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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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Manuscripts

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3 1 **Recruitment, adherence, and retention of endometrial cancer survivors in a**  
4 **behavioural lifestyle programme: the Diet and Exercise in Uterine Cancer Survivors**  
5 2  
6 **(DEUS) parallel randomised pilot trial**  
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1  
2  
3 24 **Abstract**  
4

5 25 Objective: Healthy eating and physical activity may help endometrial cancer survivors (ECS)  
6  
7 26 improve their quality of life. However, most ECS do not meet the relevant guidelines. This  
8  
9 27 pilot trial aimed to test the study feasibility procedures for a definitive trial of a behavioural  
10  
11 28 lifestyle programme.

12  
13  
14 29 Design and setting: This 24-week parallel two-arm randomised pilot trial took place in two  
15  
16 30 hospitals in London, UK (April 2015 - June 2016).

17  
18  
19 31 Participants: Sixty disease-free ECS within 3 years of diagnosis

20  
21  
22 32 Interventions: Participants were randomised using minimization to receive the intervention or  
23  
24 33 care as usual. The "Shape-Up following cancer treatment" programme used self-monitoring,  
25  
26 34 goal-setting, self-incentives, problem-solving, and group social support for 12 hours over 8  
27  
28 35 weeks to help survivors improve their eating and physical activity.

29  
30  
31 36 Outcome measures: The main outcome measures were recruitment, adherence, and  
32  
33 37 retention rates. Further outcomes included barriers to participation and feedback on  
34  
35 38 programme satisfaction.

36  
37 39 Results: Of the 296 potentially eligible ECS, 20% (n=60) were randomly allocated to the  
38  
39 40 active intervention (n=29) or control group (n=31). Three participants in each arm were  
40  
41 41 deemed ineligible after randomisation and excluded from analysis. Twenty participants  
42  
43 42 (77%; 95% CI: 61%-93%) adhered to the intervention and provided generally favourable  
44  
45 43 feedback. At 24 weeks, 25/26 (96%; 95% CI: 89%-100%) intervention and 24/28 (86%; 95%  
46  
47 44 CI: 73%-99%) control participants completed their assessment. No intervention-related  
48  
49 45 adverse events were reported. Among eligible survivors who declined study participation  
50  
51 46 (n=83), inconvenience (78%; 95% CI: 69%-87%) was the most common barrier.

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3 47 Conclusions: The trial was feasible to deliver based on the a priori feasibility criteria.  
4  
5 48 Enhancing recruitment and adherence in a definitive trial will require designs that promote  
6  
7 49 convenience and consider ECS-reported barriers.  
8

9  
10 50 Trial Registration: ClinicalTrials.gov identifier: NCT02433080, 20 April 2015  
11

12 51 Trial funding: University College London, St. Bartholomew's Hospital Nurses League, and  
13  
14 52 NIHR University College London Hospitals Biomedical Research Centre  
15  
16

17 53 **Keywords**  
18

19  
20 54 Endometrial cancer, survivorship, behaviour change, healthy eating, physical activity,  
21  
22 55 intervention  
23

24 56 **Strengths and limitations of this study**  
25

- 26  
27 57 • This trial tested the feasibility of a standardised theory-based behavioural lifestyle  
28  
29 58 programme for endometrial cancer survivors using a robust randomised parallel  
30  
31 59 design.  
32  
33 60 • Barriers to participation were systematically assessed.  
34  
35 61 • The study aimed to minimise these barriers by recruiting survivors within the  
36  
37 62 “teachable moment” period and capitalizing on the endorsement of the study from  
38  
39 63 their clinicians.  
40  
41 64 • The small sample size and recruitment from London-based hospitals limit the  
42  
43 65 generalisability of the outcomes.  
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## 66 Introduction

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

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

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

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2  
3 91 participants, potential adverse events, barriers to participation, reasons for attrition, and  
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5 92 participants' study experience <sup>15</sup>.  
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7

## 8 93 **Methods**

### 9 10 11 94 **Study design and participants**

12  
13  
14 95 The trial protocol has been published.<sup>15</sup> The DEUS (Diet and Exercise in Uterine Cancer  
15  
16 96 Survivors) pilot trial was an eight-week, two-arm, parallel, controlled pilot trial with 1:1  
17  
18 97 randomisation comparing the use of the "Shape-Up following cancer treatment" programme  
19  
20 98 to care as usual.

21  
22  
23 99 Women aged ≥18 years who had been diagnosed with endometrial cancer (ICD C54.1)  
24  
25 100 within the previous 36 months were eligible to take part in the study. Women were excluded  
26  
27 101 if (a) they were diagnosed with stage IVB cancer; (b) they were on active anti-cancer, and/or  
28  
29 102 palliative treatment; (c) they had a second primary cancer; (d) they lacked mental capacity to  
30  
31 103 decide to take part in the study and to participate in it; (e) they had severe depression; (f)  
32  
33 104 they were unavailable for longitudinal follow-up assessments; (g) they had participated in a  
34  
35 105 professionally delivered weight loss or exercise programme during the previous 6 months;  
36  
37 106 (h) their performance score was 3-4<sup>16</sup> (i) or they were unable to understand spoken and  
38  
39 107 written English.

40  
41  
42 108 At the 5<sup>th</sup> week of recruitment, the inclusion criterion "women willing to attend all sessions"  
43  
44 109 was removed given the subjective nature of its interpretation and the exclusion criterion  
45  
46 110 "women with secondary cancer" was added to ensure homogeneity.  
47

### 48 49 111 **Recruitment**

50  
51  
52 112 Potential participants were recruited from the gynaecology outpatient clinics at University  
53  
54 113 College London Hospitals (UCLH) and Barts Health. Interested and potentially eligible  
55  
56 114 participants were introduced to the study by clinicians and researchers attending the clinics  
57  
58 115 as previously described.<sup>15</sup>  
59  
60

1  
2  
3 116 The clinicians at UCLH also identified potential participants that had been treated there but  
4  
5 117 followed up at local sites. Following GP's verification that the patients were alive, invitation  
6  
7 118 letters signed by the consultant were sent to these women together with the participant  
8  
9 119 information sheet, an opt-in form, a barriers to participation survey, and a business reply  
10  
11 120 envelope.

### 14 121 **Randomisation and blinding**

16  
17 122 Consented participants were randomised with a 1:1 allocation to receive either the  
18  
19 123 intervention or usual care through minimization using age and BMI as stratified variables.  
20  
21 124 The process has been previously described in detail.<sup>15</sup> The researcher assessing the 8-week  
22  
23 125 outcomes (MM) was blinded to intervention allocation and participants were requested prior  
24  
25 126 to the assessment not to disclose their allocation.

### 28 127 **Shape-Up following cancer treatment intervention**

30  
31 128 In addition to usual care, intervention arm participants received the "Shape-Up following  
32  
33 129 cancer treatment" manual and were assigned to groups of three to eight, although the initial  
34  
35 130 plan was that they would be assigned in groups of eight. The allocation to groups was on a  
36  
37 131 first-come first-served basis to avoid delays in delivering the intervention to randomised  
38  
39 132 participants and aimed to match participant preferences for dates and times of the group  
40  
41 133 meetings. The five groups met weekly for eight weeks at UCLH. Each session lasted  
42  
43 134 approximately 90 minutes. The theory-based intervention has been previously described.<sup>15</sup>  
44  
45 135 In brief, it included advice on healthy eating, physical activity, management of triggers of  
46  
47 136 unhealthy behaviours, and behavioural relapse prevention. A dietitian (DAK) trained on the  
48  
49 137 programme facilitated the group sessions following a standardized and scripted protocol. An  
50  
51 138 extra trained provider (psychologist or dietitian) attended the meetings of the four groups to  
52  
53 139 aid with facilitation but did not participate in the discussion. DAK was the only facilitator in  
54  
55 140 the last group because of last minute cancellations. The participants in the fourth and final  
56  
57 141 round of randomisation were split into two small intervention groups for convenience  
58  
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3 142 purposes. A participant from the control group that had completed the study was invited to  
4  
5 143 participate in the last group (final n=4 in group 5) to enhance the group experience but was  
6  
7 144 not included in the analysis. There were no other modifications. The completed CONSORT<sup>17</sup>  
8  
9 145 and TIDieR checklists<sup>18</sup> are available in Supplementary appendix S1 and S2, respectively.

#### 11 12 146 **Care as usual**

13  
14  
15 147 Participants in the control arm were offered usual care. After the final follow-up, they  
16  
17 148 received a booklet with healthy lifestyle advice for cancer survivors.<sup>19</sup>

#### 19 20 149 **Outcomes**

21  
22  
23 150 Recruitment rates were calculated separately for each strategy and site. We adapted an  
24  
25 151 existing framework of hierarchical recruitment barriers (availability by disease characteristics,  
26  
27 152 eligibility, physician triage, trial discussion, interest, consent, and enrolment)<sup>20</sup> to describe  
28  
29 153 the recruitment process. In contrast with the original framework, the category “interest”  
30  
31 154 preceded that of “trial discussed” to fit the current recruitment process. Participants who  
32  
33 155 were introduced to the study and decided not to enrol completed a 25-item investigator-  
34  
35 156 designed survey<sup>21</sup> about barriers to participation. UCLH clinicians were interviewed about  
36  
37 157 their views on study recruitment using a semi-structured protocol by phone or face to face  
38  
39 158 (Supplementary appendix S3).

40  
41  
42 159 All intervention sessions were audiotaped. RJB attended one intervention session and one  
43  
44 160 study assessment and scored them against a predefined checklist. Engaged intervention-  
45  
46 161 arm participants completed and posted an 18-item programme evaluation questionnaire.<sup>22</sup>  
47  
48 162 Only two follow-up qualitative interviews with intervention participants were performed at  
49  
50 163 study completion, as the data from the open-ended feedback questionnaire were deemed  
51  
52 164 sufficient.

#### 53 54 55 165 **Statistical and qualitative analysis**

1  
2  
3 166 Despite the pilot nature of the study, a sample size of 32 participants per arm was estimated  
4  
5 167 for examining recruitment, adherence, and retention rates. The study would be deemed  
6  
7 168 feasible if the lower 95% confidence limits for recruitment, adherence, and retention rates  
8  
9 169 were at least 15%, 60%, and 60%, respectively.<sup>15</sup>

10  
11 170 Primary outcomes are reported in proportions with 95% confidence intervals (CIs).  
12  
13 171 Descriptive statistics are reported for continuous variables. Categorical variables are  
14  
15 172 summarized using frequencies and percentages. The interviews with clinicians lasted 10  
16  
17 173 minutes on average, were digitally recorded, transcribed verbatim by a professional  
18  
19 174 company, and checked for accuracy. Given the structured interview and short replies, data  
20  
21 175 were analysed with content analysis using NVivo version 10 (QSR International Pty Ltd,  
22  
23 176 2014) software. The open-ended questions were analysed using manifest content analysis<sup>23</sup>  
24  
25  
26 177 in Microsoft Office Excel 2011.

## 27 28 29 178 **Results**

### 30 31 32 179 **Recruitment**

33  
34  
35 180 Recruitment took place over a period of 27 and 18 weeks (April 2015 – December 2015) at  
36  
37 181 UCLH and Barts Health, respectively (Figure S1, Supplementary appendix S3). The  
38  
39 182 difference in recruitment period between sites was primarily explained by substantial delay of  
40  
41 183 NHS Research and Development (R&D) management approval at Barts Health. Among the  
42  
43 184 first 64 eligible participants approached, 20 consented to participate, leading to rejection of  
44  
45 185 the null hypothesis that recruitment would be  $\leq 15\%$ . Therefore, recruitment continued for  
46  
47 186 enrolling the projected sample of 64 participants but stopped after enrolling 60 participants  
48  
49 187 due to resource constraints. Out of 296 potentially eligible participants, 20.3% (95% CI: 15.7,  
50  
51 188 24.9) enrolled in the study. Among screened participants, rates of consent were similar for  
52  
53 189 the face-to-face recruitment at the two recruitment sites but lower for the mail out (Table S1  
54  
55 190 and Table S2).

1  
2  
3 191 Reasons for non-participation were documented for 36.7% (n=83) of those who were  
4  
5 192 potentially eligible but did not consent and 90.2% of those that were approached.  
6  
7 193 Inconvenience to everyday life (78%) and transport to trial site (63%) were the main barriers  
8  
9 194 to participation, with further barriers detailed in Figure 1. The CONSORT flow diagram  
10  
11 195 shows the progress through the trial stages (Figure 2).

#### 14 196 **Clinicians' views on recruitment**

15  
16  
17 197 Clinicians were supportive of the study and did not have particular concerns about  
18  
19 198 introducing the study to patients. They felt the study might be beneficial to patients, but they  
20  
21 199 believed travelling and commitment would be the main barriers for recruitment.

22  
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24 200 They deemed the recruitment strategy highly effective, with potentially eligible patients being  
25  
26 201 flagged prior to the clinic, researchers being present and reminding them about approaching  
27  
28 202 patients, and through the existence of a separate space for study recruitment in the clinic.  
29  
30 203 These strategies minimized additional clinician workload.

31  
32  
33 204 Clinicians did not anticipate adverse events from the intervention or changes in their  
34  
35 205 relationship with the patients. The framing and content of such an intervention was also  
36  
37 206 highlighted as a potential barrier to recruitment. In particular, approaching patients in a non-  
38  
39 207 discriminatory way was deemed to enhance recruitment. Furthermore, framing of its content  
40  
41 208 as a lifestyle programme was thought to be superior to a weight loss programme, strict diet  
42  
43 209 regime, or educational programme.

#### 46 210 **Sample characteristics**

47  
48  
49 211 Participant characteristics at baseline are shown in Table 1. Women were on average ( $\pm$ SD)  
50  
51 212  $62.1 \pm 8.3$  years old, White (67%), married (53%),  $1.2 \pm 1.0$  years from diagnosis, with a BMI  
52  
53 213 of  $28.0 \pm 6.3$ kg/m<sup>2</sup>. They were diagnosed mostly with stage IA (49%), type 1 (82%)  
54  
55 214 endometrial cancer.

#### 58 215 **Adherence**

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3 216 Out of 26 participants in the intervention arm, 21 (81%; 95% CI: 66%-96%) engaged and 20  
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5 217 (77%; 95% CI: 61%-93%) adhered to the intervention, based on our pre-determined criteria  
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7 218 <sup>15</sup>. The lower confidence limit was above 60% indicating feasibility.  
8

9  
10 219 The percentage of participants who attended zero, five, six, seven, and eight (all) sessions  
11  
12 220 was 15%, 8%, 12%, 35%, 15%, respectively. The mean overall attendance of sessions was  
13  
14 221 63% (95% CI: 49%, 77%). The mean attendance rates of those who engaged and those who  
15  
16 222 adhered were 79% (95% CI: 70%, 88%) and 82% (95% CI: 74%, 89%), respectively.  
17  
18 223 Reasons for non-adherence were mostly of practical nature, with details available in  
19  
20 224 Supplementary appendix S3.  
21

### 22 225 **Programme satisfaction**

23  
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25  
26 226 Eighteen participants randomised to the intervention group who adhered provided feedback  
27  
28 227 for the programme. They scored the programme highly with 44% and 39% reporting that it  
29  
30 228 met or exceeded their expectations, respectively. All aspects of the programme were scored  
31  
32 229 highly (Figure 3). Additionally, most participants ranked self-monitoring, setting SMART  
33  
34 230 (specific, measureable, achievable, relevant, and time-specific) goals, and social support as  
35  
36 231 either very or somewhat helpful in making dietary and physical activity changes (Figure 4). In  
37  
38 232 contrast, the responses for self-incentives were mixed with 28% of participants rating this  
39  
40 233 technique as unhelpful.  
41

42  
43 234 A range of topics were regarded as most useful (Figure S2). Among them, most participants  
44  
45 235 agreed that the sections about keeping an eye on portion sizes, food labelling, and internal  
46  
47 236 triggers were the most useful. Others mentioned self-incentives, internal and external  
48  
49 237 triggers, and getting a healthier balance of foods to be the least useful topics (Figure S3).  
50  
51 238 For example, one participant mentioned:

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53  
54 239 *I also did not understand the concept of the rewards - better health*  
55  
56 240 *should be its own reward (Participant in group 4).*  
57  
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3 241 Suggestions for additions to the programme were primarily focused on physical activity, such  
4  
5 242 as provision of relevant DVDs, physical activity during the programme sessions, and diaries  
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7 243 to report physical activity and sedentary behaviour in more detail. Most participants did not  
8  
9 244 consider that topics should be eliminated from the programme. Similar feedback was  
10  
11 245 provided for the booklet; most participants did not suggest changes while a few suggested  
12  
13 246 design changes. Further suggestions included the addition of follow-up support and a  
14  
15 247 preference for a larger group (mentioned by participants in smaller groups) to boost the  
16  
17 248 peer-education component.

