management approval at Barts Health. Among the first 64 eligible participants approached, 20 consented to participate, leading to rejection of the null hypothesis that recruitment would be ≤15%. Therefore, recruitment continued for enrolling the projected sample of 64 participants but stopped after enrolling 60 participants due to resource constraints. Out of 296 potentially eligible participants, 20.3% (95% CI: 15.7, 24.9) enrolled in the study. Among screened participants, rates of consent were similar for

the face-to-face recruitment at the two recruitment sites but lower for the mail out (Table S1 and Table S2).

Reasons for non-participation were documented for 36.7% (n=83) of those who were potentially eligible but did not consent and 90.2% of those that were approached. Inconvenience to everyday life (78%) and transport to trial site (63%) were the main barriers to participation, with further barriers detailed in Table 1 and less frequent barriers in Table S3. The CONSORT flow diagram shows the progress through the trial stages (Figure 1).

Clinicians' views on recruitment

Clinicians were supportive of the study and did not have particular concerns about introducing the study to patients. They felt the study might be beneficial to patients, but they believed travelling and commitment would be the main barriers for recruitment.

They deemed the recruitment strategy highly effective, with potentially eligible patients being flagged prior to the clinic, researchers being present and reminding them about approaching patients, and through the existence of a separate space for study recruitment in the clinic. These strategies minimized additional clinician workload.

Clinicians did not anticipate adverse events from the intervention or changes in their relationship with the patients. The framing and content of such an intervention was also highlighted as a potential barrier to recruitment. In particular, approaching patients in a non-discriminatory way was deemed to enhance recruitment. Furthermore, framing of its content as a lifestyle programme was thought to be superior to a weight loss programme, strict diet regime, or educational programme.

Sample characteristics

Participant characteristics at baseline are shown in Table 2. Women were on average (±SD) 62.1 ± 8.3 years old, White (67%), married (53%), 1.2 ± 1.0 years from diagnosis, with a BMI

of 28.0 ± 6.3kg/m^2. They were diagnosed mostly with stage IA (49%), type 1 (82%) endometrial cancer.

Adherence

Out of 26 participants in the intervention arm, 21 (81%; 95% CI: 66%, 96%) engaged and 20 (77%; 95% CI: 61%, 93%) adhered to the intervention, based on our pre-determined criteria [15]. The lower confidence limit was above 60% indicating feasibility.

The percentage of participants who attended zero, five, six, seven, and eight (all) sessions was 15%, 8%, 12%, 35%, 15%, respectively. The mean overall attendance of sessions was 63% (95% CI: 49%, 77%). The mean attendance rates of those who engaged and those who adhered were 79% (95% CI: 70%, 88%) and 82% (95% CI: 74%, 89%), respectively. Reasons for not commencing the intervention (i.e. attendance of zero sessions) included inconvenience to everyday life (n=1), family commitments (n=1), lack of perceived benefit (n=1), or travel burden (n=1). The remaining two dropouts occurred in the first two sessions due to program content and travelling abroad. Absence from the group sessions among adhered participants were mostly of practical nature, with details available in Supplementary appendix S3.

Programme satisfaction

Eighteen participants randomised to the intervention group who adhered provided feedback for the programme. They scored the programme highly with 44% and 39% reporting that it met or exceeded their expectations, respectively. All aspects of the programme were scored highly (Table 3). Additionally, most participants ranked self-monitoring, setting SMART (specific, measureable, achievable, relevant, and time-specific) goals, and social support as either very or somewhat helpful in making dietary and physical activity changes (Table 4). In contrast, the responses for self-incentives were mixed with 28% of participants rating this technique as unhelpful.

A range of topics were regarded as most useful (Figure S2). Among them, most participants agreed that the sections about keeping an eye on portion sizes, food labelling, and internal triggers were the most useful. Others mentioned self-incentives, internal and external triggers, and getting a healthier balance of foods to be the least useful topics (Figure S3). For example, one participant mentioned:

> *I also did not understand the concept of the rewards - better health should be its own reward (Participant in group 4).*

Suggestions for additions to the programme were primarily focused on physical activity, such as provision of relevant DVDs, physical activity during the programme sessions, and diaries to report physical activity and sedentary behaviour in more detail. Most participants did not consider that topics should be eliminated from the programme. Similar feedback was provided for the booklet; most participants did not suggest changes while a few suggested design changes. Further suggestions included the addition of follow-up support and a preference for a larger group (mentioned by participants in smaller groups) to boost the peer-education component.

Peer support of the group, both the focus of the programme and their own interest in health promotion, the feeling of giving back to the care system, the facilitators, and the doctor's referral to the programme facilitated study participation. In contrast, most did not report factors discouraging them to participate but some mentioned inconvenience to everyday life, self-monitoring and identification as a cancer survivor.

Regarding the trial procedures, two participants mentioned their difficulty recalling and quantifying their diet and physical activity. Excellent fidelity to the protocol for both the group sessions (85%) and the assessments (100%) was demonstrated in the study auditing.

Retention

Retention rate was 92% (95% CI: 85%, 100%), with 24/28 (86%; 95% CI: 73%, 99%) and 25/26 (96%; 95% CI: 89%, 100%) eligible participants in the control and intervention arm completing all assessments, respectively (*P*=0.61 for difference between proportions). This indicated an absence of attrition bias and the rejection of the null hypothesis that retention rate would be less than 60%.

Adverse events and control arm contamination

No intervention-related adverse events or unintended consequences were reported. Adverse events unrelated to the intervention and reasons for control arm contamination are detailed in the Supplementary appendix S3.

