

1 **Title Page**

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3 **Comparing hospital and telephone follow-up for patients treated for Stage I endometrial cancer**

4 **(ENDCAT Trial): a randomised, multicentre, non-inferiority trial**

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90 Short running title:

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92 Telephone follow-up for endometrial cancer

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94 **Comparing hospital and telephone follow-up for patients treated for Stage I endometrial cancer**
95 **(ENDCAT Trial): a randomised, multicentre, non-inferiority trial**

96

97

ABSTRACT

98 **Objective** To evaluate the effectiveness of nurse-led telephone follow-up (TFU) for Stage I endometrial
99 cancer patients.

100 **Design** Multicentre, randomised, non-inferiority trial

101 **Setting** Five centres in the North West of England

102 **Sample** 259 women treated for Stage I endometrial cancer attending hospital outpatient clinics for
103 routine follow-up

104 **Methods** Participants were randomly allocated to receive traditional hospital based follow-up (HFU) or
105 nurse-led TFU.

106 **Main outcome measures** Primary outcomes were psychological morbidity (State Trait Anxiety Inventory,
107 STAI-S) and patient satisfaction with information. Secondary outcomes included patient satisfaction with
108 service, quality of life, and time to detection of recurrence.

109 **Results** STAI-S scores post-randomisation were similar between groups (mean [SD] TFU 33.0 [11.0], HFU
110 35.5 [13.0]). The estimated between group difference in STAI was 0.7 (95%CI -1.9 to 3.3); the CI lies
111 above the non-inferiority limit (-3.5) indicating non-inferiority of TFU. There was no significant difference
112 between groups in reported satisfaction with information (OR 0.9, 95% CI 0.4 to 2.1, p=0.83). The HFU
113 group were more likely to report being kept waiting for their appointment (p=0.001), that they did not
114 need any information (p=0.003) and were less likely to report that the nurse knew about their particular
115 case and situation (p=0.005).

116 **Conclusions** TFU provides an effective alternative to HFU for Stage I endometrial cancer patients, with
117 no reported physical or psychological detriment. Patient satisfaction with information was high, with
118 similar levels between groups

119 **Keywords** Endometrial cancer, telephone follow-up, gynaecology, oncology, patient satisfaction,
120 psychological morbidity

121 **Word count:** 239

122

123 **Trial Registration Number:** ISRCTN75220876.

124

125 **Tweetable abstract** (108 characters with spaces)

126 ENDCAT trial shows effectiveness of nurse-led telephone follow-up for Stage I endometrial cancer

127 patients.

128 **INTRODUCTION**

129 Most (75%) endometrial cancer patients present with Stage I disease (confined to the uterus); five year
130 relative survival is over 70%.^{1,2} More than 80% of all recurrences occur during the first three years.³
131 Historically, patients in the United Kingdom (UK) have attended hospital outpatient appointments at
132 regular but decreasing intervals for a period of three to five years. However, routine clinical review after
133 gynaecology malignancy demonstrates little or no survival benefit; early detection of recurrence does
134 not improve outcome or reduce morbidity.²⁻⁴ A European study reported one asymptomatic recurrence
135 for every 653 routine consultations.⁵ Hence, there has been a call for prospective trials to evaluate
136 alternative follow-up strategies for gynaecological cancers.⁴

137

138 UK Department of Health (DoH) guidance suggests that women treated for endometrial cancer should
139 be informed about the lack of known benefit of follow-up, although retaining some degree of support
140 post treatment.⁶ The National Cancer Survivorship Initiative (NCSI) was key to the Cancer Reform
141 Strategy,⁷ aiming to improve services for cancer survivors in England and **advocating supported self-**
142 **management approaches to follow-up, accompanied by risk stratification (based on clinical and**
143 **individual need).**⁸ Current follow-up practice does not meet cancer survivors' full range of needs.^{8,9} A
144 recent rapid review of service provision following cancer treatment concluded that addressing the needs
145 of cancer survivors, particularly with the predicted increase in numbers, requires new models of follow-
146 up.¹⁰ There are also increasing financial pressures to devise more efficient care pathways. Alternative
147 strategies include nurse-led **and supported self-management** approaches. A systematic review of nurse-
148 led versus conventional physician-led follow-up for patients with cancer concluded that patients are
149 generally satisfied with nurse-led follow-up,¹¹ and a meta-analysis concluded that nurse-led telephone
150 follow-up (TFU) services were acceptable, appropriate and effective.¹² **Patients with early stage cancers**
151 **at low risk of recurrence could be empowered to take responsibility for their care if sufficiently**