18  
19  
20 249 Peer support of the group, both the focus of the programme and their own interest in health  
21  
22 250 promotion, the feeling of giving back to the care system, the facilitators, and the doctor's  
23  
24 251 referral to the programme facilitated study participation. In contrast, most did not report  
25  
26 252 factors discouraging them to participate but some mentioned inconvenience to everyday life,  
27  
28 253 self-monitoring and identification as a cancer survivor.

29  
30  
31 254 Regarding the trial procedures, two participants mentioned their difficulty recalling and  
32  
33 255 quantifying their diet and physical activity. Excellent fidelity to the protocol for both the group  
34  
35 256 sessions (85%) and the assessments (100%) was demonstrated in the study auditing.

### 36 37 38 257 **Retention**

39  
40  
41 258 Retention rate was 92% (95% CI: 85%, 100%), with 24/28 (86%; 95% CI: 73%-99%) and  
42  
43 259 25/26 (96%; 95% CI: 89%-100%) eligible participants in the control and intervention arm  
44  
45 260 completing all assessments, respectively ( $P=0.61$  for difference between proportions). This  
46  
47 261 indicated an absence of attrition bias and the rejection of the null hypothesis that retention  
48  
49 262 rate would be less than 60%.

### 50 51 52 263 **Adverse events and control arm contamination**

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3 264 No intervention-related adverse events or unintended consequences were reported. Adverse  
4  
5 265 events unrelated to the intervention and reasons for control arm contamination are detailed  
6  
7 266 in the Supplementary appendix S3.  
8  
9

## 10 267 **Discussion**

11  
12  
13 268 This is the first pilot study of a health behaviour change intervention in endometrial cancer  
14  
15 269 survivors in the UK to demonstrate feasibility in terms of recruitment, adherence, and  
16  
17 270 retention. The collaboration of the clinical and research team led to an efficient recruitment  
18  
19 271 process. Participants rated the programme highly and provided rich feedback for refinement.  
20  
21 272 Consistent with the literature<sup>24</sup> and the qualitative findings,<sup>7</sup> the DEUS pilot study aimed to  
22  
23 273 minimize accrual barriers by enrolling survivors within the “teachable moment” period,  
24  
25 274 capitalizing on the endorsement of the study from survivors’ clinicians, utilizing a strong  
26  
27 275 behaviour theory-based design, and ensuring standardized delivery of the intervention.  
28  
29 276 These study strengths were also reflected in the reported factors associated with programme  
30  
31 277 involvement. Furthermore, the frameworks for reporting barriers to participation<sup>20 21</sup> provided  
32  
33 278 a comprehensive understanding of these barriers and can be a valuable resource to  
34  
35 279 understand barriers in for future trials.<sup>25</sup> Limitations of the study include the small sample  
36  
37 280 size, recruitment from only two London-based sites, generalizability of the recruited sample,  
38  
39 281 as socio-demographic data from decliners were missing. The relatively low median BMI of  
40  
41 282 participants compared to epidemiological studies<sup>26</sup> indicates healthy volunteer effect biases.  
42  
43 283 The wide socio-economic and demographic differences of the population pools of the two  
44  
45 284 hospitals<sup>27</sup> and the similar recruitment rates at both sites were reassuring and suggest these  
46  
47 285 factors should not impact recruitment and retention.  
48  
49

50 286 The focus of the study on healthy lifestyle changes rather than weight loss was postulated to  
51  
52 287 increase uptake and acceptability of the programme.<sup>7</sup> The overall recruitment estimate was  
53  
54 288 similar or somewhat higher than that in other lifestyle intervention trials, although differences  
55  
56 289 in recruitment strategies, eligibility criteria, cancer site, programme length and intensity do  
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3 290 not allow for direct comparisons. The group-based, six-month SUCCEED intervention had a  
4  
5 291 19% recruitment rate using mail-out.<sup>12</sup> A 12-week group-based physical activity intervention  
6  
7 292 recruited 20% of the eligible endometrial cancer survivors through fliers and telephone  
8  
9 293 recruitment.<sup>28</sup> Similar to DEUS, a more intensive lifestyle intervention in UK breast cancer  
10  
11 294 survivors had a mail-out rate of 17%.<sup>29</sup> While removing the transport and time barriers would  
12  
13 295 theoretically improve recruitment rates, USA home-based lifestyle interventions recruiting  
14  
15 296 cancer survivors from registries have shown much smaller recruitment rates (5.7%) with  
16  
17 297 women, younger, White survivors and those closer to their cancer diagnosis more likely to  
18  
19 298 enrol.<sup>30</sup>

20  
21  
22 299 The observed adherence was lower compared with the weight loss SUCCEED intervention  
23  
24 300 (84.1%) comprising of 16 group sessions<sup>12</sup> but similar to that of a group-based 12-week  
25  
26 301 physical activity intervention.<sup>28</sup> While this might indicate that survivors are more committed in  
27  
28 302 weight loss programmes compared to healthy lifestyle programmes, the main reported  
29  
30 303 reasons regarding non-attendance in the current study were around practicalities and life  
31  
32 304 commitments rather than disengagement with the programme. Sending a standardized e-  
33  
34 305 mail to non-attendees about topics covered in the missed session and preparation for the  
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36 306 next session helped maintain their engagement.

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39 307 Having a specific research room and two committed researchers in clinic facilitated  
40  
41 308 recruitment. Screening participants using electronic forms and implementing further pre-  
42  
43 309 randomisation eligibility checks from medical notes could minimize randomisation of  
44  
45 310 ineligible participants. The recruitment rate, while similar between the two sites, was lower in  
46  
47 311 the clinician-endorsed mail-out, indicating the higher effectiveness of the first approach that  
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49 312 needs to be balanced with its higher resource requirements in larger trials. Practical reasons  
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51 313 rendered intervention adherence acceptable but not optimal. The difficulty of trying to  
52  
53 314 arrange a weekly group meeting with approximately eight people was evident, although a  
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55 315 range of potential times was offered to participants and involved working around the logistics  
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57 316 to find the most convenient date. Given the wide variability of participants' availability,  
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3 317 simultaneous offers of a group on a weekday early evening or Saturday morning facilitated  
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5 318 engagement in Groups 2 and 3. In future studies, larger groups will be possible by un-  
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7 319 blinding investigators after enough participants are allocated to each trial arm to run two  
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9 320 groups.

10  
11 321 Opting for the group-based and face-to-face design aimed to meet survivors' preferences<sup>7</sup>  
12  
13 322 but was in contrast with some previous studies reporting proximity as a particular barrier in  
14  
15 323 this population.<sup>24</sup> The lack of dropouts after the second group session indicated the overall  
16  
17 324 acceptability of the intervention and the favourable rating of most programme aspects  
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19 325 provides confidence that only minor content adaptations are needed before testing the study  
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21 326 in a large trial. As multiple facilitators will deliver the intervention in a pragmatic setting,  
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23 327 future large-scale trials should also measure differences in intervention delivery between  
24  
25 328 various facilitators. Inconvenience and transport were the main barriers to accrual in the  
26  
27 329 current study. Increasing reach might be more feasible with blended designs of group  
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29 330 meetings and remote intervention delivery, especially as home-based interventions have  
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31 331 typically experienced much lower recruitment rates compared with group-based  
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33 332 interventions. In the current programme, even those who adhered mentioned convenience  
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35 333 reasons as discouraging participation but the peer support as encouraging. This might  
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37 334 suggest delivering some sessions in person and others remotely, potentially through web or  
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39 335 mobile technology. A pilot weight loss study with endometrial and breast cancer survivors  
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41 336 delivered via a mobile application has shown promising results in a pre-post design.<sup>31</sup>  
42  
43 337 However, further research on mobile applications for weight management is needed, as  
44  
45 338 most lack evidence-based behaviour change techniques, involvement of health care  
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47 339 professionals and scientific evaluation.<sup>32</sup>  
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50  
51 340 In conclusion, this self-help lifestyle intervention trial was feasible in terms of recruitment,  
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53 341 adherence, and retention. Scaling the trial will require close monitoring of recruitment and  
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55 342 attempts should be made to reduce the burden on participants. Further qualitative work  
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57 343 could inform a blended in-person and remote design to enhance adherence while retaining  
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3 344 the valued peer support. This should be considered before proceeding to a definitive trial.  
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5 345 Overall, the lessons learnt from this pilot should inform the design of future studies in this  
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For peer review only

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3 347 **Full protocol availability**  
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5  
6 348 The full protocol of the study has been previously published<sup>15</sup> and it can also be found in the  
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8 349 Supplementary Appendix S4.  
9

10  
11 350 **Funding**  
12

13  
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21  
22 355 analysis, and interpretation of data; writing of the report; and the decision to submit the  
23  
24 356 report for publication.  
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26  
27 357 **Competing interests' statement**  
28

29  
30 358 DAK and RJB are volunteers for the charity Weight Concern, which developed the original  
31  
32 359 Shape-Up programme for the general population. All other authors have no conflicts of  
33  
34 360 interest to declare.  
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36  
37 361 **Contribution to Authorship**  
38

39  
40 362 The authors' contributions were as follows. Anne Lanceley (AL) and M. Tish Knobf (MTK)  
41  
42 363 conceived the study and were the grant holders. AL and Ranjit Manchanda (RM) were the  
43  
44 364 site investigators for University College London Hospitals and Barts Health, respectively.  
45  
46 365 Dimitrios A. Koutoukidis (DAK), AL, Rebecca J Beeken (RJB) and MTK initiated the study  
47  
48 366 design, and RM helped with protocol development and implementation. DAK and Moscho  
49  
50 367 Michalopoulou (MM) recruited the study participants. RJB was responsible for randomisation  
51  
52 368 and auditing. DAK was the trial manager, ran the group sessions, and conducted the  
53  
54 369 baseline and 24-week follow-up assessments. MM conducted the 8-week follow-up  
55  
56 370 assessments. Matthew Burnell (MB) provided the statistical support, and DAK conducted the  
57  
58 371 statistical analysis. DAK drafted the manuscript, which was amended following comments  
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3 372 from all other authors. All authors read and approved the submitted manuscript. All listed  
4  
5 373 authors meet the criteria for authorship and no individual meeting these criteria has been  
6  
7 374 omitted.

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20 379 **Ethical approval**

21  
22  
23 380 The study protocol and documents have been reviewed and approved by the relevant  
24  
25 381 sponsor and National Research Ethics Service Committee London - City Road and  
26  
27 382 Hampstead (Reference: 15/LO/0154).

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30 383 **Availability of data and materials**

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33 384 The materials and datasets used and/or analysed during the current study available from the  
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35 385 corresponding author on reasonable request.  
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386 **References**

- 387 1. Global Burden of Disease Cancer C, Fitzmaurice C, Allen C, et al. Global, Regional, and National  
388 Cancer Incidence, Mortality, Years of Life Lost, Years Lived With Disability, and Disability-  
389 Adjusted Life-years for 32 Cancer Groups, 1990 to 2015: A Systematic Analysis for the Global  
390 Burden of Disease Study. *JAMA Oncol* 2016.
- 391 2. Quaresma M, Coleman MP, Rachet B. 40-year trends in an index of survival for all cancers  
392 combined and survival adjusted for age and sex for each cancer in England and Wales, 1971-  
393 2011: a population-based study. *Lancet* 2015;**385**(9974):1206-18.
- 394 3. Leach CR, Weaver KE, Aziz NM, et al. The complex health profile of long-term cancer survivors:  
395 prevalence and predictors of comorbid conditions. *J Cancer Surviv* 2015;**9**(2):239-51.
- 396 4. Ward KK, Shah NR, Saenz CC, et al. Cardiovascular disease is the leading cause of death among  
397 endometrial cancer patients. *Gynecol Oncol* 2012;**126**(2):176-9.
- 398 5. Koutoukidis DA, Knobf MT, Lanceley A. Obesity, diet, physical activity, and health-related quality  
399 of life in endometrial cancer survivors. *Nutr Rev* 2015;**73**(6):399-408.
- 400 6. von Gruenigen VE, Waggoner SE, Frasure HE, et al. Lifestyle challenges in endometrial cancer  
401 survivorship. *Obstet Gynecol* 2011;**117**(1):93-100.
- 402 7. Koutoukidis DA, Beeken RJ, Lopes S, et al. Attitudes, challenges, and needs about diet and physical  
403 activity in endometrial cancer survivors: a qualitative study. *Eur J Cancer Care (Engl)* 2016.
- 404 8. Zhu G, Zhang X, Wang Y, et al. Effects of exercise intervention in breast cancer survivors: a meta-  
405 analysis of 33 randomized controlled trials. *Onco Targets Ther* 2016;**9**:2153-68.
- 406 9. Stacey FG, James EL, Chapman K, et al. A systematic review and meta-analysis of social cognitive  
407 theory-based physical activity and/or nutrition behavior change interventions for cancer  
408 survivors. *J Cancer Surviv* 2014.
- 409 10. Morey MC, Snyder DC, Sloane R, et al. Effects of home-based diet and exercise on functional  
410 outcomes among older, overweight long-term cancer survivors: RENEW: a randomized  
411 controlled trial. *JAMA* 2009;**301**(18):1883-91.