Discussion

This is the first pilot study of a health behaviour change intervention in endometrial cancer survivors in the UK to demonstrate feasibility in terms of recruitment, adherence, and retention. The collaboration of the clinical and research team led to an efficient recruitment process. Participants rated the programme highly and provided rich feedback for refinement. Consistent with the literature[24] and the qualitative findings,[7] the DEUS pilot study aimed to minimize accrual barriers by enrolling survivors within the "teachable moment" period, capitalizing on the endorsement of the study from survivors' clinicians, utilizing a strong behaviour theory-based design, and ensuring standardized delivery of the intervention. These study strengths were also reflected in the reported factors associated with programme involvement. Furthermore, the frameworks for reporting barriers to participation[20 21] provided a comprehensive understanding of these barriers and can be a valuable resource to understand barriers in for future trials.[25] Limitations of the study include the small sample size, recruitment from only two London-based sites, generalizability of the recruited sample, as socio-demographic data from decliners were missing. The relatively low median BMI of participants compared to epidemiological studies[26] indicates healthy volunteer effect biases. The wide socio-economic and demographic differences of the population pools of the two

hospitals[27] and the similar recruitment rates at both sites were reassuring and suggest these factors should not impact recruitment and retention.

The focus of the study on healthy lifestyle changes rather than weight loss was postulated to increase uptake and acceptability of the programme.[7] The overall recruitment estimate was similar or somewhat higher than that in other lifestyle intervention trials, although differences in recruitment strategies, eligibility criteria, cancer site, programme length and intensity do not allow for direct comparisons. The group-based, six-month SUCCEED intervention had a 19% recruitment rate using mail-out.[12] A 12-week group-based physical activity intervention recruited 20% of the eligible endometrial cancer survivors through fliers and telephone recruitment.[28] Similar to DEUS, a more intensive lifestyle intervention in UK breast cancer survivors had a mail-out rate of 17%.[29] While removing the transport and time barriers would theoretically improve recruitment rates, USA home-based lifestyle interventions recruiting cancer survivors from registries have shown much smaller recruitment rates (5.7%) with women, younger, White survivors and those closer to their cancer diagnosis more likely to enrol.[30]

The observed adherence was lower compared with the weight loss SUCCEED intervention (84.1%) comprising of 16 group sessions[12] but similar to that of a group-based 12-week physical activity intervention.[28] While this might indicate that survivors are more committed in weight loss programmes compared to healthy lifestyle programmes, the main reported reasons regarding non-attendance in the current study were around practicalities and life commitments rather than disengagement with the programme. Sending a standardized e-mail to non-attendees about topics covered in the missed session and preparation for the next session helped maintain their engagement.

Having a specific research room and two committed researchers in clinic facilitated recruitment. Screening participants using electronic forms and implementing further pre-randomisation eligibility checks from medical notes could minimize randomisation of ineligible participants. The recruitment rate, while similar between the two sites, was lower in

the clinician-endorsed mail-out, indicating the higher effectiveness of the first approach that needs to be balanced with its higher resource requirements in larger trials. Practical reasons rendered intervention adherence acceptable but not optimal. The difficulty of trying to arrange a weekly group meeting with approximately eight people was evident, although a range of potential times was offered to participants and involved working around the logistics to find the most convenient date. Given the wide variability of participants' availability, simultaneous offers of a group on a weekday early evening or Saturday morning facilitated engagement in Groups 2 and 3. In future studies, larger groups will be possible by un-blinding investigators after enough participants are allocated to each trial arm to run two groups.

Opting for the group-based and face-to-face design aimed to meet survivors' preferences[7] but was in contrast with some previous studies reporting proximity as a particular barrier in this population.[24] The lack of dropouts after the second group session indicated the overall acceptability of the intervention and the favourable rating of most programme aspects provides confidence that only minor content adaptations are needed before testing the study in a large trial. As multiple facilitators will deliver the intervention in a pragmatic setting, future large-scale trials should also measure differences in intervention delivery between various facilitators. Inconvenience and transport were the main barriers to accrual in the current study. Increasing reach might be more feasible with blended designs of group meetings and remote intervention delivery, especially as home-based interventions have typically experienced much lower recruitment rates compared with group-based interventions. In the current programme, even those who adhered mentioned convenience reasons as discouraging participation but the peer support as encouraging. This might suggest delivering some sessions in person and others remotely, potentially through web or mobile technology. A pilot weight loss study with endometrial and breast cancer survivors delivered via a mobile application has shown promising results in a pre-post design.[31] However, further research on mobile applications for weight management is needed, as

most lack evidence-based behaviour change techniques, involvement of health care professionals and scientific evaluation.[32]

In conclusion, this self-help lifestyle intervention trial was feasible in terms of recruitment, adherence, and retention. Scaling the trial will require close monitoring of recruitment and attempts should be made to reduce the burden on participants. Further qualitative work could inform a blended in-person and remote design to enhance adherence while retaining the valued peer support. This should be considered before proceeding to a definitive trial. Overall, the lessons learnt from this pilot should inform the design of future studies in this area.

Full protocol availability

The full protocol of the study has been previously published[15] and it can also be found in the Supplementary Appendix S4.

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Competing interests' statement

DAK and RJB are volunteers for the charity Weight Concern, which developed the original Shape-Up programme for the general population. All other authors have no conflicts of interest to declare.

Contribution to Authorship

The authors' contributions were as follows. Anne Lanceley (AL) and M. Tish Knobf (MTK) conceived the study and were the grant holders. AL and Ranjit Manchanda (RM) were the site investigators for University College London Hospitals and Barts Health, respectively. Dimitrios A. Koutoukidis (DAK), AL, Rebecca J Beeken (RJB) and MTK initiated the study design, and RM helped with protocol development and implementation. DAK and Moscho Michalopoulou (MM) recruited the study participants. RJB was responsible for randomisation and auditing. DAK was the trial manager, ran the group sessions, and conducted the baseline and 24-week follow-up assessments. MM conducted the 8-week follow-up assessments. Matthew Burnell (MB) provided the statistical support, and DAK conducted the statistical analysis. DAK drafted the manuscript, which was amended following comments

from all other authors. All authors read and approved the submitted manuscript. All listed authors meet the criteria for authorship and no individual meeting these criteria has been omitted.

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Ethical approval

The study protocol and documents have been reviewed and approved by the relevant sponsor and National Research Ethics Service Committee London - City Road and Hampstead (Reference: 15/LO/0154).