152 supported, with rapid access back to secondary care if needed. Individual responsibility and self-
153 management have been highlighted as central principles for successful implementation of the 2015-
154 2020 strategy for improving cancer outcomes, empowering individuals to manage their own health care
155 needs¹³. However, the NCSI reported that these models needed further testing and evaluation.⁸ The
156 model we proposed for Stage I endometrial cancer follow-up built on previous studies of nurse-led TFU
157 for breast and colorectal cancer patients,¹⁴⁻¹⁶ demonstrating that specialist nurses can meet the
158 information needs and concerns of people treated for cancer, with no physical or psychological
159 detriment. We therefore designed a trial to test for non-inferiority of nurse-led TFU relative to
160 traditional hospital based follow-up (HFU) following treatment for Stage I endometrial cancer.

161

162 **METHODS**

163 **Study design and sample**

164 We carried out a two group, parallel, multicentre randomised non-inferiority trial in five hospitals in
165 North West England. Eligible patients had completed primary treatment for Stage I endometrial cancer
166 and were returning to hospital outpatient clinics for routine monitoring. We excluded patients if they
167 had hearing impairments or did not have access to a telephone. Patients were not excluded on the basis
168 of language difficulties as this would need to be addressed regardless of study group allocation. Patient
169 recruitment took place between 3rd January 2012 and 2nd January 2014.

170

171 **Randomisation and masking**

172 Patients were randomly assigned (1:1) to HFU or TFU using a computer based system. Randomisation
173 was performed using permuted blocks, with randomly varying block sizes, within 10 strata defined by
174 the combinations of the five hospitals and follow-up duration (less than 1 year or 1 year or more post
175 diagnosis). The trial statistician was masked to group allocation. It was not possible to mask clinical staff

176 or participants as they would have been aware that follow-up care was being delivered over the
177 telephone or in hospital clinics.

178

179 **Outcomes**

180 Primary outcomes were psychological morbidity and patient satisfaction with information. Secondary
181 outcomes included patient satisfaction with service, quality of life, and time to detection of recurrence.

182 We assessed non-inferiority in terms of effectiveness (for psychological morbidity, quality of life, and
183 time to detection of recurrence) and superiority in terms of patient satisfaction with information and
184 service. Time to detection of recurrence was defined as the time from randomisation to the date when
185 recurrence was communicated to the patient; we also report the time between the first indications of a
186 suspicion of recurrence to the date when recurrence was communicated to the patient.

187

188 Psychological morbidity was measured using a standard instrument, the State Trait Anxiety Inventory
189 (STAI).^{17,18} Patient satisfaction with information and service was recorded using questionnaires adapted
190 from previous work on breast cancer patients,¹⁴ with the question used for the primary outcome being
191 “Did you get all the information you needed at your hospital or telephone appointment?”. Participants
192 were asked about the frequency and duration of their appointments. Baseline and post-randomisation
193 questionnaires contained similar questions although some questions were re-worded post-
194 randomisation to reflect that patients could have had a hospital or telephone appointment. Quality of
195 life was measured using the European Organization for Research and Treatment (EORTC) QLQ-C30
196 (version 3) and a specific module for endometrial cancer (QLQ-EN24).^{19,20}

197

198

199 **Procedures**

200 Potential participants were identified by clinical staff in hospital outpatient clinics. All participants
201 completed baseline measures prior to randomisation. Patients allocated to HFU continued to receive
202 hospital based follow-up as per hospital policy at the study locations. This consisted of appointments
203 every three or four months for the first two years post treatment followed by appointments at
204 decreasing intervals (six monthly and annually) up to a period of three to five years. At the end of this
205 period, patients were discharged to the care of their General Practitioner (GP). Although there was no
206 standard format to hospital based consultations, they would usually include a clinical examination
207 (bimanual examination and inspection of the vagina) and questions about any signs of recurrent disease
208 (e.g. vaginal bleeding, unusual discharge). In the TFU arm, a telephone intervention was administered
209 by gynaecology oncology nurse specialists at intervals consistent with hospital policy at the study
210 locations. At each study site, the frequency of delivery of the telephone intervention would mirror the
211 frequency of scheduled hospital appointments for the control arm. Seven experienced gynaecology
212 oncology nurse specialists administered the telephone intervention during the study period; these
213 nurses had advanced practitioner roles with specialist knowledge and expertise in gynaecology. Patients
214 were sent appointment cards with a date and time for their telephone appointments. The intervention
215 was designed to be delivered in 20 minutes. Questions in the intervention were focused on physical,
216 psychological and social aspects of care (Appendix S1). Training on the delivery of the intervention
217 involved two half-day sessions, discussing issues related to telephone consultations, a detailed
218 exploration of each intervention item and the practicalities of setting up telephone clinics.