- 1  
2  
3 412 11. von Gruenigen VE, Gibbons HE, Kavanagh MB, et al. A randomized trial of a lifestyle intervention  
4  
5 413 in obese endometrial cancer survivors: quality of life outcomes and mediators of behavior  
6  
7 414 change. *Health Qual Life Outcomes* 2009;**7**:17.  
8  
9 415 12. von Gruenigen V, Frasure H, Kavanagh MB, et al. Survivors of uterine cancer empowered by  
10  
11 416 exercise and healthy diet (SUCCEED): a randomized controlled trial. *Gynecol Oncol*  
12  
13 417 2012;**125**(3):699-704.  
14  
15 418 13. Wardle J, Liao LM, Rapoport L, et al. *Shape-Up: A lifestyle programme to manage your weight*.  
16  
17 419 London: Weight Concern, 2016.  
18  
19 420 14. Use of intervention mapping to adapt a lifestyle intervention for endometrial cancer survivors  
20  
21 421 International Congress of Behavioral Medicine; 2016; Melbourne, Australia.  
22  
23 422 15. Koutoukidis DA, Beeken RJ, Manchanda R, et al. Diet and exercise in uterine cancer survivors  
24  
25 423 (DEUS pilot) - piloting a healthy eating and physical activity program: study protocol for a  
26  
27 424 randomized controlled trial. *Trials* 2016;**17**(1):130.  
28  
29 425 16. Oken MM, Creech RH, Tormey DC, et al. Toxicity and response criteria of the Eastern Cooperative  
30  
31 426 Oncology Group. *Am J Clin Oncol* 1982;**5**(6):649-55.  
32  
33 427 17. Eldridge SM, Chan CL, Campbell MJ, et al. CONSORT 2010 statement: extension to randomised  
34  
35 428 pilot and feasibility trials. *Pilot and feasibility studies* 2016;**2**:64.  
36  
37 429 18. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for  
38  
39 430 intervention description and replication (TIDieR) checklist and guide. *Bmj* 2014;**348**:g1687.  
40  
41 431 19. WCRF. Healthy living after cancer. Secondary Healthy living after cancer 2015.  
42  
43 432 <https://www.wcrf-uk.org/sites/default/files/healthy-living-after-cancer-guide.pdf>.  
44  
45 433 20. Kanarek NF, Kanarek MS, Olatoye D, et al. Removing barriers to participation in clinical trials, a  
46  
47 434 conceptual framework and retrospective chart review study. *Trials* 2012;**13**:237.  
48  
49 435 21. Mills EJ, Seely D, Rachlis B, et al. Barriers to participation in clinical trials of cancer: a meta-  
50  
51 436 analysis and systematic review of patient-reported factors. *Lancet Oncol* 2006;**7**(2):141-8.  
52  
53  
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55  
56  
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- 1  
2  
3 437 22. Queensland\_Health. Participant Satisfaction Survey. Secondary Participant Satisfaction Survey  
4  
5 438 2014. <http://www.health.qld.gov.au/stayonyourfeet/toolkits/phase4/tools-temp.asp>.  
6  
7 439 23. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. Qual Health Res  
8  
9 440 2005;**15**(9):1277-88.  
10  
11 441 24. Stull VB, Snyder DC, Demark-Wahnefried W. Lifestyle interventions in cancer survivors: designing  
12  
13 442 programs that meet the needs of this vulnerable and growing population. J Nutr 2007;**137**(1  
14  
15 443 Suppl):243S-48S.  
16  
17 444 25. Denicoff AM, McCaskill-Stevens W, Grubbs SS, et al. The National Cancer Institute-American  
18  
19 445 Society of Clinical Oncology Cancer Trial Accrual Symposium: summary and  
20  
21 446 recommendations. J Oncol Pract 2013;**9**(6):267-76.  
22  
23 447 26. Arem H, Park Y, Pelsler C, et al. Prediagnosis body mass index, physical activity, and mortality in  
24  
25 448 endometrial cancer patients. J Natl Cancer Inst 2013;**105**(5):342-9.  
26  
27 449 27. UKDE. Census 2011: Wards in London. Secondary Census 2011: Wards in London 2011.  
28  
29 450 <http://ukdataexplorer.com/census/london/#KS401EW0020>.  
30  
31 451 28. Rossi A, Garber CE, Ortiz M, et al. Feasibility of a physical activity intervention for obese,  
32  
33 452 socioculturally diverse endometrial cancer survivors. Gynecol Oncol 2016;**142**(2):304-10.  
34  
35 453 29. Scott E, Daley AJ, Doll H, et al. Effects of an exercise and hypocaloric healthy eating program on  
36  
37 454 biomarkers associated with long-term prognosis after early-stage breast cancer: a  
38  
39 455 randomized controlled trial. Cancer Causes Control 2013;**24**(1):181-91.  
40  
41 456 30. Adams RN, Mosher CE, Blair CK, et al. Cancer survivors' uptake and adherence in diet and  
42  
43 457 exercise intervention trials: An integrative data analysis. Cancer 2014.  
44  
45 458 31. McCarroll ML, Armbruster S, Pohle-Krauza RJ, et al. Feasibility of a lifestyle intervention for  
46  
47 459 overweight/obese endometrial and breast cancer survivors using an interactive mobile  
48  
49 460 application. Gynecol Oncol 2015;**137**(3):508-15.  
50  
51 461 32. Rivera J, McPherson A, Hamilton J, et al. Mobile Apps for Weight Management: A Scoping  
52  
53 462 Review. JMIR Mhealth Uhealth 2016;**4**(3):e87.  
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3 463 List of legends  
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6 464 Table 1 DEUS pilot trial baseline participant characteristics  
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8 465 Figure 1 Percentage of each barrier to participation with SE  
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11 466 Figure 2 CONSORT diagram of the trial with framework on barriers to participation in the  
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13 467 exclusion box  
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16 468 Figure 3 Percentage programme satisfaction (n=18)  
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18 469 Figure 4 Helpfulness of the main behaviour change techniques for dietary and physical  
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20 470 activity changes (n=18)  
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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 (61.4)
% 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

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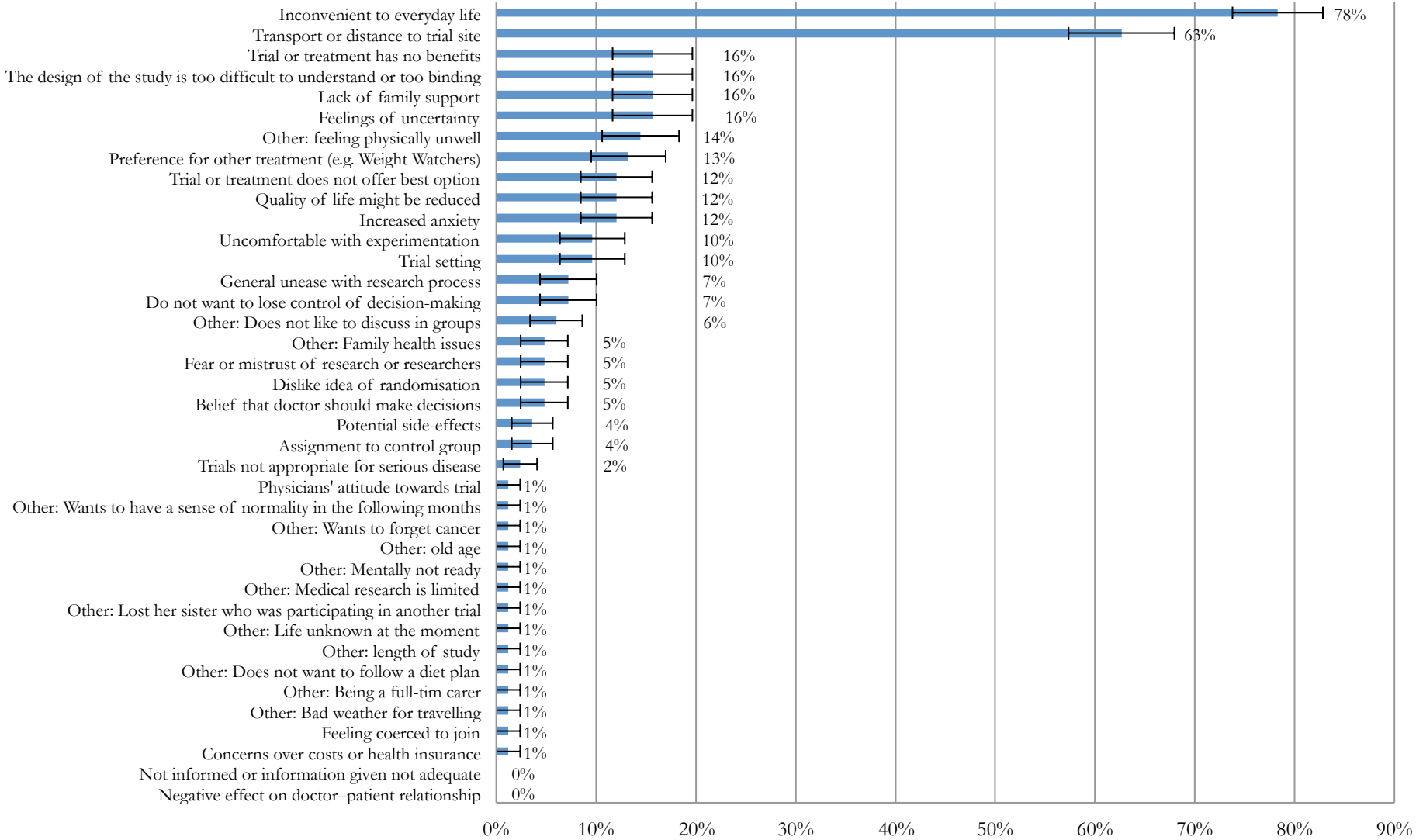
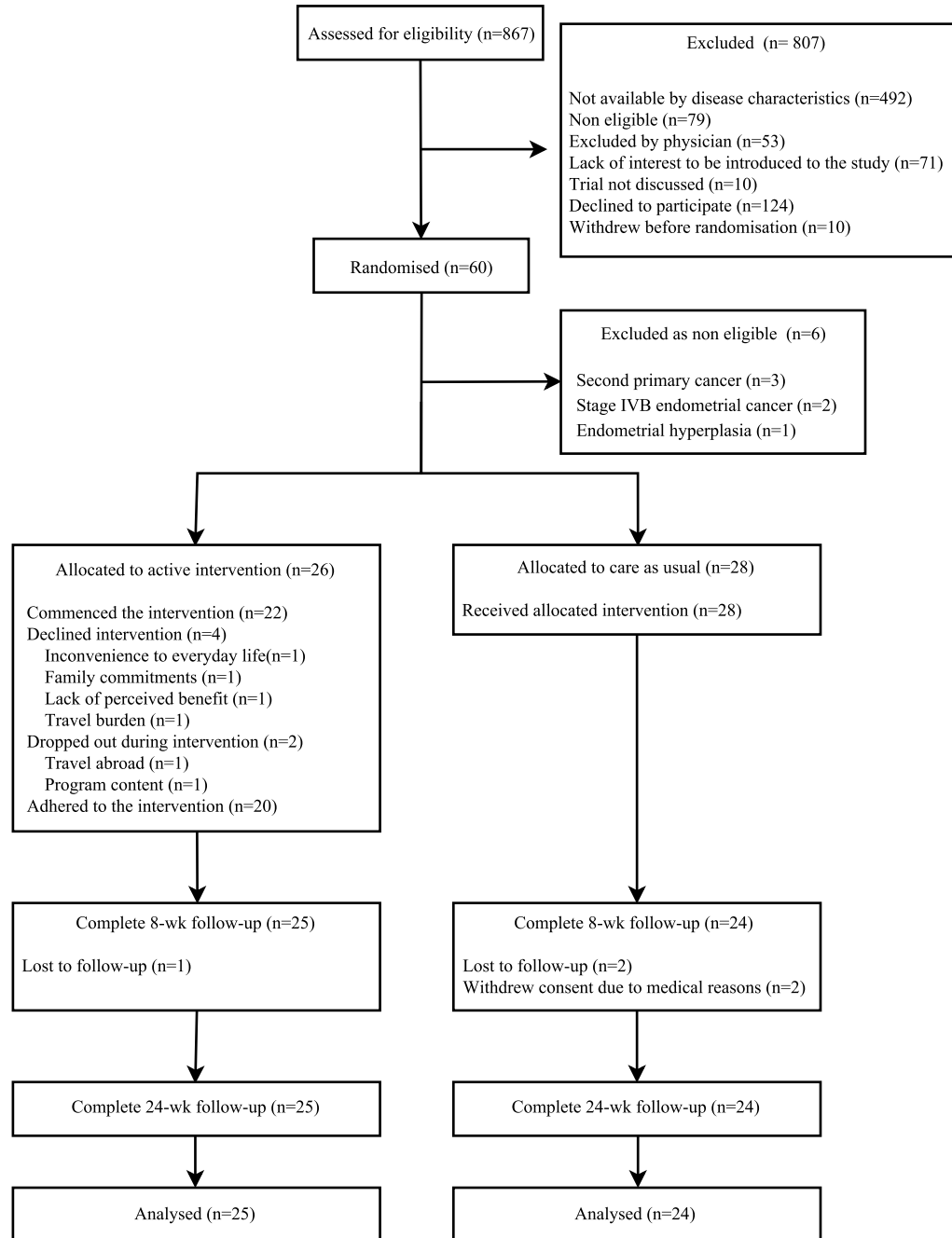


Figure 1 Percentage of each barrier to participation with SE (n=83)

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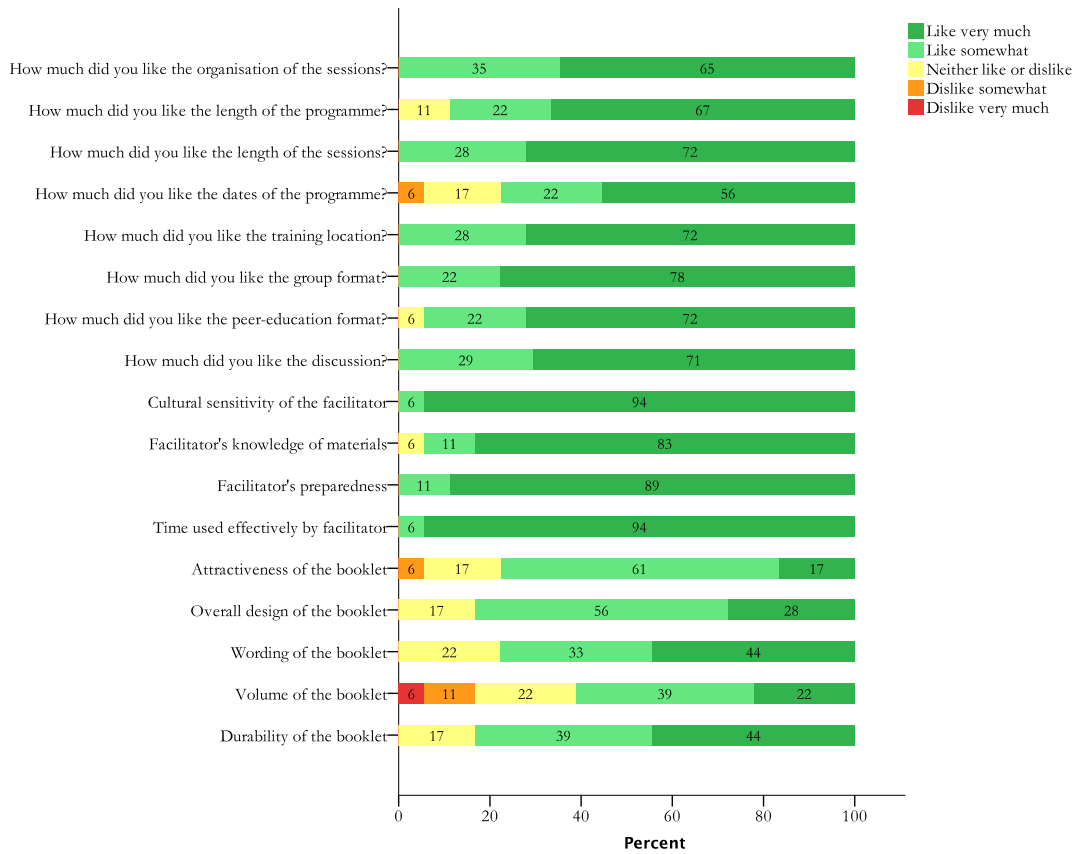


Figure 3 Percentage program satisfaction (n=18)