Availability of data and materials

The materials and datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

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Table 1 Percentage of each barrier to participation with standard error (SE) among eligible survivors who declined participation (n=83)

Table 2 DEUS pilot trial baseline participant characteristics

Table 3 Percentage programme satisfaction (n=18)

Table 4 Helpfulness of the main behaviour change techniques for dietary and physical activity changes (n=18)

Figure 1 CONSORT diagram of the trial with framework on barriers to participation in the exclusion box

Table 1 Percentage of each barrier to participation with standard error (SE) among eligible survivors who declined participation (n=83)

Barrier to participation	% (SE)
Inconvenient to everyday life	78.3 (4.5)
Transport or distance to trial site	62.7 (5.3)
Feelings of uncertainty	15.7 (4.0)
Lack of family support	15.7 (4.0)
The design of the study is too difficult to understand or too binding	15.7 (4.0)
Trial or treatment has no benefits	15.7 (4.0)
Other: feeling physically unwell	14.5 (3.9)
Preference for other treatment (e.g. Weight Watchers)	13.3 (3.7)
Increased anxiety	12.1 (3.6)
Quality of life might be reduced	12.1 (3.6)
Trial or treatment does not offer best option	12.1 (3.6)
Trial setting	9.6 (3.2)
Uncomfortable with experimentation	9.6 (3.2)
Do not want to lose control of decision-making	7.2 (2.8)
General unease with research process	7.2 (2.8)
Other: Does not like to discuss in groups	6.0 (2.6)
Belief that doctor should make decisions	4.8 (2.4)
Dislike idea of randomisation	4.8 (2.4)
Fear or mistrust of research or researchers	4.8 (2.4)
Other: Family health issues	4.8 (2.4)
Assignment to control group	3.6 (2.1)
Potential side-effects	3.6 (2.1)
Trials not appropriate for serious disease	2.4 (1.7)

Table 2 DEUS pilot trial baseline participant characteristics

Characteristic	Shape-Up (n=25)	Care as usual (n=24)	Total
Age, mean (SD)	62.6 (9.0)	61.5 (7.7)	62.1 (8.3)
Race			
White	17 (68)	16 (67)	33 (67)
Asian	4 (16)	5 (21)	9 (18)
Other	4 (16)	3 (12)	7 (14)
Living arrangement			
Own outright / mortgage	17 (68)	15 (63)	32 (65)
Rent	8 (30)	9 (38)	17 (35)
Marital status			
Married / Living with partner / Civil partnership	12 (48)	15 (63)	27 (55)
Separated / Divorced	7 (28)	3 (12)	10 (20)
Widowed / Single	6 (24)	6 (25)	12 (24)
Education			
Degree / Higher degree / Higher education below degree level	11 (44)	12 (50)	23 (47)
Secondary education	11 (44)	10 (42)	21 (42)
No formal qualifications	3 (12)	2 (8)	5 (10)
Employment			
Full time / self-employed	9 (36)	11 (46)	20 (41)
Part time / Other	6 (24)	2 (8)	8 (16)
Retired	10 (40)	11 (46)	21 (43)
Smoking			
Current	2 (8)	2 (8)	4 (8)
Former	4 (16)	5 (21)	9 (18)
IMD (quintile)			
1 – most deprived	5 (20)	4 (17)	9 (18)
2	9 (36)	6 (25)	15 (31)
3	4 (16)	7 (29)	11 (22)
4	3 (12)	3 (13)	6 (12)
5 – least deprived	4 (16)	4 (17)	8 (16)
Time since diagnosis in months, mean (SD)	19.2 (11.2)	21.4 (11.3)	20.3 (11.2)
Time since completion of	17.1 (11.2)	18.5 (11.7)	17.8 (11.3)

Characteristic	Shape-Up (n=25)	Care as usual (n=24)	Total
primary treatment in months, mean (SD)			
Surgery	25 (100)	24 (100)	49 (100)
Chemotherapy treatment	3 (12)	5 (21)	8 (16)
External beam radiotherapy	6 (24)	12 (50)	18 (37)
Brachytherapy	11 (44)	13 (54)	24 (49)
Cancer stage			
IA	11 (44)	13 (54)	24 (49)
IB	11 (44)	6 (25)	17 (35)
II	2 (8)	3 (13)	5 (10)
IIIA	1 (4)	2 (8)	3 (6)
Cancer grade			
1	6 (24)	7 (29)	13 (27)
2	13 (52)	9 (38)	22 (45)
3	6 (24)	8 (33)	14 (29)
Histology			
Endometrioid adenocarcinoma	21 (84)	19 (79)	40 (82)
Serous carcinoma	1 (4)	3 (13)	4 (8)
Mixed carcinoma	1 (4)	0 (0)	1 (2)
Serous surface papillary carcinoma	0 (0)	1 (4)	1 (2)
Carcinosarcoma	2 (8)	0 (0)	2 (4)
Adenosquamous carcinoma	0 (0)	1 (4)	1 (2)
Histological type			
Type I	21 (84)	19 (79)	40 (82)
Type II	4 (16)	5 (21)	9 (18)
Charlson Comorbidity Index			
2	18 (75)	21 (84)	39 (80)
3	6 (25)	4 (16)	10 (20)
WHO performance status			
0	20 (83)	20 (80)	40 (82)
1	3 (13)	5 (20)	8 (16)
2	1 (4)	0 (0)	1 (2)
Selected comorbidities			
Diabetes	3 (12)	4 (17)	7 (14)

Characteristic	Shape-Up (n=25)	Care as usual (n=24)	Total
Hypertension	6 (24)	7 (29)	13 (27)
Dyslipidaemia	3 (12)	3 (13)	6 (12)
Asthma	1 (4)	2 (8)	3 (6)
Osteoporosis	2 (8)	4 (17)	6 (12)
Weight, mean kg (SD)	69.8 (14.8)	71.9 (15.2)	70.9 (14.9)
BMI, mean kg/m^2 (SD)	27.3 (6.5)	28.8 (6.1)	28.0 (6.3)
BMI, median kg/m^2 (IQR)	26.2 (24.3)	26.9 (8.6)	26.8 (6l.4)
% Fat, mean (SD)	35.3 (7.7)	36.9 (6.3)	36.1 (7.0)