219

220 All outcome data were collected at baseline (pre-randomisation) and immediately after the next HFU or
221 TFU appointment (post-randomisation). The post-randomisation data collection time point depended on
222 whether women were on a three monthly, six monthly or annual follow-up schedule. Hence, the post-

223 randomisation time point could range from three to 12 months from baseline data collection. Study
224 participants were sent postal questionnaires, once formal written consent had been received, and were
225 asked to return the questionnaires in pre-paid envelopes to a university address. Careful attention was
226 paid to ensuring questionnaires were dispatched immediately post consultation to ensure women's
227 responses were targeted at the most recent hospital or telephone appointment. Introductory
228 information on questionnaires instructed participants to refer to their 'most recent appointment'. Data
229 on signs of recurrent disease were collected prospectively on 'record of clinic visit' and 'record of
230 telephone consultation' proformas for all participants at all consultations throughout the study period.
231 Participants' attendance at the next scheduled appointment (hospital or telephone) post-randomisation
232 acted as a trigger for posting out the post-randomisation questionnaires to study participants. A full
233 review of all participants' medical records was carried out at the end of the study follow-up period to
234 ensure all pertinent data had been captured on the clinical proformas. Any indication of recurrent
235 disease was monitored and tracked. Participants who were diagnosed with recurrence were withdrawn
236 from intervention delivery and trial follow-up but their clinical trajectory was monitored. Hence, data on
237 time to detection of recurrence could be reported.

238

239 **Sample size**

240 The sample size was based on a pre-stated margin of non-inferiority (3.5) for the intervention effect on
241 the STAI-S and data (SD 10) from a previous trial of TFU for breast cancer patients.¹⁴ We planned for 80%
242 power, a 5% significance level, and allowed for 20% attrition; the target sample size was 128 participants
243 per group. For the co-primary outcome of 'satisfaction with information' it was calculated that this
244 sample size would provide 80% power to detect an OR of at least 2.25 using ordinal regression
245 techniques (5% significance level) based on control percentages of: 'very satisfied' 54%, 'satisfied' 39%

246 and 'not very satisfied' or 'very unsatisfied' 7%, approximate values from our previous trial; however the
247 phrasing of the question was subsequently changed for use in ENDCAT. ¹⁴

248

249 **Statistical methods**

250 Analysis was performed using SPSS (V 22) and Stata (V 13). Demographic and baseline characteristics
251 were summarised using: mean (standard deviation), or median (inter-quartile range), as appropriate, if
252 quantitative (continuous or count); median (inter-quartile range) or frequency (percentage), as
253 appropriate, if ordinal; frequency (percentage) if categorical. Characteristics of participants and non-
254 participants were compared using chi-square test or independent samples t-test, as appropriate. The
255 primary statistical analysis of psychological morbidity (STAI S-anxiety) scores was based on an
256 instrumental variables regression analysis using the intervention group factor as instrument, with
257 participation/non-participation in the allocated follow-up appointment type at first follow-up as
258 mediator (a 'complier-adjuster' causal analysis). This is the approach which was used in our previous
259 breast cancer trial and enables comparison of findings between the two trials.¹⁴ The model used also
260 included the following baseline covariates to improve statistical efficiency: age, level of education
261 and/or occupational group, hospital (randomisation stratum), follow-up duration (less than or at least
262 one year post diagnosis at the time of recruitment), STAI S-anxiety, and STAI T-anxiety. Linear modelling,
263 adjusting for the same set of factors, was used for a comparable analysis of the effect of intervention
264 arm using 'as treated', 'as randomised' and 'per-protocol' (i.e. including only those who had their first
265 post-randomisation appointment in line with the randomisation) populations. For the analysis of
266 satisfaction with information received, ordinal logistic regression was used; those who did not need
267 information were excluded, although a sensitivity analysis was performed to investigate the impact of
268 handling this group differently (e.g. including them with those who reported that they got none of the

269 information they needed). Adjustment was for the same baseline factors as for the STAI-S, except the
270 STAI measures were not included whereas the satisfaction with information was included.