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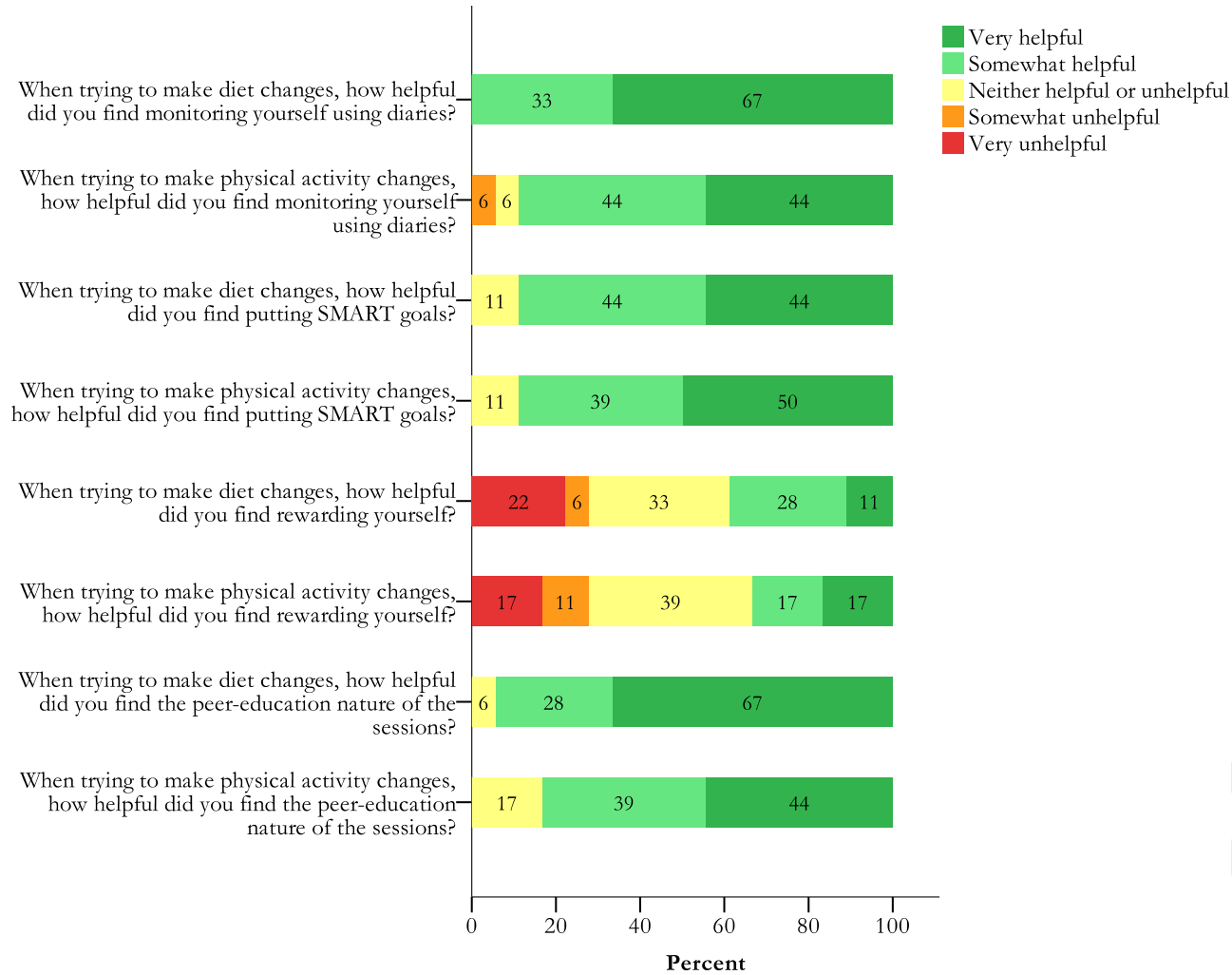


Figure 4 Helpfulness of the main behaviour change techniques for dietary and physical activity changes (n=18)

## 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
<b>Title and abstract</b>			
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
<b>Introduction</b>			
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
<b>Methods</b>			
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

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3	Sample size:			
4	7a	How sample size was determined	Rationale for numbers in the pilot trial	Protocol paper
5	7b	When applicable, explanation of any interim analyses and stopping guidelines		n/a
6				
7				
8	Randomisation:			
9	Sequence generation:			
10	8a	Method used to generate the random allocation sequence		6 and protocol paper
11	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
12				
13				
14	Allocation concealment mechanism:			
15	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
16				
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18	Implementation:			
19	10	Who generated the random allocation sequence, enrolled participants, and assigned participants to interventions		Protocol paper
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26	Blinding:			
27	11a	If done, who was blinded after assignment to interventions (eg, participants, care providers, those assessing outcomes) and how		6 and protocol paper
28	11b	If relevant, description of the similarity of interventions		
29				
30	Analytical methods:			
31	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
32	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Not applicable	n/a
33				
34	<b>Results</b>			
35	Participant flow (a diagram is strongly recommended):			
36	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
37	13b	For each group, losses and exclusions after randomisation, together with reasons		Figure 2
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39	Recruitment:			
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3	14a	Dates defining the periods of recruitment and follow-up		8
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5	14b	Why the trial ended or was stopped	Why the pilot trial ended or was stopped	8
6				
7	Baseline data:			
8	15	A table showing baseline demographic and clinical characteristics for each group		Table 1
9				
10				
11	Numbers analysed:			
12	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
13				
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18	Outcomes and estimation:			
19	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
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25	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable	n/a
26				
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28	Ancillary analyses:			
29	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
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34	Harms:			
35	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)		12 and Suppl. material
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39	19a		If relevant, other important unintended consequences	n/a
40				
41	<b>Discussion</b>			
42				
43	Limitations:			
44	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
45				
46				
47	Generalisability:			
48	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
49				
50				
51	Interpretation:			
52	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
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56	22a		Implications for progression from pilot to future definitive trial, including any proposed amendments	
57				
58				
59				
60	<b>Other information</b>			

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3 Registration:4 23 Registration number and name of trial Registration number for pilot trial and  
5 registry name of trial registry6  
7 Protocol:8 24 Where the full trial protocol can be Where the pilot trial protocol can be  
9 accessed, if available accessed, if available

## 10 Funding:

11 25 Sources of funding and other support  
12 (such as supply of drugs), role of  
13 funders14  
15 26 Ethical approval or approval by research  
16 review committee, confirmed with  
17 reference number

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18 \*Here a pilot trial means any randomised study conducted in preparation for a future definitive RCT, where the  
19 main objective of the pilot trial is to assess feasibility.  
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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)
1.	<b>BRIEF NAME</b> Provide the name or a phrase that describes the intervention.	Abstract	_____
2.	<b>WHY</b> 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)_____
3.	<b>WHAT</b> 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_____
5.	<b>WHO PROVIDED</b> 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_____

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3	<b>HOW</b>		
4	6. Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or	Shape-Up	_____
5	telephone) of the intervention and whether it was provided individually or in a group.	following cancer	
6		treatment	
7		intervention	
8			
9			
10	<b>WHERE</b>		
11	7. Describe the type(s) of location(s) where the intervention occurred, including any necessary	Shape-Up	_____
12	infrastructure or relevant features.	following cancer	
13		treatment	
14		intervention	
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19	<b>WHEN and HOW MUCH</b>		
20	8. Describe the number of times the intervention was delivered and over what period of time including	Shape-Up	Protocol
21	the number of sessions, their schedule, and their duration, intensity or dose.	following cancer	paper_____
22		treatment	
23		intervention	
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28	<b>TAILORING</b>		
29	9. If the intervention was planned to be personalised, titrated or adapted, then describe what, why,	Shape-Up	Protocol
30	when, and how.	following cancer	paper_____
31		treatment	
32		intervention	
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36	<b>MODIFICATIONS</b>		
37	10.† If the intervention was modified during the course of the study, describe the changes (what, why,	Shape-Up	_____
38	when, and how).	following cancer	
39		treatment	
40		intervention	
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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](http://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](http://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](http://www.equator-network.org)).

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3 **Supplementary appendix (S3)**  
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9 **Recruitment, adherence, and retention of endometrial cancer survivors in a**  
10 **behavioral lifestyle program: the Diet and Exercise in Uterine Cancer Survivors**  
11 **(DEUS) parallel randomized pilot trial**  
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19 Dimitrios A. Koutoukidis, Rebecca J. Beeken, Ranjit Manchanda, Moscho  
20 Michalopoulou, Matthew Burnell, M. Tish Knobf, Anne Lanceley  
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**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?

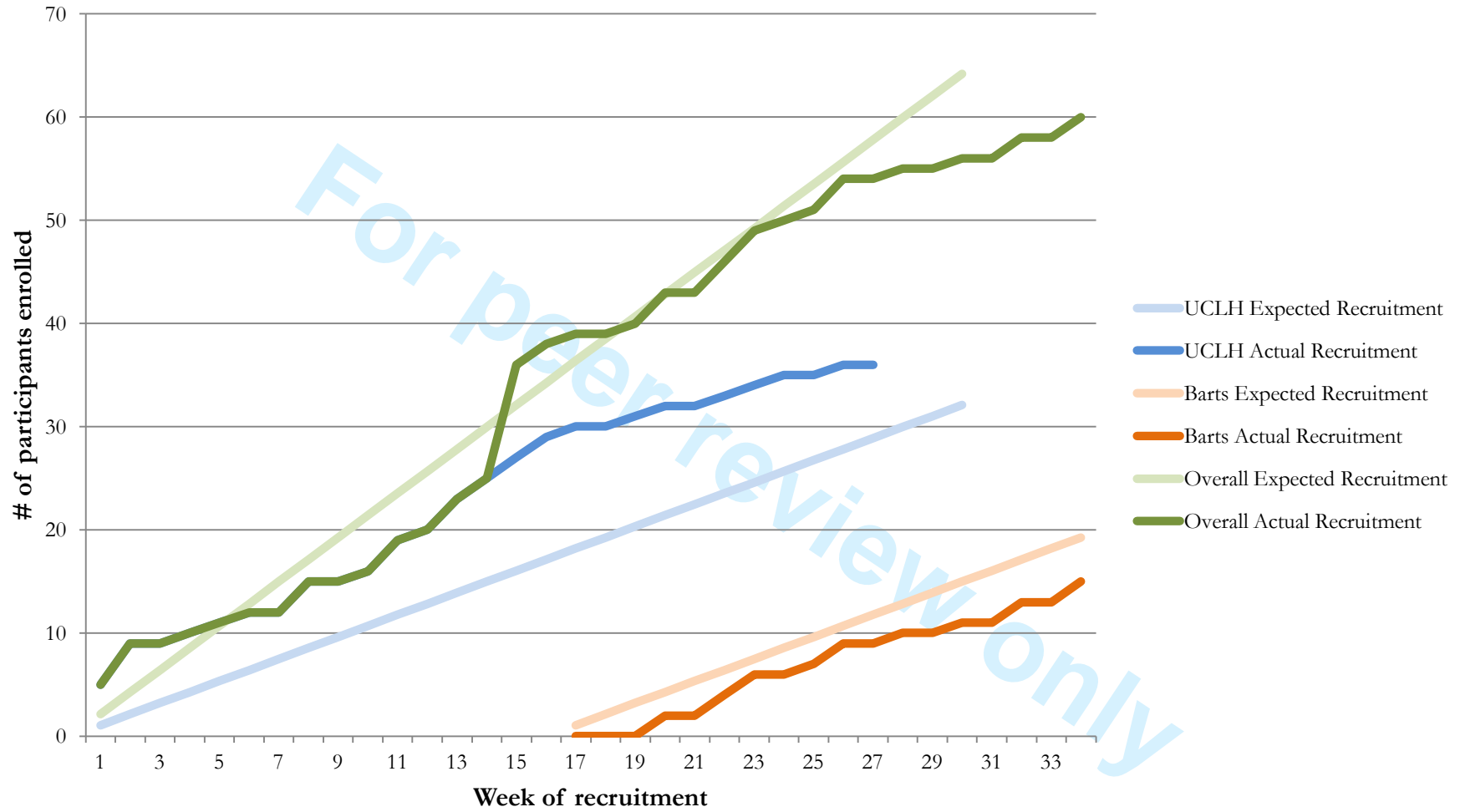


Figure S1 Projected and actual recruitment by site. The sharp spike in week 13 in overall recruitment indicated the recruited participants through mail out.



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

	UCLH	Barts	Hospitals combined	Mai-out	Total
<b>1. Women in gynecologic oncology clinic</b>	<b>2305</b>	<b>1047</b>	<b>3352</b>	<b>294</b>	<b>3646</b>
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
<b>2. Available for trial by disease characteristics</b>	<b>223</b>	<b>88</b>	<b>311</b>	<b>64</b>	<b>375</b>
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
<b>3. Eligible for participation</b>	<b>176</b>	<b>65</b>	<b>241</b>	<b>55</b>	<b>296</b>
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
<b>4. Physician Triage &amp; introduced to the study</b>	<b>140</b>	<b>48</b>	<b>188</b>	<b>55</b>	<b>243</b>
Not interested to hear about study	23	9	32	-	32
Long wait / too busy to talk about study	2	-	2	-	2
<b>5. Participants interested</b>	<b>115</b>	<b>39</b>	<b>154</b>	<b>18</b>	<b>172</b>
Lost in clinic - talking to other eligible participants	1	0	1		
<b>6. Trial discussed</b>	<b>114</b>	<b>39</b>	<b>153</b>	<b>9</b>	<b>162</b>
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
<b>7. Participant consented</b>	<b>46</b>	<b>15</b>	<b>61</b>	<b>9</b>	<b>70</b>
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
<b>8. Participant enrolled (randomized)</b>	<b>38</b>	<b>13</b>	<b>51</b>	<b>9</b>	<b>60</b>

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)

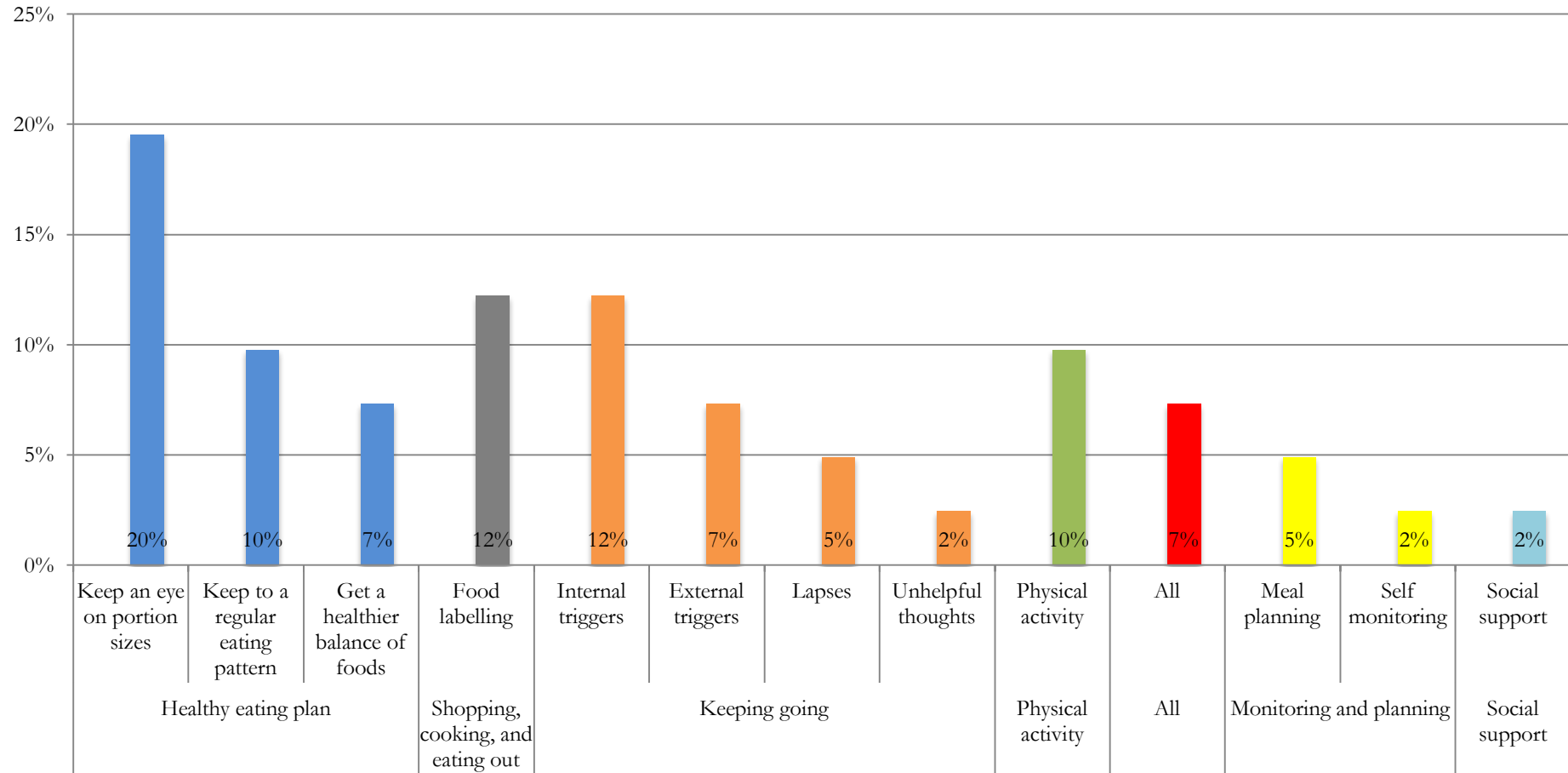


Figure S2 Percentage responses to the question "Which topic of the programme did you find the most useful?" by topic and programme section (in colour)