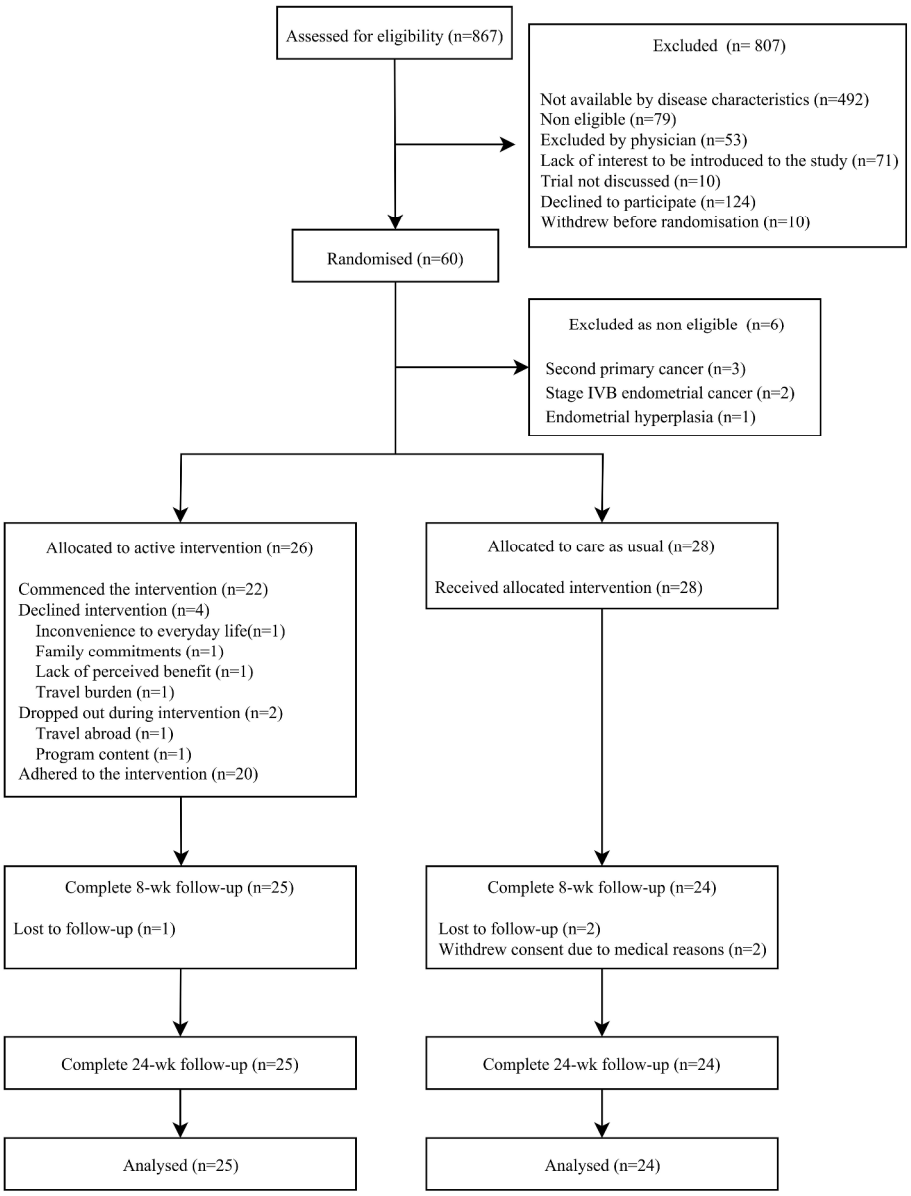
Percentages might not add to 100 due to rounding
IMD: Index of multiple deprivation, IQR: Interquartile range
Data are presented as n (%) unless otherwise specified
Body composition data for usual care n=23

Table 3 Percentage program satisfaction (n=18)

How much did you like the…	Dislike	Neither like or dislike	Like
Organisation of the sessions	-	-	100%
Length of the programme	-	11%	89%
Dates of the programme	6%	17%	78%
Length of the sessions	-	-	100%
Training location	-	-	100%
Group format	-	-	100%
Peer-education format	-	6%	94%
Group discussion	-	-	100%
Cultural sensitivity of the facilitator	-	-	100%
Facilitator's knowledge of materials	-	6%	94%
Facilitator's preparedness	-	-	100%
Time used effectively by facilitator	-	-	100%
Attractiveness of the booklet	6%	17%	78%
Overall design of the booklet	-	17%	84%
Wording of the booklet	-	22%	77%
Volume of the booklet	17%	22%	61%
Durability of the booklet	-	17%	83%

Table 4 Helpfulness of the main behaviour change techniques for dietary and physical activity changes (n=18)

	Unhelpful	Neither helpful or unhelpful	Helpful
When trying to make diet changes, how helpful did you find monitoring yourself using diaries?	-	-	100%
When trying to make physical activity changes, how helpful did you find monitoring yourself using diaries?	6%	6%	88%
When trying to make diet changes, how helpful did you find putting SMART goals?	-	11%	88%
When trying to make physical activity changes, how helpful did you find putting SMART goals?	-	11%	89%
When trying to make diet changes, how helpful did you find rewarding yourself?	28%	33%	39%
When trying to make physical activity changes, how helpful did you find rewarding yourself?	28%	39%	34%
When trying to make diet changes, how helpful did you find the peer-education nature of the sessions?	-	6%	95%
When trying to make physical activity changes, how helpful did you find the peer-education nature of the sessions?	-	17%	83%



CONSORT diagram of the trial with framework on barriers to participation in the exclusion box

454x593mm (300 x 300 DPI)