271
272 Similar approaches were used for the following secondary outcome measures: linear modelling for
273 overall satisfaction with service and ordinal logistic regression for satisfaction with individual aspects of
274 service; logistic regression for patient information needs; instrumental variables regression for EORTC
275 QLQ-C30 and EORTC QLQ-EN24 subscales. Adjustment used the same of baseline factors, but replacing
276 the STAI measures with the baseline measure of the corresponding outcome. For satisfaction with
277 individual aspects of service, the categories 'strongly agree' and 'agree' were merged, as were the
278 categories 'strongly disagree' and 'disagree', due to sparse categories. For any categorical outcome
279 measures, if categories remained sparse, Fisher's exact test was used (not adjusting for baseline factors).
280 Inferential results are presented as 95% confidence intervals (CIs), with p-value when testing superiority;
281 for testing, two-sided tests with a 5% significance level were used.

282
283 Exploratory subgroup analyses for the primary outcomes were performed by adding the relevant
284 interaction terms to the model for the following pre-specified factors: routine follow-up interval at
285 recruitment (<6 months vs ≥6 months); age (<70 vs ≥70); level of education (no qualification vs some
286 qualification without degree vs degree); work status (actively working vs not actively working);
287 occupational group. A p-value of <0.1 was deemed suggestive of a potential differential intervention
288 effect across subgroups.

289

290 **RESULTS**

291 We recruited 259 participants; 129 were randomised to TFU and 130 to HFU (Figure 1). As patients had
292 repeat visits in outpatient clinics, some patients declined consent on one occasion but asked to be

293 considered at subsequent appointments. It was challenging to obtain accurate data on the numbers of
294 such individuals; some will have subsequently consented but many will have remained as 'pending'.
295 Figure 1 contains accurate data on number of appointments but, in attempting to avoid double
296 counting, the number of known refusers (n=92) may reflect an under-estimate as it excludes any
297 remaining as 'pending' or 'missed'. **Nine randomised women did not have subsequent follow-up**
298 **appointments (Figure 1) due to non-attendance (n=5), illness (n=2) and death (n=2).**

299

300

Insert Figure 1 here

301

302 Participants were a median age of 65 years and a median of 12 months from diagnosis, with most (63%)
303 on three or four month routine follow-up schedules; **51% were less than one year post surgery**. Socio-
304 demographic and treatment characteristics of the study sample are shown in Table 1. Seventy
305 participants who were eligible for inclusion but refused participation were willing to provide socio-
306 demographic details; non-participants were more likely to be from Black, Asian and Minority ethnic
307 groups (p=0.019), not actively working (p=0.047), from non-skilled occupational classes (p=0.039), and
308 had lower levels of education (p=0.060). The main reasons reported for non-participation included
309 reassurance provided by clinical examinations, too soon after surgery and family members preferring
310 patients to continue with HFU.

311

312

Insert Table 1 here

313 STAI-S scores at baseline (mean [SD] TFU 33.5 [11.3], HFU 35.9 [12.4]) were similar to scores post
314 randomisation (mean [SD] TFU 33.0 [11.0], HFU 35.5 [13.0]). Using 'adjusted for treatment received' the
315 estimated between group difference in STAI was 0.7 (95%CI -1.9 to 3.3); the CI lies above the non-
316 inferiority limit (-3.5) indicating non-inferiority of TFU (Figure 2). Sensitivity analysis using alternative

317 'analysis sets' ('as treated', 'as randomised' and 'per protocol') all showed very similar results,
318 supporting the conclusion of non-inferiority of TFU (Figure 2).

319

320 Insert Figure 2 here

321

322 There was no significant difference in reported satisfaction with information at the most recent
323 appointment between groups (OR 1.1, 95% CI 0.5 to 2.4, $p=0.89$), with 75/96 (78%) of the TFU group and
324 62/78 (79%) of the HFU group who expressed an opinion reporting that they got all the information they
325 needed (Table S1). However, more participants in the HFU group than the TFU group (27.8% vs. 13.5%)
326 stated that they did not need any information ($p=0.003$) and, when a sensitivity analysis was performed
327 including these as 'got none of the information I needed', this showed a significant between-groups
328 difference in reported satisfaction with information at the most recent appointment (OR 2.0, 95% CI 1.1
329 to 3.5, $p=0.019$).