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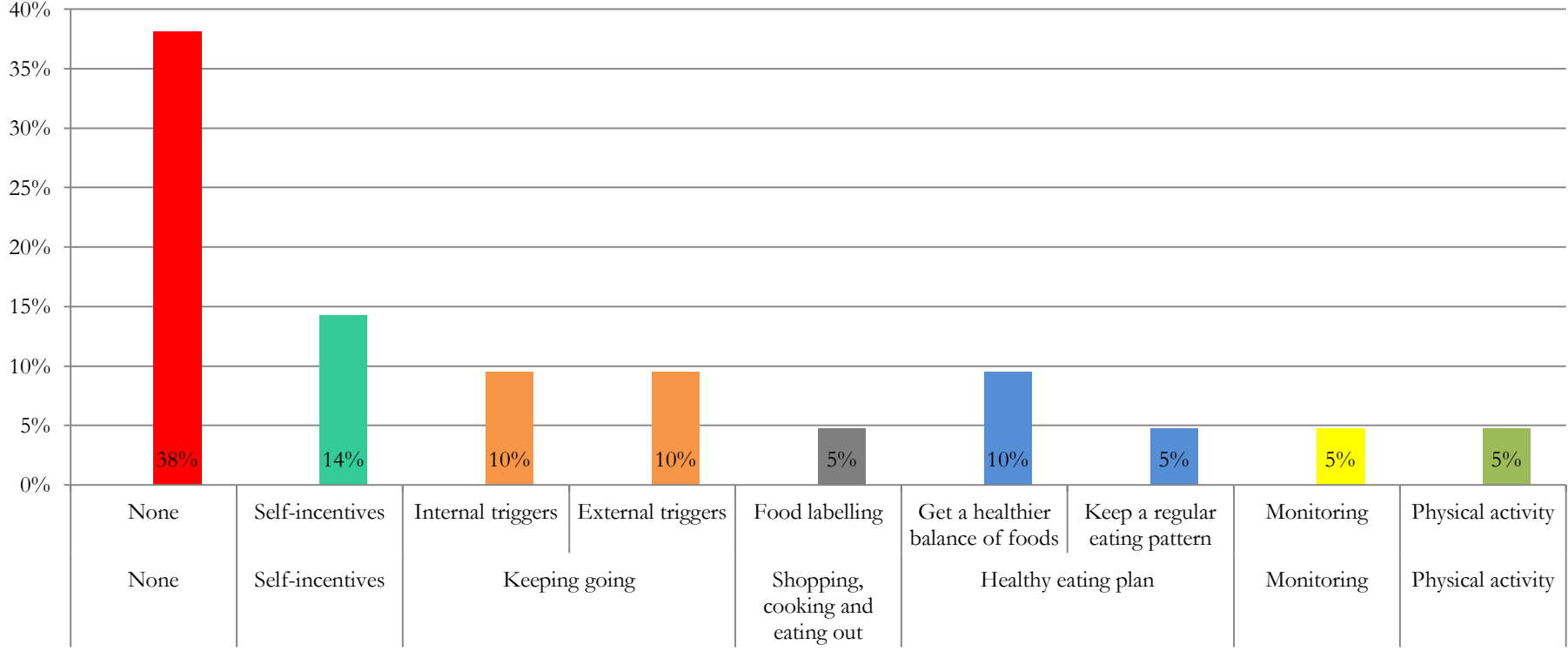


Figure S3 Percentage responses to the question "Which topic of the programme did you find the least useful?" by topic and programme section (in colour)

### 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.

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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.

For peer review only

# 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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-018015.R1
Article Type:	Research
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 Institute, 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
<b>Primary Subject Heading</b>:	Obstetrics and gynaecology
Secondary Subject Heading:	Nutrition and metabolism
Keywords:	Endometrial cancer, survivorship, behaviour change, healthy eating, physical activity, intervention

SCHOLARONE™  
Manuscripts



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3 1 **Recruitment, adherence, and retention of endometrial cancer survivors in a**  
4 **behavioural lifestyle programme: the Diet and Exercise in Uterine Cancer Survivors**  
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6 **(DEUS) parallel randomised pilot trial**  
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12 5 Dimitrios A. Koutoukidis<sup>a,b</sup>, Rebecca J. Beeken<sup>b,c</sup>, Ranjit Manchanda<sup>a,d,e</sup>, Moscho  
13 6 Michalopoulou<sup>a</sup>, Matthew Burnell<sup>a</sup>, M. Tish Knobf<sup>a,f</sup>, Anne Lanceley<sup>a</sup>  
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1  
2  
3 25 **Abstract**  
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5 26 Objective: Healthy eating and physical activity may help endometrial cancer survivors (ECS)  
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7 27 improve their quality of life. However, most ECS do not meet the relevant guidelines. This  
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9 28 pilot trial aimed to test the study feasibility procedures for a definitive trial of a behavioural  
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11 29 lifestyle programme.  
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14 30 Design and setting: This 24-week parallel two-arm randomised pilot trial took place in two  
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16 31 hospitals in London, UK (April 2015 - June 2016).  
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19 32 Participants: Sixty disease-free ECS within 3 years of diagnosis  
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22 33 Interventions: Participants were randomised using minimization to receive the intervention or  
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24 34 care as usual. The "Shape-Up following cancer treatment" programme used self-monitoring,  
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26 35 goal-setting, self-incentives, problem-solving, and group social support for 12 hours over 8  
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28 36 weeks to help survivors improve their eating and physical activity.  
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31 37 Outcome measures: The main outcome measures were recruitment, adherence, and  
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33 38 retention rates. Further outcomes included barriers to participation and feedback on  
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35 39 programme satisfaction.  
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38 40 Results: Of the 296 potentially eligible ECS, 20% (n=60) were randomly allocated to the  
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40 41 active intervention (n=29) or control group (n=31). Three participants in each arm were  
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42 42 deemed ineligible after randomisation and excluded from analysis. Twenty participants  
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44 43 (77%; 95% CI: 61%, 93%) adhered to the intervention and provided generally favourable  
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46 44 feedback. At 24 weeks, 25/26 (96%; 95% CI: 89%, 100%) intervention and 24/28 (86%; 95%  
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48 45 CI: 73%, 99%) control participants completed their assessment. No intervention-related  
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50 46 adverse events were reported. Among eligible survivors who declined study participation  
51  
52 47 (n=83), inconvenience (78%; 95% CI: 69%, 87%) was the most common barrier.  
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3 48 Conclusions: The trial was feasible to deliver based on the a priori feasibility criteria.  
4  
5 49 Enhancing recruitment and adherence in a definitive trial will require designs that promote  
6  
7 50 convenience and consider ECS-reported barriers.  
8

9  
10 51 Trial Registration: ClinicalTrials.gov identifier: NCT02433080, 20 April 2015  
11

12 52 Trial funding: University College London, St. Bartholomew's Hospital Nurses League, and  
13  
14 53 NIHR University College London Hospitals Biomedical Research Centre  
15

16  
17 54 **Keywords**  
18

19  
20 55 Endometrial cancer, survivorship, behaviour change, healthy eating, physical activity,  
21  
22 56 intervention  
23

24  
25 57 **Strengths and limitations of this study**  
26

- 27  
28 58 • This trial tested the feasibility of a standardised theory-based behavioural lifestyle  
29  
30 59 programme for endometrial cancer survivors using a robust randomised parallel  
31  
32 60 design.  
33  
34 61 • Barriers to participation were systematically assessed.  
35  
36 62 • The study aimed to minimise these barriers by recruiting survivors within the  
37  
38 63 “teachable moment” period and capitalizing on the endorsement of the study from  
39  
40 64 their clinicians.  
41  
42 65 • The small sample size and recruitment from London-based hospitals limit the  
43  
44 66 generalisability of the outcomes.  
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## 67 Introduction

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

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

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

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3 92 participants, potential adverse events, barriers to participation, reasons for attrition, and  
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5 93 participants' study experience <sup>15</sup>.  
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7

## 8 94 **Methods**

### 9 10 11 95 **Study design and participants**

12  
13  
14 96 The trial protocol has been published.<sup>15</sup> The DEUS (Diet and Exercise in Uterine Cancer  
15  
16 97 Survivors) pilot trial was an eight-week, two-arm, parallel, controlled pilot trial with 1:1  
17  
18 98 randomisation comparing the use of the "Shape-Up following cancer treatment" programme  
19  
20 99 to care as usual.

21  
22  
23 100 Women aged ≥18 years who had been diagnosed with endometrial cancer (ICD C54.1)  
24  
25 101 within the previous 36 months were eligible to take part in the study. Women were excluded  
26  
27 102 if (a) they were diagnosed with stage IVB cancer; (b) they were on active anti-cancer, and/or  
28  
29 103 palliative treatment; (c) they had a second primary cancer; (d) they lacked mental capacity to  
30  
31 104 decide to take part in the study and to participate in it; (e) they had severe depression; (f)  
32  
33 105 they were unavailable for longitudinal follow-up assessments; (g) they had participated in a  
34  
35 106 professionally delivered weight loss or exercise programme during the previous 6 months;  
36  
37 107 (h) their performance score was 3-4<sup>16</sup> (i) or they were unable to understand spoken and  
38  
39 108 written English.

40  
41  
42 109 At the 5<sup>th</sup> week of recruitment, the inclusion criterion "women willing to attend all sessions"  
43  
44 110 was removed given the subjective nature of its interpretation and the exclusion criterion  
45  
46 111 "women with secondary cancer" was added to ensure homogeneity.  
47

### 48 49 112 **Recruitment**

50  
51  
52 113 Potential participants were recruited from the gynaecology outpatient clinics at University  
53  
54 114 College London Hospitals (UCLH) and Barts Health. Interested and potentially eligible  
55  
56 115 participants were introduced to the study by clinicians and researchers attending the clinics  
57  
58 116 as previously described.<sup>15</sup>  
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2  
3 117 The clinicians at UCLH also identified potential participants that had been treated there but  
4  
5 118 followed up at local sites. Following GP's verification that the patients were alive, invitation  
6  
7 119 letters signed by the consultant were sent to these women together with the participant  
8  
9 120 information sheet, an opt-in form, a barriers to participation survey, and a business reply  
10  
11 121 envelope.

## 12 123 13 124 14 125 **Randomisation and blinding**

15  
16  
17 123 Consented participants were randomised with a 1:1 allocation to receive either the  
18  
19 124 intervention or usual care through minimization using age and BMI as stratified variables.  
20  
21 125 The process has been previously described in detail.<sup>15</sup> The researcher assessing the 8-week  
22  
23 126 outcomes (MM) was blinded to intervention allocation and participants were requested prior  
24  
25 127 to the assessment not to disclose their allocation.

## 26 27 28 128 **Shape-Up following cancer treatment intervention**

29  
30  
31 129 In addition to usual care, intervention arm participants received the "Shape-Up following  
32  
33 130 cancer treatment" manual and were assigned to groups of three to eight, although the initial  
34  
35 131 plan was that they would be assigned in groups of eight. The allocation to groups was on a  
36  
37 132 first-come first-served basis to avoid delays in delivering the intervention to randomised  
38  
39 133 participants and aimed to match participant preferences for dates and times of the group  
40  
41 134 meetings. The five groups met weekly for eight weeks at UCLH. Each session lasted  
42  
43 135 approximately 90 minutes. The theory-based intervention has been previously described.<sup>15</sup>  
44  
45 136 In brief, it included advice on healthy eating, physical activity, management of triggers of  
46  
47 137 unhealthy behaviours, and behavioural relapse prevention. A dietitian (DAK) trained on the  
48  
49 138 programme facilitated the group sessions following a standardized and scripted protocol. An  
50  
51 139 extra trained provider (psychologist or dietitian) attended the meetings of the four groups to  
52  
53 140 aid with facilitation but did not participate in the discussion. DAK was the only facilitator in  
54  
55 141 the last group because of last minute cancellations. The participants in the fourth and final  
56  
57 142 round of randomisation were split into two small intervention groups for convenience  
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3 143 purposes. A participant from the control group that had completed the study was invited to  
4  
5 144 participate in the last group (final n=4 in group 5) to enhance the group experience but was  
6  
7 145 not included in the analysis. There were no other modifications. The completed CONSORT<sup>17</sup>  
8  
9 146 and TIDieR checklists<sup>18</sup> are available in Supplementary appendix S1 and S2, respectively.

#### 11 12 147 **Care as usual**

13  
14  
15 148 Participants in the control arm were offered usual care. After the final follow-up, they  
16  
17 149 received a booklet with healthy lifestyle advice for cancer survivors.<sup>19</sup>

#### 18 19 20 150 **Outcomes**

21  
22  
23 151 Recruitment rates were calculated separately for each strategy and site. We adapted an  
24  
25 152 existing framework of hierarchical recruitment barriers (availability by disease characteristics,  
26  
27 153 eligibility, physician triage, trial discussion, interest, consent, and enrolment)<sup>20</sup> to describe  
28  
29 154 the recruitment process. In contrast with the original framework, the category “interest”  
30  
31 155 preceded that of “trial discussed” to fit the current recruitment process. Participants who  
32  
33 156 were introduced to the study and decided not to enrol completed a 25-item investigator-  
34  
35 157 designed survey<sup>21</sup> about barriers to participation. Eight UCLH clinicians were interviewed  
36  
37 158 about their views on study recruitment using a semi-structured protocol by phone or face to  
38  
39 159 face (Supplementary appendix S3).

40  
41  
42 160 Participants attended a 90-minute baseline site visit with a trained researcher (DAK) to  
43  
44 161 complete their measurements and questionnaires. The visit was repeated at 8- and 24-  
45  
46 162 weeks with MM and DAK, respectively. All intervention sessions were audiotaped. RJB  
47  
48 163 attended one intervention session and one study assessment and scored them against a  
49  
50 164 predefined checklist. Engaged intervention-arm participants completed and posted an 18-  
51  
52 165 item programme evaluation questionnaire.<sup>22</sup> Only two follow-up qualitative interviews with  
53  
54 166 intervention participants were performed at study completion, as the data from the open-  
55  
56 167 ended feedback questionnaire were deemed sufficient.