CONSORT checklist of information to include when reporting a pilot trial*

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
Title and abstract			
1a	Identification as a randomised trial in the title	Identification as a pilot or feasibility randomised trial in the title	1
1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives:			
2a	Scientific background and explanation of rationale	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	4
2b	Specific objectives or hypotheses	Specific objectives or research questions for pilot trial	4-5
Methods			
Trial design:			
3a	Description of trial design (such as parallel, factorial) including allocation ratio	Description of pilot trial design (such as parallel, factorial) including allocation ratio	5
3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	5
Participants:			
4a	Eligibility criteria for participants		5
4b	Settings and locations where the data were collected		5
4c		How participants were identified and consented	5-6 and protocol paper
Interventions:			
5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered		6-7 and protocol paper
Outcomes:			
6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	7 and protocol paper
6b	Any changes to trial outcomes after the trial commenced, with reasons	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	5
6c		If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	n/a

Sample size:			
7a	How sample size was determined	Rationale for numbers in the pilot trial	Protocol paper
7b	When applicable, explanation of any interim analyses and stopping guidelines		n/a
Randomisation:			
Sequence generation:			
8a	Method used to generate the random allocation sequence		6 and protocol paperr
8b	Type of randomisation; details of any restriction (such as blocking and block size)	Type of randomisation(s); details of any restriction (such as blocking and block size)	6 and protocol paper
Allocation concealment mechanism:			
9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned		Protocol paper
Implementation:			
10	Who generated the random allocation sequence, enrolled participants, and assigned participants to interventions		Protocol paper
Blinding:			
11a	If done, who was blinded after assignment to interventions (eg, participants, care providers, those assessing outcomes) and how		6 and protocol paper
11b	If relevant, description of the similarity of interventions		
Analytical methods:			
12a	Statistical methods used to compare groups for primary and secondary outcomes	Methods used to address each pilot trial objective whether qualitative or quantitative	7-8
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Not applicable	n/a
Results			
Participant flow (a diagram is strongly recommended):			
13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	8-9, Figure 2 Table S1
13b	For each group, losses and exclusions after randomisation, together with reasons		Figure 2
Recruitment:			

14a	Dates defining the periods of recruitment and follow-up		8
14b	Why the trial ended or was stopped	Why the pilot trial ended or was stopped	8
Baseline data:			
15	A table showing baseline demographic and clinical characteristics for each group		Table 1
Numbers analysed:			
16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	8-12
Outcomes and estimation:			
17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	8-12
17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable	n/a
Ancillary analyses:			
18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	Results of any other analyses performed that could be used to inform the future definitive trial	n/a
Harms:			
19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)		12 and Suppl. material
19a		If relevant, other important unintended consequences	n/a
Discussion			
Limitations:			
20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	12, 14
Generalisability:			
21	Generalisability (external validity, applicability) of the trial findings	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	12-13
Interpretation:			
22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	12-15
22a		Implications for progression from pilot to future definitive trial, including any proposed amendments	
Other information			

Registration:		
23	Registration number and name of trial registry	Registration number for pilot trial and name of trial registry
Protocol:		
24	Where the full trial protocol can be accessed, if available	Where the pilot trial protocol can be accessed, if available
Funding:		
25	Sources of funding and other support (such as supply of drugs), role of funders	
26		Ethical approval or approval by research review committee, confirmed with reference number

*Here a pilot trial means any randomised study conducted in preparation for a future definitive RCT, where the main objective of the pilot trial is to assess feasibility.

TIDieR Template for Intervention Description and Replication

^^The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (section)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	Abstract	_____
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	Shape-Up following cancer treatment intervention	Protocol paper (see below for reference)_____
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	Shape-Up following cancer treatment intervention	Protocol paper_____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	Shape-Up following cancer treatment intervention	Protocol paper_____
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	Shape-Up following cancer treatment	Protocol paper_____

		intervention	
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Shape-Up following cancer treatment intervention	_____
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	Shape-Up following cancer treatment intervention	_____
	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Shape-Up following cancer treatment intervention	Protocol paper_____
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	Shape-Up following cancer treatment intervention	Protocol paper_____
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	Shape-Up following cancer treatment intervention	_____

	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Outcomes	Protocol paper_____
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Program satisfaction	_____

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

Protocol paper: D.A. Koutoukidis, R.J. Beeken, R. Manchanda, M. Burnell, M.T. Knobf, A. Lanceley, Diet and exercise in uterine cancer survivors (DEUS pilot) - piloting a healthy eating and physical activity program: study protocol for a randomized controlled trial. Trials, 2016. 17(1): p. 130. 10.1186/s13063-016-1260-1.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

Supplementary appendix (S3)

Recruitment, adherence, and retention of endometrial cancer survivors in a behavioral lifestyle program: the Diet and Exercise in Uterine Cancer Survivors (DEUS) parallel randomized pilot trial

Dimitrios A. Koutoukidis, Rebecca J. Beeken, Ranjit Manchanda, Moscho Michalopoulou, Matthew Burnell, M. Tish Knobf, Anne Lanceley

Interview protocol with clinicians

1. What are your views on the trial?
    a. Prompt: effects on clinical practice
    b. Prompt: Benefits to participants
2. What are your views on recruiting participants for the trial?
3. What can make recruitment more difficult?
    a. Prompt: Potential harm to patients
    b. Prompt: Perceived patient barriers
4. What can make recruitment easier?
    a. Prompt: Individual benefits to clinicians
5. Is there anything that can make you think twice about recruiting eligible participants?
6. How can recruitment for this trial affect your relationship with your patient?