## 168 **Statistical and qualitative analysis**

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

173 Primary outcomes are reported in proportions with 95% confidence intervals (CIs).  
174 Descriptive statistics are reported for continuous variables. Categorical variables are  
175 summarized using frequencies and percentages. The interviews with clinicians lasted 10  
176 minutes on average, were digitally recorded, transcribed verbatim by a professional  
177 company, and checked for accuracy. Given the structured interview and short replies, data  
178 were analysed with content analysis using NVivo version 10 (QSR International Pty Ltd,  
179 2014) software. The open-ended questions were analysed using manifest content analysis<sup>23</sup>  
180 in Microsoft Office Excel 2011. This process involved determining the frequency of words  
181 and content in the text.

## 182 **Results**

### 183 **Recruitment**

184 Recruitment took place over a period of 27 and 18 weeks (April 2015 – December 2015) at  
185 UCLH and Barts Health, respectively (Figure S1, Supplementary appendix S3). The  
186 difference in recruitment period between sites was primarily explained by substantial delay of  
187 NHS Research and Development (R&D) management approval at Barts Health. Among the  
188 first 64 eligible participants approached, 20 consented to participate, leading to rejection of  
189 the null hypothesis that recruitment would be  $\leq 15\%$ . Therefore, recruitment continued for  
190 enrolling the projected sample of 64 participants but stopped after enrolling 60 participants  
191 due to resource constraints. Out of 296 potentially eligible participants, 20.3% (95% CI: 15.7,  
192 24.9) enrolled in the study. Among screened participants, rates of consent were similar for



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2  
3 193 the face-to-face recruitment at the two recruitment sites but lower for the mail out (Table S1  
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5 194 and Table S2).

6  
7  
8 195 Reasons for non-participation were documented for 36.7% (n=83) of those who were  
9  
10 196 potentially eligible but did not consent and 90.2% of those that were approached.  
11  
12 197 Inconvenience to everyday life (78%) and transport to trial site (63%) were the main barriers  
13  
14 198 to participation, with further barriers detailed in Table 1 and less frequent barriers in Table  
15  
16 199 S3. The CONSORT flow diagram shows the progress through the trial stages (Figure 1).

### 17 18 19 200 **Clinicians' views on recruitment**

20  
21  
22 201 Clinicians were supportive of the study and did not have particular concerns about  
23  
24 202 introducing the study to patients. They felt the study might be beneficial to patients, but they  
25  
26 203 believed travelling and commitment would be the main barriers for recruitment.

27  
28  
29 204 They deemed the recruitment strategy highly effective, with potentially eligible patients being  
30  
31 205 flagged prior to the clinic, researchers being present and reminding them about approaching  
32  
33 206 patients, and through the existence of a separate space for study recruitment in the clinic.  
34  
35 207 These strategies minimized additional clinician workload.

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38 208 Clinicians did not anticipate adverse events from the intervention or changes in their  
39  
40 209 relationship with the patients. The framing and content of such an intervention was also  
41  
42 210 highlighted as a potential barrier to recruitment. In particular, approaching patients in a non-  
43  
44 211 discriminatory way was deemed to enhance recruitment. Furthermore, framing of its content  
45  
46 212 as a lifestyle programme was thought to be superior to a weight loss programme, strict diet  
47  
48 213 regime, or educational programme.

### 49 50 214 **Sample characteristics**

51  
52  
53 215 Participant characteristics at baseline are shown in Table 2. Women were on average ( $\pm$ SD)  
54  
55 216  $62.1 \pm 8.3$  years old, White (67%), married (53%),  $1.2 \pm 1.0$  years from diagnosis, with a BMI

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2  
3 217 of 28.0 ± 6.3kg/m<sup>2</sup>. They were diagnosed mostly with stage IA (49%), type 1 (82%)  
4  
5 218 endometrial cancer.

### 219 **Adherence**

220 Out of 26 participants in the intervention arm, 21 (81%; 95% CI: 66%, 96%) engaged and 20  
221 (77%; 95% CI: 61%, 93%) adhered to the intervention, based on our pre-determined criteria  
222 <sup>15</sup>. The lower confidence limit was above 60% indicating feasibility.

223 The percentage of participants who attended zero, five, six, seven, and eight (all) sessions  
224 was 15%, 8%, 12%, 35%, 15%, respectively. The mean overall attendance of sessions was  
225 63% (95% CI: 49%, 77%). The mean attendance rates of those who engaged and those who  
226 adhered were 79% (95% CI: 70%, 88%) and 82% (95% CI: 74%, 89%), respectively.  
227 Reasons for not commencing the intervention (i.e. attendance of zero sessions) included  
228 inconvenience to everyday life (n=1), family commitments (n=1), lack of perceived benefit  
229 (n=1), or travel burden (n=1). The remaining two dropouts occurred in the first two sessions  
230 due to program content and travelling abroad. Absence from the group sessions among  
231 adhered participants were mostly of practical nature, with details available in Supplementary  
232 appendix S3.

### 233 **Programme satisfaction**

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

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3 242 A range of topics were regarded as most useful (Figure S2). Among them, most participants  
4  
5 243 agreed that the sections about keeping an eye on portion sizes, food labelling, and internal  
6  
7 244 triggers were the most useful. Others mentioned self-incentives, internal and external  
8  
9 245 triggers, and getting a healthier balance of foods to be the least useful topics (Figure S3).  
10  
11 246 For example, one participant mentioned:

12  
13  
14 247 *I also did not understand the concept of the rewards - better health*  
15  
16 248 *should be its own reward (Participant in group 4).*

17  
18 249 Suggestions for additions to the programme were primarily focused on physical activity, such  
19  
20 250 as provision of relevant DVDs, physical activity during the programme sessions, and diaries  
21  
22 251 to report physical activity and sedentary behaviour in more detail. Most participants did not  
23  
24 252 consider that topics should be eliminated from the programme. Similar feedback was  
25  
26 253 provided for the booklet; most participants did not suggest changes while a few suggested  
27  
28 254 design changes. Further suggestions included the addition of follow-up support and a  
29  
30 255 preference for a larger group (mentioned by participants in smaller groups) to boost the  
31  
32 256 peer-education component.

33  
34  
35 257 Peer support of the group, both the focus of the programme and their own interest in health  
36  
37 258 promotion, the feeling of giving back to the care system, the facilitators, and the doctor's  
38  
39 259 referral to the programme facilitated study participation. In contrast, most did not report  
40  
41 260 factors discouraging them to participate but some mentioned inconvenience to everyday life,  
42  
43 261 self-monitoring and identification as a cancer survivor.

44  
45  
46 262 Regarding the trial procedures, two participants mentioned their difficulty recalling and  
47  
48 263 quantifying their diet and physical activity. Excellent fidelity to the protocol for both the group  
49  
50 264 sessions (85%) and the assessments (100%) was demonstrated in the study auditing.

51  
52  
53 265 **Retention**

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3 266 Retention rate was 92% (95% CI: 85%, 100%), with 24/28 (86%; 95% CI: 73%, 99%) and  
4  
5 267 25/26 (96%; 95% CI: 89%, 100%) eligible participants in the control and intervention arm  
6  
7 268 completing all assessments, respectively ( $P=0.61$  for difference between proportions). This  
8  
9 269 indicated an absence of attrition bias and the rejection of the null hypothesis that retention  
10  
11 270 rate would be less than 60%.

#### 14 271 **Adverse events and control arm contamination**

15  
16  
17 272 No intervention-related adverse events or unintended consequences were reported. Adverse  
18  
19 273 events unrelated to the intervention and reasons for control arm contamination are detailed  
20  
21 274 in the Supplementary appendix S3.

#### 24 275 **Discussion**

25  
26  
27 276 This is the first pilot study of a health behaviour change intervention in endometrial cancer  
28  
29 277 survivors in the UK to demonstrate feasibility in terms of recruitment, adherence, and  
30  
31 278 retention. The collaboration of the clinical and research team led to an efficient recruitment  
32  
33 279 process. Participants rated the programme highly and provided rich feedback for refinement.  
34  
35 280 Consistent with the literature<sup>24</sup> and the qualitative findings,<sup>7</sup> the DEUS pilot study aimed to  
36  
37 281 minimize accrual barriers by enrolling survivors within the “teachable moment” period,  
38  
39 282 capitalizing on the endorsement of the study from survivors’ clinicians, utilizing a strong  
40  
41 283 behaviour theory-based design, and ensuring standardized delivery of the intervention.  
42  
43 284 These study strengths were also reflected in the reported factors associated with programme  
44  
45 285 involvement. Furthermore, the frameworks for reporting barriers to participation<sup>20 21</sup> provided  
46  
47 286 a comprehensive understanding of these barriers and can be a valuable resource to  
48  
49 287 understand barriers in for future trials.<sup>25</sup> Limitations of the study include the small sample  
50  
51 288 size, recruitment from only two London-based sites, generalizability of the recruited sample,  
52  
53 289 as socio-demographic data from decliners were missing. The relatively low median BMI of  
54  
55 290 participants compared to epidemiological studies<sup>26</sup> indicates healthy volunteer effect biases.  
56  
57 291 The wide socio-economic and demographic differences of the population pools of the two  
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3 292 hospitals<sup>27</sup> and the similar recruitment rates at both sites were reassuring and suggest these  
4  
5 293 factors should not impact recruitment and retention.  
6

7  
8 294 The focus of the study on healthy lifestyle changes rather than weight loss was postulated to  
9  
10 295 increase uptake and acceptability of the programme.<sup>7</sup> The overall recruitment estimate was  
11  
12 296 similar or somewhat higher than that in other lifestyle intervention trials, although differences  
13  
14 297 in recruitment strategies, eligibility criteria, cancer site, programme length and intensity do  
15  
16 298 not allow for direct comparisons. The group-based, six-month SUCCEED intervention had a  
17  
18 299 19% recruitment rate using mail-out.<sup>12</sup> A 12-week group-based physical activity intervention  
19  
20 300 recruited 20% of the eligible endometrial cancer survivors through fliers and telephone  
21  
22 301 recruitment.<sup>28</sup> Similar to DEUS, a more intensive lifestyle intervention in UK breast cancer  
23  
24 302 survivors had a mail-out rate of 17%.<sup>29</sup> While removing the transport and time barriers would  
25  
26 303 theoretically improve recruitment rates, USA home-based lifestyle interventions recruiting  
27  
28 304 cancer survivors from registries have shown much smaller recruitment rates (5.7%) with  
29  
30 305 women, younger, White survivors and those closer to their cancer diagnosis more likely to  
31  
32 306 enrol.<sup>30</sup>  
33

34  
35 307 The observed adherence was lower compared with the weight loss SUCCEED intervention  
36  
37 308 (84.1%) comprising of 16 group sessions<sup>12</sup> but similar to that of a group-based 12-week  
38  
39 309 physical activity intervention.<sup>28</sup> While this might indicate that survivors are more committed in  
40  
41 310 weight loss programmes compared to healthy lifestyle programmes, the main reported  
42  
43 311 reasons regarding non-attendance in the current study were around practicalities and life  
44  
45 312 commitments rather than disengagement with the programme. Sending a standardized e-  
46  
47 313 mail to non-attendees about topics covered in the missed session and preparation for the  
48  
49 314 next session helped maintain their engagement.  
50

51  
52 315 Having a specific research room and two committed researchers in clinic facilitated  
53  
54 316 recruitment. Screening participants using electronic forms and implementing further pre-  
55  
56 317 randomisation eligibility checks from medical notes could minimize randomisation of  
57  
58 318 ineligible participants. The recruitment rate, while similar between the two sites, was lower in  
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3 319 the clinician-endorsed mail-out, indicating the higher effectiveness of the first approach that  
4  
5 320 needs to be balanced with its higher resource requirements in larger trials. Practical reasons  
6  
7 321 rendered intervention adherence acceptable but not optimal. The difficulty of trying to  
8  
9 322 arrange a weekly group meeting with approximately eight people was evident, although a  
10  
11 323 range of potential times was offered to participants and involved working around the logistics  
12  
13 324 to find the most convenient date. Given the wide variability of participants' availability,  
14  
15 325 simultaneous offers of a group on a weekday early evening or Saturday morning facilitated  
16  
17 326 engagement in Groups 2 and 3. In future studies, larger groups will be possible by un-  
18  
19 327 blinding investigators after enough participants are allocated to each trial arm to run two  
20  
21 328 groups.

22  
23  
24 329 Opting for the group-based and face-to-face design aimed to meet survivors' preferences<sup>7</sup>  
25  
26 330 but was in contrast with some previous studies reporting proximity as a particular barrier in  
27  
28 331 this population.<sup>24</sup> The lack of dropouts after the second group session indicated the overall  
29  
30 332 acceptability of the intervention and the favourable rating of most programme aspects  
31  
32 333 provides confidence that only minor content adaptations are needed before testing the study  
33  
34 334 in a large trial. As multiple facilitators will deliver the intervention in a pragmatic setting,  
35  
36 335 future large-scale trials should also measure differences in intervention delivery between  
37  
38 336 various facilitators. Inconvenience and transport were the main barriers to accrual in the  
39  
40 337 current study. Increasing reach might be more feasible with blended designs of group  
41  
42 338 meetings and remote intervention delivery, especially as home-based interventions have  
43  
44 339 typically experienced much lower recruitment rates compared with group-based  
45  
46 340 interventions. In the current programme, even those who adhered mentioned convenience  
47  
48 341 reasons as discouraging participation but the peer support as encouraging. This might  
49  
50 342 suggest delivering some sessions in person and others remotely, potentially through web or  
51  
52 343 mobile technology. A pilot weight loss study with endometrial and breast cancer survivors  
53  
54 344 delivered via a mobile application has shown promising results in a pre-post design.<sup>31</sup>  
55  
56 345 However, further research on mobile applications for weight management is needed, as  
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2  
3 346 most lack evidence-based behaviour change techniques, involvement of health care  
4  
5 347 professionals and scientific evaluation.<sup>32</sup>  
6  
7

8 348 In conclusion, this self-help lifestyle intervention trial was feasible in terms of recruitment,  
9  
10 349 adherence, and retention. Scaling the trial will require close monitoring of recruitment and  
11  
12 350 attempts should be made to reduce the burden on participants. Further qualitative work  
13  
14 351 could inform a blended in-person and remote design to enhance adherence while retaining  
15  
16 352 the valued peer support. This should be considered before proceeding to a definitive trial.  
17

18 353 Overall, the lessons learnt from this pilot should inform the design of future studies in this  
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20 354 area.  
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3 355 **Full protocol availability**  
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6 356 The full protocol of the study has been previously published<sup>15</sup> and it can also be found in the  
7  
8 357 Supplementary Appendix S4.  
9

10  
11 358 **Funding**  
12

13  
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15  
16 360 Hospital Nurses League, the Department of Women's Cancer at The UCL EGA Institute for  
17  
18 361 Women's Health, and NIHR University College London Hospitals Biomedical Research  
19  
20 362 Centre, London, UK. The funders had no role in the study design; collection, management,  
21  
22 363 analysis, and interpretation of data; writing of the report; and the decision to submit the  
23  
24 364 report for publication.  
25

26  
27 365 **Competing interests' statement**  
28

29  
30 366 DAK and RJB are volunteers for the charity Weight Concern, which developed the original  
31  
32 367 Shape-Up programme for the general population. All other authors have no conflicts of  
33  
34 368 interest to declare.  
35

36  
37 369 **Contribution to Authorship**  
38

39  
40 370 The authors' contributions were as follows. Anne Lanceley (AL) and M. Tish Knobf (MTK)  
41  
42 371 conceived the study and were the grant holders. AL and Ranjit Manchanda (RM) were the  
43  
44 372 site investigators for University College London Hospitals and Barts Health, respectively.  
45  
46 373 Dimitrios A. Koutoukidis (DAK), AL, Rebecca J Beeken (RJB) and MTK initiated the study  
47  
48 374 design, and RM helped with protocol development and implementation. DAK and Moscho  
49  
50 375 Michalopoulou (MM) recruited the study participants. RJB was responsible for randomisation  
51  
52 376 and auditing. DAK was the trial manager, ran the group sessions, and conducted the  
53  
54 377 baseline and 24-week follow-up assessments. MM conducted the 8-week follow-up  
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56 378 assessments. Matthew Burnell (MB) provided the statistical support, and DAK conducted the  
57  
58 379 statistical analysis. DAK drafted the manuscript, which was amended following comments  
59  
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3 380 from all other authors. All authors read and approved the submitted manuscript. All listed  
4  
5 381 authors meet the criteria for authorship and no individual meeting these criteria has been  
6  
7 382 omitted.

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13 384 The authors would like to thank the study participants, the second facilitators, the external  
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16  
17 386 Institute of Sport Exercise and Health for providing the resources for the study assessments.

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20 387 **Ethical approval**

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22  
23 388 The study protocol and documents have been reviewed and approved by the relevant  
24  
25 389 sponsor and National Research Ethics Service Committee London - City Road and  
26  
27 390 Hampstead (Reference: 15/LO/0154).

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30 391 **Availability of data and materials**

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33 392 The materials and datasets used and/or analysed during the current study available from the  
34  
35 393 corresponding author on reasonable request.  
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394 **References**

- 395 1. Global Burden of Disease Cancer C, Fitzmaurice C, Allen C, et al. Global, Regional, and National  
396 Cancer Incidence, Mortality, Years of Life Lost, Years Lived With Disability, and Disability-  
397 Adjusted Life-years for 32 Cancer Groups, 1990 to 2015: A Systematic Analysis for the Global  
398 Burden of Disease Study. *JAMA Oncol* 2016.
- 399 2. Quaresma M, Coleman MP, Rachet B. 40-year trends in an index of survival for all cancers  
400 combined and survival adjusted for age and sex for each cancer in England and Wales, 1971-  
401 2011: a population-based study. *Lancet* 2015;**385**(9974):1206-18.
- 402 3. Leach CR, Weaver KE, Aziz NM, et al. The complex health profile of long-term cancer survivors:  
403 prevalence and predictors of comorbid conditions. *J Cancer Surviv* 2015;**9**(2):239-51.
- 404 4. Ward KK, Shah NR, Saenz CC, et al. Cardiovascular disease is the leading cause of death among  
405 endometrial cancer patients. *Gynecol Oncol* 2012;**126**(2):176-9.
- 406 5. Koutoukidis DA, Knobf MT, Lanceley A. Obesity, diet, physical activity, and health-related quality  
407 of life in endometrial cancer survivors. *Nutr Rev* 2015;**73**(6):399-408.
- 408 6. von Gruenigen VE, Waggoner SE, Frasure HE, et al. Lifestyle challenges in endometrial cancer  
409 survivorship. *Obstet Gynecol* 2011;**117**(1):93-100.
- 410 7. Koutoukidis DA, Beeken RJ, Lopes S, et al. Attitudes, challenges, and needs about diet and physical  
411 activity in endometrial cancer survivors: a qualitative study. *Eur J Cancer Care (Engl)* 2016.
- 412 8. Zhu G, Zhang X, Wang Y, et al. Effects of exercise intervention in breast cancer survivors: a meta-  
413 analysis of 33 randomized controlled trials. *Onco Targets Ther* 2016;**9**:2153-68.
- 414 9. Stacey FG, James EL, Chapman K, et al. A systematic review and meta-analysis of social cognitive  
415 theory-based physical activity and/or nutrition behavior change interventions for cancer  
416 survivors. *J Cancer Surviv* 2014.
- 417 10. Morey MC, Snyder DC, Sloane R, et al. Effects of home-based diet and exercise on functional  
418 outcomes among older, overweight long-term cancer survivors: RENEW: a randomized  
419 controlled trial. *JAMA* 2009;**301**(18):1883-91.

- 1  
2  
3 420 11. von Gruenigen VE, Gibbons HE, Kavanagh MB, et al. A randomized trial of a lifestyle intervention  
4  
5 421 in obese endometrial cancer survivors: quality of life outcomes and mediators of behavior  
6  
7 422 change. *Health Qual Life Outcomes* 2009;**7**:17.  
8  
9 423 12. von Gruenigen V, Frasure H, Kavanagh MB, et al. Survivors of uterine cancer empowered by  
10  
11 424 exercise and healthy diet (SUCCEED): a randomized controlled trial. *Gynecol Oncol*  
12  
13 425 2012;**125**(3):699-704.  
14  
15 426 13. Wardle J, Liao LM, Rapoport L, et al. *Shape-Up: A lifestyle programme to manage your weight*.  
16  
17 427 London: Weight Concern, 2016.  
18  
19 428 14. Use of intervention mapping to adapt a lifestyle intervention for endometrial cancer survivors  
20  
21 429 International Congress of Behavioral Medicine; 2016; Melbourne, Australia.  
22  
23 430 15. Koutoukidis DA, Beeken RJ, Manchanda R, et al. Diet and exercise in uterine cancer survivors  
24  
25 431 (DEUS pilot) - piloting a healthy eating and physical activity program: study protocol for a  
26  
27 432 randomized controlled trial. *Trials* 2016;**17**(1):130.  
28  
29 433 16. Oken MM, Creech RH, Tormey DC, et al. Toxicity and response criteria of the Eastern Cooperative  
30  
31 434 Oncology Group. *Am J Clin Oncol* 1982;**5**(6):649-55.  
32  
33 435 17. Eldridge SM, Chan CL, Campbell MJ, et al. CONSORT 2010 statement: extension to randomised  
34  
35 436 pilot and feasibility trials. *Pilot and feasibility studies* 2016;**2**:64.  
36  
37 437 18. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for  
38  
39 438 intervention description and replication (TIDieR) checklist and guide. *Bmj* 2014;**348**:g1687.  
40  
41 439 19. WCRF. Healthy living after cancer. Secondary Healthy living after cancer 2015.  
42  
43 440 <https://www.wcrf-uk.org/sites/default/files/healthy-living-after-cancer-guide.pdf>.  
44  
45 441 20. Kanarek NF, Kanarek MS, Olatoye D, et al. Removing barriers to participation in clinical trials, a  
46  
47 442 conceptual framework and retrospective chart review study. *Trials* 2012;**13**:237.  
48  
49 443 21. Mills EJ, Seely D, Rachlis B, et al. Barriers to participation in clinical trials of cancer: a meta-  
50  
51 444 analysis and systematic review of patient-reported factors. *Lancet Oncol* 2006;**7**(2):141-8.  
52  
53  
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3 445 22. Queensland\_Health. Participant Satisfaction Survey. Secondary Participant Satisfaction Survey  
4  
5 446 2014. <http://www.health.qld.gov.au/stayonyourfeet/toolkits/phase4/tools-temp.asp>.  
6  
7 447 23. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. Qual Health Res  
8  
9 448 2005;**15**(9):1277-88.  
10  
11 449 24. Stull VB, Snyder DC, Demark-Wahnefried W. Lifestyle interventions in cancer survivors: designing  
12  
13 450 programs that meet the needs of this vulnerable and growing population. J Nutr 2007;**137**(1  
14  
15 451 Suppl):243S-48S.  
16  
17 452 25. Denicoff AM, McCaskill-Stevens W, Grubbs SS, et al. The National Cancer Institute-American  
18  
19 453 Society of Clinical Oncology Cancer Trial Accrual Symposium: summary and  
20  
21 454 recommendations. J Oncol Pract 2013;**9**(6):267-76.  
22  
23 455 26. Arem H, Park Y, Pelsler C, et al. Prediagnosis body mass index, physical activity, and mortality in  
24  
25 456 endometrial cancer patients. J Natl Cancer Inst 2013;**105**(5):342-9.  
26  
27 457 27. UKDE. Census 2011: Wards in London. Secondary Census 2011: Wards in London 2011.  
28  
29 458 <http://ukdataexplorer.com/census/london/#KS401EW0020>.  
30  
31 459 28. Rossi A, Garber CE, Ortiz M, et al. Feasibility of a physical activity intervention for obese,  
32  
33 460 socioculturally diverse endometrial cancer survivors. Gynecol Oncol 2016;**142**(2):304-10.  
34  
35 461 29. Scott E, Daley AJ, Doll H, et al. Effects of an exercise and hypocaloric healthy eating program on  
36  
37 462 biomarkers associated with long-term prognosis after early-stage breast cancer: a  
38  
39 463 randomized controlled trial. Cancer Causes Control 2013;**24**(1):181-91.  
40  
41 464 30. Adams RN, Mosher CE, Blair CK, et al. Cancer survivors' uptake and adherence in diet and  
42  
43 465 exercise intervention trials: An integrative data analysis. Cancer 2014.  
44  
45 466 31. McCarroll ML, Armbruster S, Pohle-Krauza RJ, et al. Feasibility of a lifestyle intervention for  
46  
47 467 overweight/obese endometrial and breast cancer survivors using an interactive mobile  
48  
49 468 application. Gynecol Oncol 2015;**137**(3):508-15.  
50  
51 469 32. Rivera J, McPherson A, Hamilton J, et al. Mobile Apps for Weight Management: A Scoping  
52  
53 470 Review. JMIR Mhealth Uhealth 2016;**4**(3):e87.  
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3 471 List of legends  
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5 472 Table 1 Percentage of each barrier to participation with standard error (SE) among eligible  
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7 473 survivors who declined participation (n=83)  
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10 474 Table 2 DEUS pilot trial baseline participant characteristics  
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13 475 Table 3 Percentage programme satisfaction (n=18)  
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15 476 Table 4 Helpfulness of the main behaviour change techniques for dietary and physical  
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17 477 activity changes (n=18)  
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20 478 Figure 1 CONSORT diagram of the trial with framework on barriers to participation in the  
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22 479 exclusion box  
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480 Table 1 Percentage of each barrier to participation with standard error (SE) among eligible  
 481 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)

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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 <sup>2</sup> (SD)	27.3 (6.5)	28.8 (6.1)	28.0 (6.3)
BMI, median kg/m <sup>2</sup> (IQR)	26.2 (24.3)	26.9 (8.6)	26.8 (61.4)
% 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

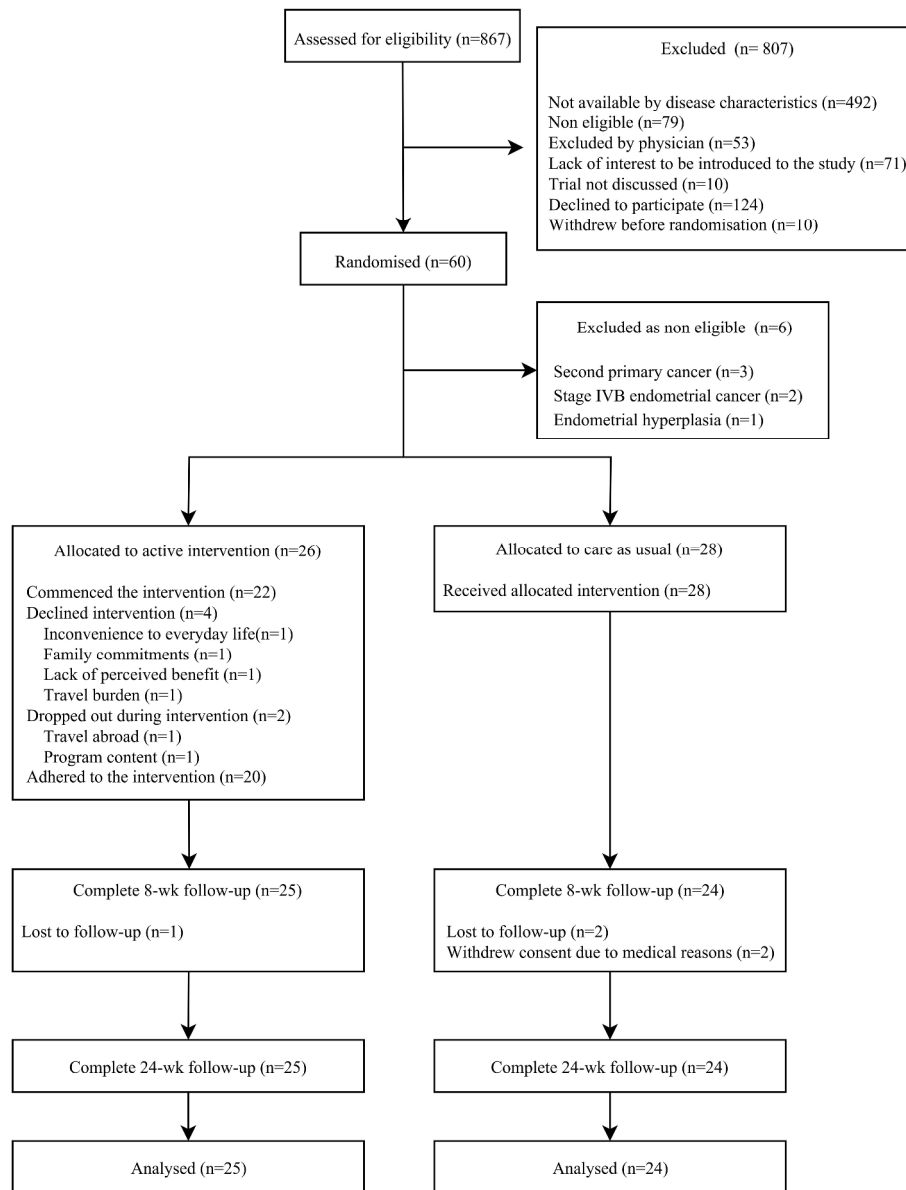
Body composition data for usual care n=23

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
<b>Title and abstract</b>			
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
<b>Introduction</b>			
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
<b>Methods</b>			
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

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3	Sample size:			
4	7a	How sample size was determined	Rationale for numbers in the pilot trial	Protocol paper
5	7b	When applicable, explanation of any interim analyses and stopping guidelines		n/a
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8	Randomisation:			
9	Sequence generation:			
10	8a	Method used to generate the random allocation sequence		6 and protocol paper
11	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
12				
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14	Allocation concealment mechanism:			
15	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
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18	Implementation:			
19	10	Who generated the random allocation sequence, enrolled participants, and assigned participants to interventions		Protocol paper
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26	Blinding:			
27	11a	If done, who was blinded after assignment to interventions (eg, participants, care providers, those assessing outcomes) and how		6 and protocol paper
28	11b	If relevant, description of the similarity of interventions		
29				
30	Analytical methods:			
31	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
32	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Not applicable	n/a
33				
34	<b>Results</b>			
35	Participant flow (a diagram is strongly recommended):			
36	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
37	13b	For each group, losses and exclusions after randomisation, together with reasons		Figure 2
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39	Recruitment:			
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3	14a	Dates defining the periods of recruitment and follow-up		8
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5	14b	Why the trial ended or was stopped	Why the pilot trial ended or was stopped	8
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7	Baseline data:			
8	15	A table showing baseline demographic and clinical characteristics for each group		Table 1
9				
10				
11	Numbers analysed:			
12	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
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18	Outcomes and estimation:			
19	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
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25	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable	n/a
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28	Ancillary analyses:			
29	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
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34	Harms:			
35	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)		12 and Suppl. material
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39	19a		If relevant, other important unintended consequences	n/a
40				
41	<b>Discussion</b>			
42				
43	Limitations:			
44	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
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47	Generalisability:			
48	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
49				
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51	Interpretation:			
52	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
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56	22a		Implications for progression from pilot to future definitive trial, including any proposed amendments	
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60	<b>Other information</b>			