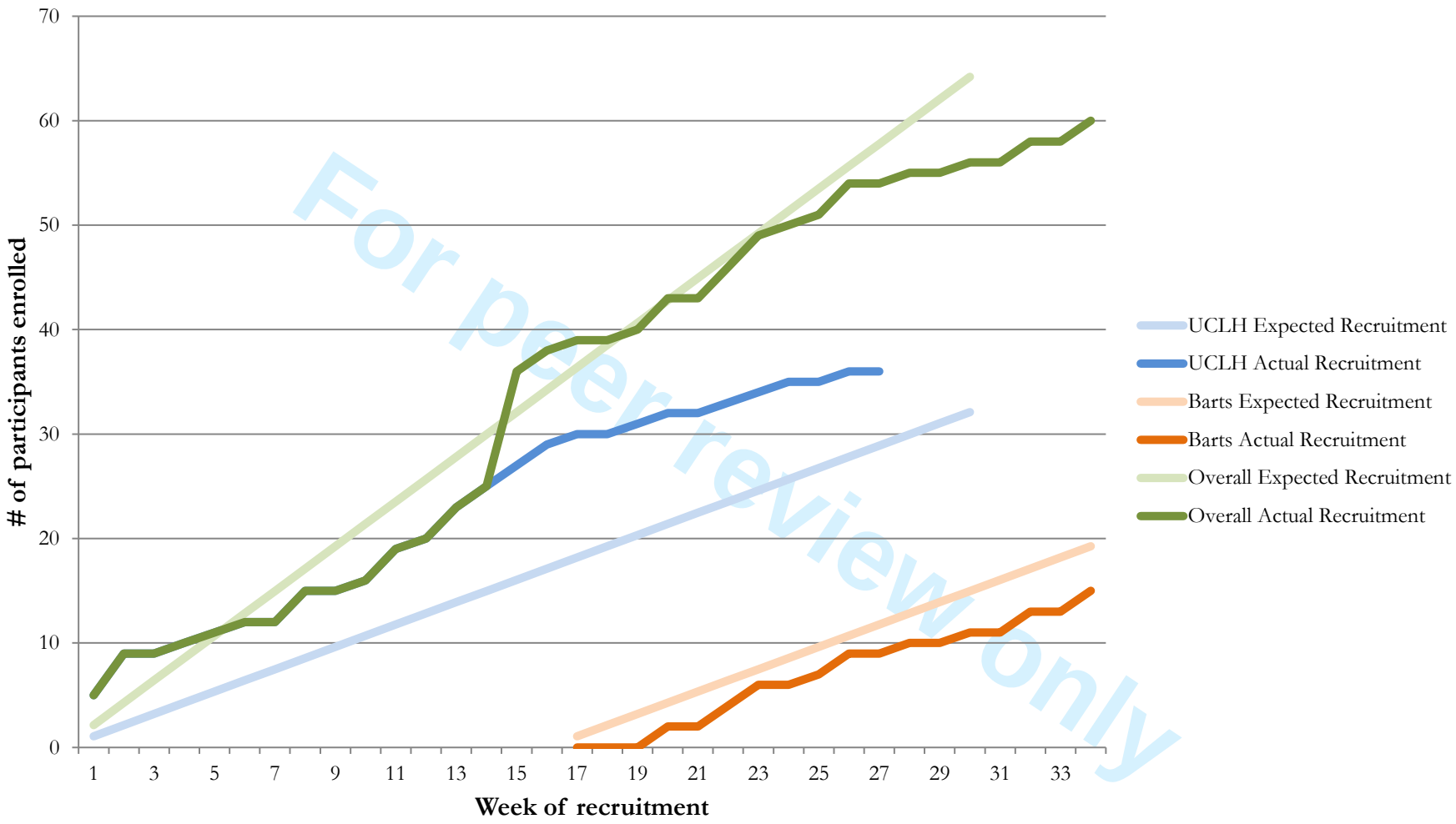


Figure S1 Projected and actual recruitment by site. The sharp spike in week 13 in overall recruitment indicated the recruited participants through mail out.

Table S1 Number of screened participants at each stage of the recruitment process

	UCLH	Barts	Hospitals combined	Mai-out	Total
1. Women in gynecologic oncology clinic	**2305**	**1047**	**3352**	**294**	**3646**
Other cancer site - not endometrial cancer	1638	828	2466	36	2502
Stage IVB (metastatic) endometrial cancer	11	7	18	14	32
Active anti-cancer, and/or palliative treatment	164	47	211	3	214
Endometrial Diagnosed >3years	67	49	116	69	185
Second primary cancer	34	8	42	2	44
Duplicates	168	3	171	106	277
2. Available for trial by disease characteristics	**223**	**88**	**311**	**64**	**375**
Not able to understand spoken and written English	23	13	36	1	37
Lack of mental capacity	3	2	5	-	5
Severe depression	2	-	2	-	2
WHO performance score 3-4	7	3	10	5	15
Unavailable for longitudinal follow-up assessments	4	3	7	2	9
Participated in a professionally delivered weight loss or exercise program during the previous 6 months	8	2	10	1	11
3. Eligible for participation	**176**	**65**	**241**	**55**	**296**
Did not attend clinic	23	13	36	-	36
Too distressed	5	-	5	-	5
Clinician did not introduce her to the study because of the long wait	1	-	1	-	1
Clinician did not introduce her due to confusion about eligibility criteria	-	2	2	-	2
Clinician did not introduce her because she had vision difficulties	1	-	1	-	1
Clinician did not introduce her because she was due for a knee operation	1	-	1	-	1

	UCLH	Barts	Hospitals combined	Mai-out	Total
Discussed with clinician and decide not to take part due to travel	2	-	2	-	2
Not approached by clinical team - medical notes missing / no pink leaflet	1	-	1	-	1
Lost her in clinic - clinician forgot to mention study	1	-	1	-	1
Not introduced to the study because researcher not in clinic	1	1	2	-	2
Pregnant	-	1	1	-	1
4. Physician Triage & introduced to the study	**140**	**48**	**188**	**55**	**243**
Not interested to hear about study	23	9	32	-	32
Long wait / too busy to talk about study	2	-	2	-	2
5. Participants interested	**115**	**39**	**154**	**18**	**172**
Lost in clinic - talking to other eligible participants	1	0	1		
6. Trial discussed	**114**	**39**	**153**	**9**	**162**
Decided not to take part and completed barriers survey	49	13	62	9	71
Decided not to take part, gave reasons, but did not complete barriers survey	6	6	12	-	12
Decided not to take part without giving reasons	1	2	3	-	3
Could not be reached back	11	3	14	-	14
Excluded due to cancer recurrence	1	0	1	-	1
7. Participant consented	**46**	**15**	**61**	**9**	**70**
Dropped out due to family reasons	2	-	2	-	2
Dropped out due to feel of no benefit	1	-	1	-	1
Dropped out due to inconvenience to everyday life	3	1	4	-	4
Dropped out due to health reasons	1	1	2	-	2
Not eligible - second primary cancer	1	-	1	-	1
8. Participant enrolled (randomized)	**38**	**13**	**51**	**9**	**60**