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3 Registration:4 23 Registration number and name of trial Registration number for pilot trial and  
5 registry name of trial registry6  
7 Protocol:8 24 Where the full trial protocol can be Where the pilot trial protocol can be  
9 accessed, if available accessed, if available

## 10 Funding:

11 25 Sources of funding and other support  
12 (such as supply of drugs), role of  
13 funders14  
15 26 Ethical approval or approval by research  
16 review committee, confirmed with  
17 reference number

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18 \*Here a pilot trial means any randomised study conducted in preparation for a future definitive RCT, where the  
19 main objective of the pilot trial is to assess feasibility.  
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## ^^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)
1.	<b>BRIEF NAME</b> Provide the name or a phrase that describes the intervention.	Abstract	_____
2.	<b>WHY</b> 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)_____
3.	<b>WHAT</b> 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_____
5.	<b>WHO PROVIDED</b> 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_____

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3	<b>HOW</b>		
4	6. Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or	Shape-Up	_____
5	telephone) of the intervention and whether it was provided individually or in a group.	following cancer	
6		treatment	
7		intervention	
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10	<b>WHERE</b>		
11	7. Describe the type(s) of location(s) where the intervention occurred, including any necessary	Shape-Up	_____
12	infrastructure or relevant features.	following cancer	
13		treatment	
14		intervention	
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19	<b>WHEN and HOW MUCH</b>		
20	8. Describe the number of times the intervention was delivered and over what period of time including	Shape-Up	Protocol
21	the number of sessions, their schedule, and their duration, intensity or dose.	following cancer	paper_____
22		treatment	
23		intervention	
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27			
28	<b>TAILORING</b>		
29	9. If the intervention was planned to be personalised, titrated or adapted, then describe what, why,	Shape-Up	Protocol
30	when, and how.	following cancer	paper_____
31		treatment	
32		intervention	
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36	<b>MODIFICATIONS</b>		
37	10.† If the intervention was modified during the course of the study, describe the changes (what, why,	Shape-Up	_____
38	when, and how).	following cancer	
39		treatment	
40		intervention	
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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](http://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](http://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](http://www.equator-network.org)).

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3 **Supplementary appendix (S3)**  
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9 **Recruitment, adherence, and retention of endometrial cancer survivors in a**  
10 **behavioral lifestyle program: the Diet and Exercise in Uterine Cancer Survivors**  
11 **(DEUS) parallel randomized pilot trial**  
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19 Dimitrios A. Koutoukidis, Rebecca J. Beeken, Ranjit Manchanda, Moscho  
20 Michalopoulou, Matthew Burnell, M. Tish Knobf, Anne Lanceley  
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### 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?

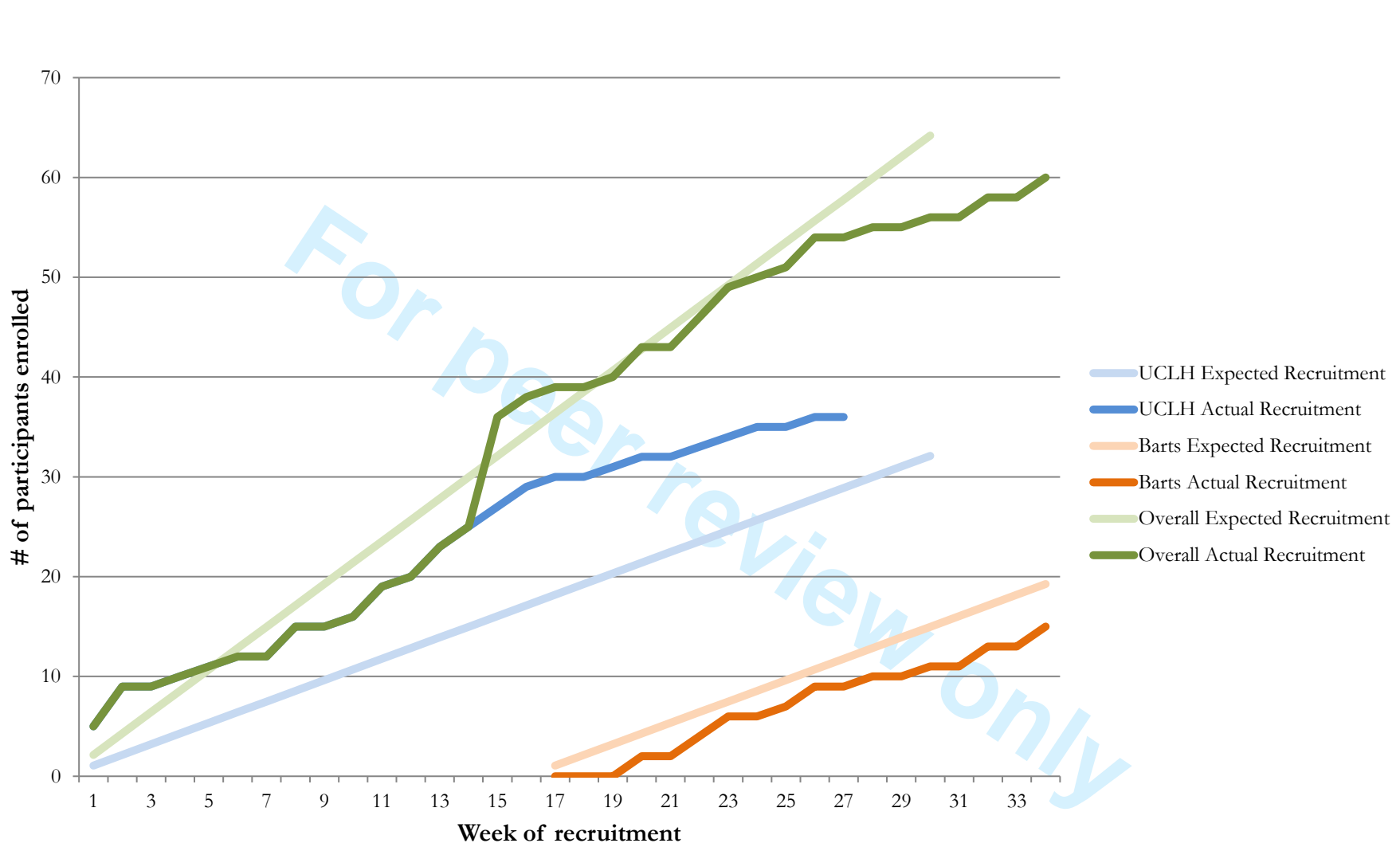


Figure S1 Projected and actual recruitment by site. The sharp spike in week 13 in overall recruitment indicated the recruited participants through mail out.

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

	UCLH	Barts	Hospitals combined	Mai-out	Total
<b>1. Women in gynecologic oncology clinic</b>	<b>2305</b>	<b>1047</b>	<b>3352</b>	<b>294</b>	<b>3646</b>
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
<b>2. Available for trial by disease characteristics</b>	<b>223</b>	<b>88</b>	<b>311</b>	<b>64</b>	<b>375</b>
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
<b>3. Eligible for participation</b>	<b>176</b>	<b>65</b>	<b>241</b>	<b>55</b>	<b>296</b>
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
<b>4. Physician Triage &amp; introduced to the study</b>	<b>140</b>	<b>48</b>	<b>188</b>	<b>55</b>	<b>243</b>
Not interested to hear about study	23	9	32	-	32
Long wait / too busy to talk about study	2	-	2	-	2
<b>5. Participants interested</b>	<b>115</b>	<b>39</b>	<b>154</b>	<b>18</b>	<b>172</b>
Lost in clinic - talking to other eligible participants	1	0	1		
<b>6. Trial discussed</b>	<b>114</b>	<b>39</b>	<b>153</b>	<b>9</b>	<b>162</b>
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
<b>7. Participant consented</b>	<b>46</b>	<b>15</b>	<b>61</b>	<b>9</b>	<b>70</b>
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
<b>8. Participant enrolled (randomized)</b>	<b>38</b>	<b>13</b>	<b>51</b>	<b>9</b>	<b>60</b>



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)

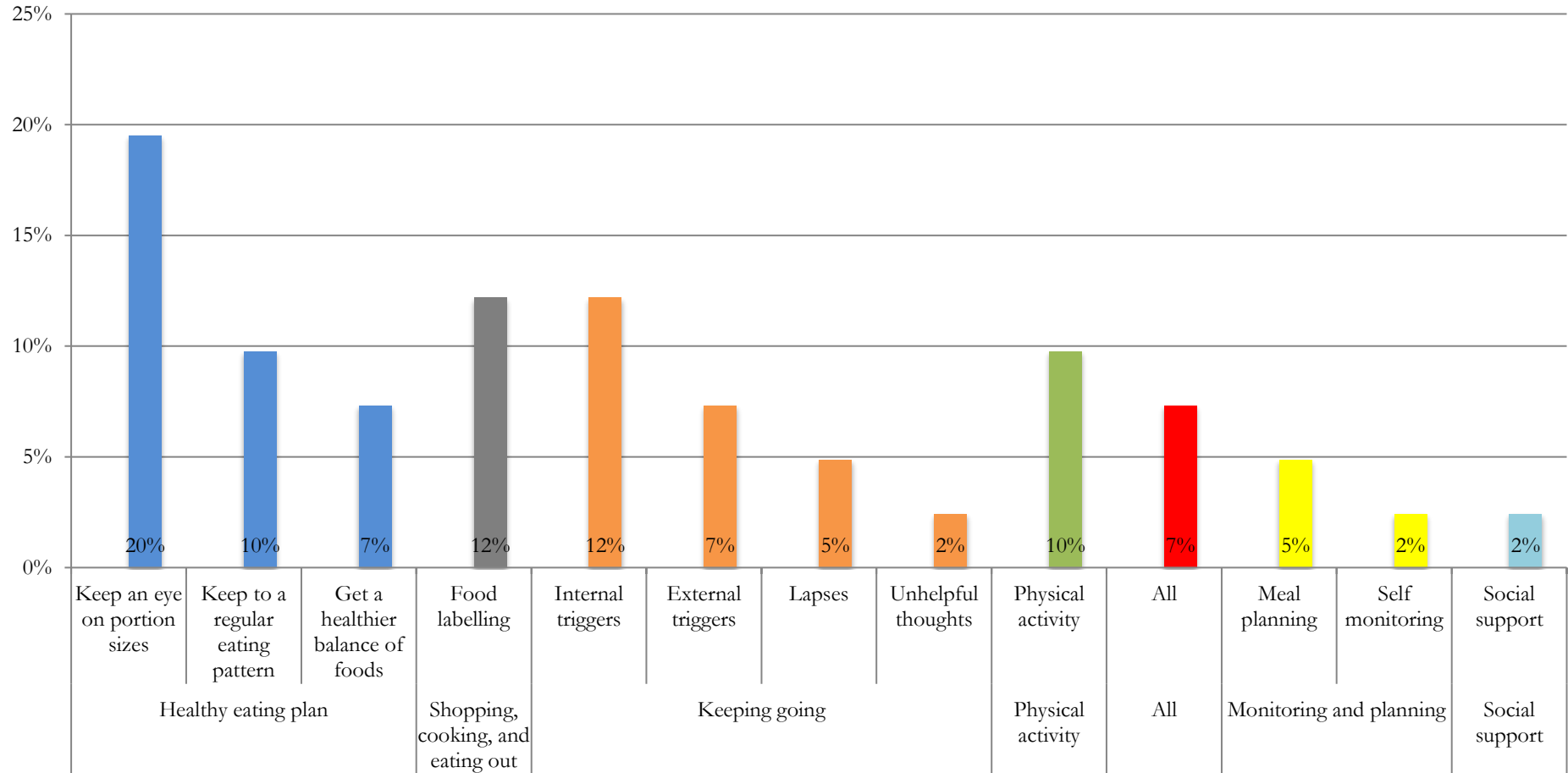


Figure S2 Percentage responses to the question "Which topic of the programme did you find the most useful?" by topic and programme section (in colour)

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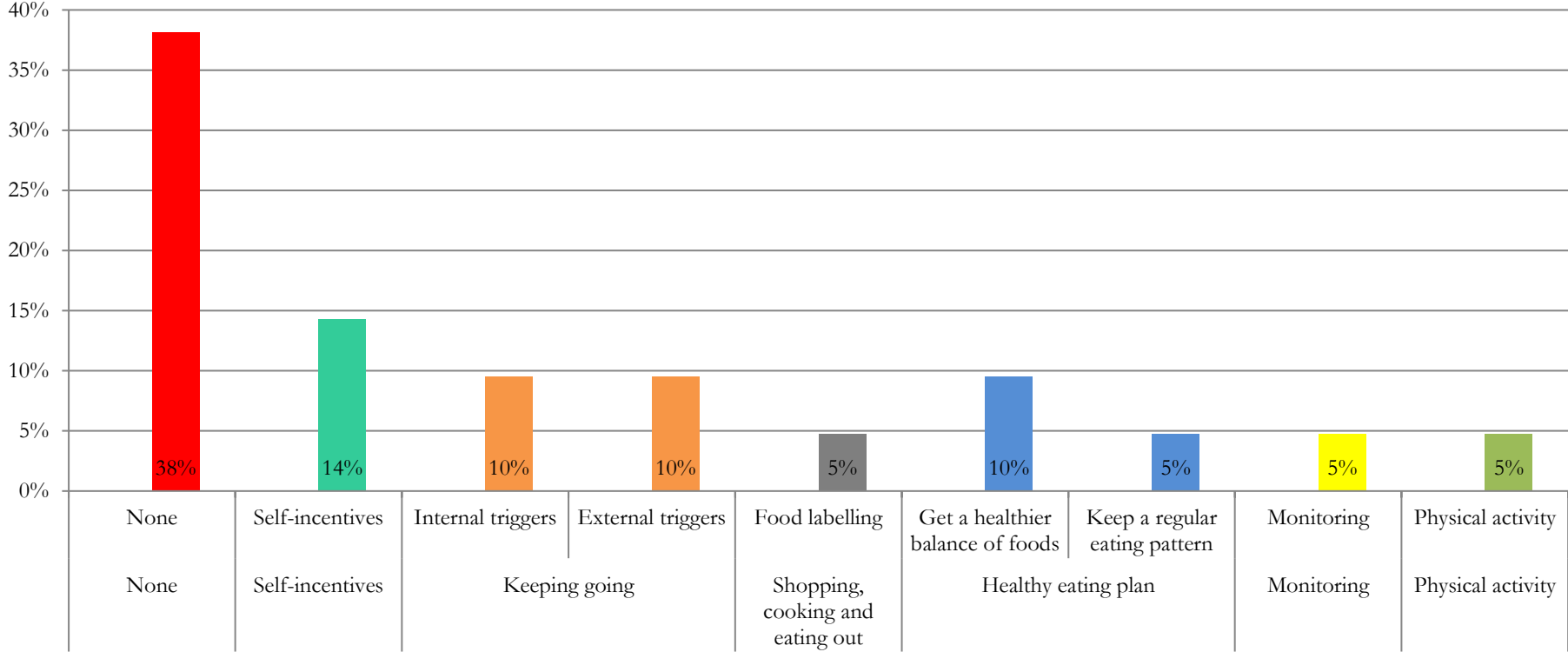


Figure S3 Percentage responses to the question "Which topic of the programme did you find the least useful?" by topic and programme section (in colour)

### 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.