Table S2 Proportions (95% CIs of consented and enrolled participants by recruitment site)

	UCLH	Barts Health	Both hospitals	Mail-out	Total
Consented participants					
% Of eligible	26.1 (19.6, 32.6)	23.1 (12.8, 33.3)	25.3 (19.8 30.8)	16.4 (6.6, 26.1)	23.6 (18.8, 28.5)
% Of physician triage	32.9 (25.9, 39.8)	31.3 (20.0, 42.5)	32.4 (26.5, 38.4)	-	-
% Of interested	40.0 (32.8, 47.2)	38.5 (26.6, 50.3)	39.6 (33.4, 45.8)	-	-
Enrolled participants					
% Of eligible	21.6 (15.5, 27.7)	20.0 (10.3, 29.7)	21.2 (16.0, 26.3)	16.4 (6.6, 26.1)	20.3 (15.7, 24.9)
% Of physician triage	27.1 (20.6, 33.7)	27.1 (16.3, 37.9)	27.1 (21.5, 32.7)	-	-
% Of interested	33.0 (26.1, 40.0)	33.3 (21.9, 44.8)	33.1 (27.2, 39.1)	-	-
% Of consented	82.6 (77.0, 88.2)	86.7 (78.4, 94.9)	83.6 (78.9, 88.3)	100	85.7 (81.7, 89.7)

Table S3 Less frequent barriers to participation (percentage with standard error (SE)) among eligible survivors who declined participation (n=83)

Barrier	% (SE)	Barrier	% (SE)
Concerns over costs or health insurance	1.2% (1.2)	Other: Life unknown at the moment	1.2% (1.2)
Feeling coerced to join	1.2% (1.2)	Other: Lost her sister who was participating in another trial	1.2% (1.2)
Other: Bad weather for travelling	1.2% (1.2)	Other: Medical research is limited	1.2% (1.2)
Other: Being a full-time carer	1.2% (1.2)	Other: Mentally not ready	1.2% (1.2)
Other: Does not want to follow a diet plan	1.2% (1.2)	Other: Old age	1.2% (1.2)
Other: Length of study	1.2% (1.2)	Other: Wants to forget cancer	1.2% (1.2)
Physicians' attitude towards trial	1.2% (1.2)	Other: Wants a sense of normality in the following months	1.2% (1.2)

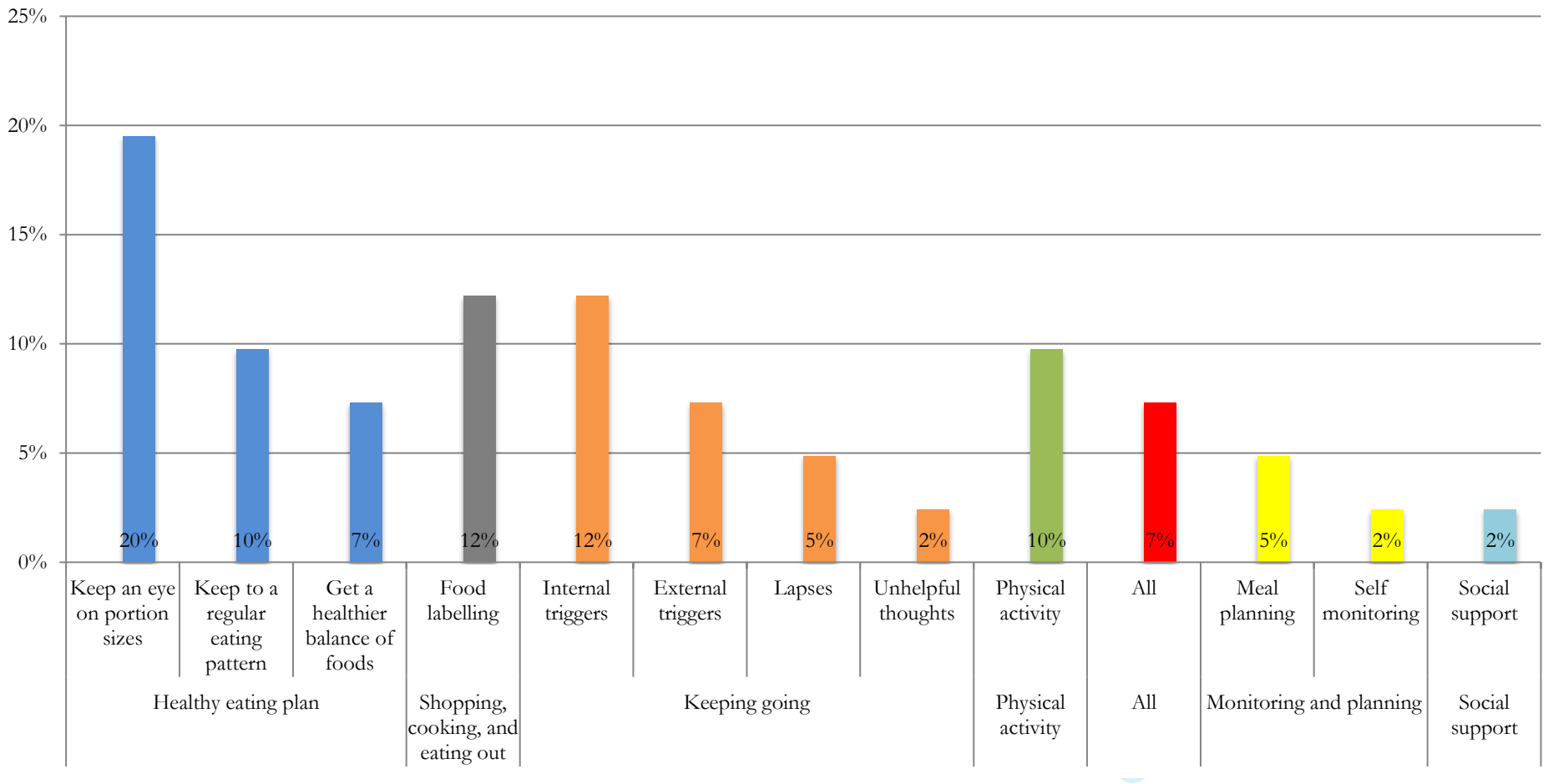


Figure S2 Percentage responses to the question "Which topic of the programme did you find the most useful?" by topic and programme section (in colour)

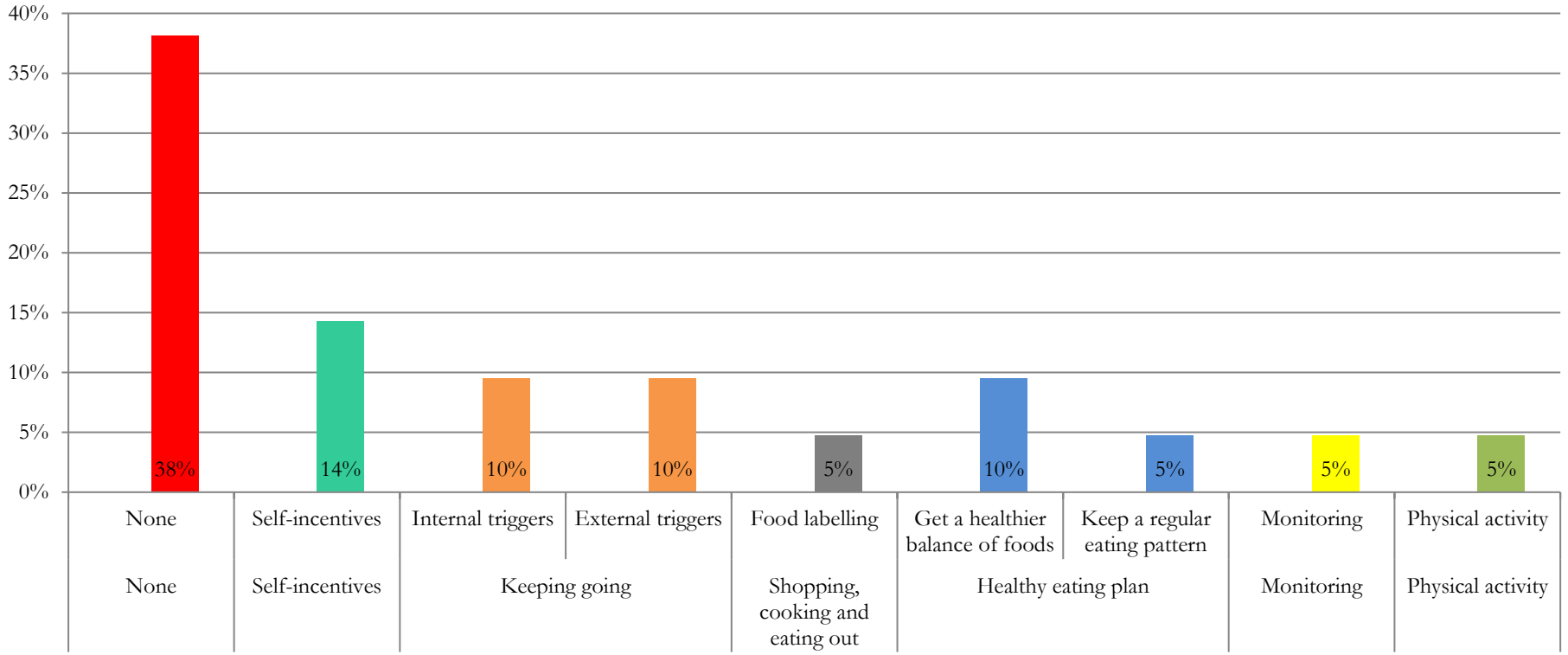


Figure S3 Percentage responses to the question "Which topic of the programme did you find the least useful?" by topic and programme section (in colour)

Reasons for non-adherence to the intervention

Of the 32 absences among the adhered participants, eight were work-related, seven were family-related, six were due to seasonal illness, four due to fatigue, three due to holidays, one due to travel disruption, and one due to other commitments.

Adverse events unrelated to the active intervention

In the intervention arm, one participant reported fatigue before and during the intervention and another reported a fractured bone after intervention completion. None were related to the intervention. Five participants in the control arm reported adverse events (ovarian cancer diagnosis, cancer recurrence, bowel obstruction, fractured bone, and swollen ankle). One unrelated severe adverse event (death) occurred to a non-eligible participant randomized to the intervention arm. The direct cause of death was metastatic bronchial carcinoma. Other significant conditions leading to death were obstructive sleep apnea and obesity hypoventilation syndrome. The participant withdrew due to medical reasons before commencement of the group sessions and, thus, the death was unrelated to the intervention. No safety concerns or complaints were reported.

Control arm contamination

Nine control arm participants (37.5%) searched for information on diet or physical activity. Two of them spoke with their GP and one with their nurse. Internet sources of information included the WCRF website (one), CRUK website (one), NHS choices (three), Change4Life (one), and other (two). One participant signed up to aerobic/tai chi classes. Two joined Slimming World; two weeks and one month before the final study follow-up, respectively, achieving 5% and 7.5% weight loss compared to their 8-week measurements.