330

331 Regardless of group allocation, participants were highly satisfied with the service they had received and
332 there were no significant differences between groups (mean [SD] TFU 9.2 [1.5], HFU 8.9 [1.7], $p=0.58$,
333 95%CI adjusted mean difference -0.5 to 0.3). Overall, participants considered that their appointments
334 had been 'about right' in terms of both frequency and duration, with no significant differences between
335 randomised groups ($p=0.76$ for frequency, $p=0.20$ for duration). Participants in the HFU arm were more
336 likely to indicate that they had been kept waiting for their appointments ($p=0.001$). Participants in the
337 TFU arm were more likely to indicate that the person they spoke to paid attention to what they were
338 saying ($p=0.042$), that they could express themselves and ask questions ($p=0.016$) and that the person
339 they spoke to knew about their particular case ($p=0.005$) (Table 2). Information needs did not differ

340 significantly between groups for any item (Table 3). Overall, information about familial risk, self-care,
341 and sexual attractiveness and sexual function were the most prevalent information needs reported.

342

343 Insert Table 2 here

344 Insert Table 3 here

345

346 There were no significant differences between groups for quality of life in relation to the EORTC QLQ-
347 C30. Only one single item showed between group differences with participants in the HFU arm more
348 likely to report problems with constipation ($p=0.035$) (Table S2). For the QLQ-EN24 there were no
349 significant differences between groups (Table S3).

350

351 Ten (4%) participants, five in each group, had a recurrence during the study period; one participant in
352 each group died as a result of their cancer. Seven recurrences were distant; three in the TFU group and
353 four in the HFU group. All recurrences were symptomatic. Symptoms included abdominal pain/swelling
354 ($n=6$), vaginal bleeding ($n=3$) and back pain ($n=1$). All recurrences presented as interval events, with
355 patients presenting symptoms to their GP ($n=6$) or contacting a nurse specialist ($n=4$) between
356 scheduled appointments. The times from randomisation to diagnosis of recurrence were variable but
357 not dissimilar in both groups (TFU median 307 days, range 48-662 days; HFU 172 days, 99-436 days) and
358 the corresponding times from reporting symptoms (TFU median seven days, range 3-18 days; HFU nine
359 days 3-70 days) were also not dissimilar.

360

361 For the five planned subgroup analyses on the two primary outcomes, there was no significant subgroup
362 effect on the STAI, nor on satisfaction with information received except work status at recruitment
363 ($p=0.080$; OR 4.92, 95%CI 0.83 to 29.3). This suggested that those in work in the HFU arm were relatively

364 less satisfied with information received than those in work in the TFU arm but this pattern was not
365 observed amongst those not working.

366

367 **DISCUSSION**

368 **Main Findings**

369 The results of the ENDCAT trial were similar to those of a previous breast cancer trial and colorectal
370 cancer pilot trial that used the same primary outcome measures.^{14,16} The ENDCAT study findings indicate
371 that specialist nurses are able to deliver a follow-up service over the telephone for Stage I endometrial
372 cancer patients; TFU was non-inferior to HFU. Hence, nurse-led TFU can replace, or complement,
373 doctor-led HFU without increasing patient anxiety or reducing overall satisfaction with information and
374 service. Furthermore, there was evidence that participants preferred the TFU process as telephone
375 appointments were more likely to be on time and patients felt more able to express themselves and ask
376 more questions. There was no evidence to suggest that diagnosis of recurrence was delayed by TFU.
377 Although recurrences were few (n=10), as would be expected in a low risk group, none of the
378 recurrences were detected by clinical examination of asymptomatic patients; all recurrences were
379 symptomatic and interval events.

380

381 **Strengths and Limitations**

382 Our study is the only trial of nurse-led telephone follow-up for endometrial cancer patients that has
383 been published to date. The study was conducted in the North West of England, although we see no
384 reason why the findings should not be generalisable to other NHS regions. The geographical locations
385 were diverse in terms of populations and ethnic diversity, although this was not represented in the
386 sample, which was predominantly white British. Although ethnic group was associated with refusal to
387 participate, numbers of eligible women from minority ethnic groups was low overall. This may reflect a

388 more international problem of under-representation of minority groups in cancer clinical trials^{21, 22}.
389 Although more white women are diagnosed with endometrial cancer in England than other ethnic
390 minority groups, age standardised incidence rates are similar for white and South Asian women and are
391 higher for black and Chinese women²³. Hence, the low numbers of women from ethnic minority groups
392 eligible for recruitment cannot be readily explained and can be considered a limitation. For practical
393 reasons, and limitations to the funding period, it was not possible to recruit all participants immediately
394 after their first post-treatment outpatient appointment. Although 51% of women were less than one
395 year post surgery, many would have experienced a number of hospital outpatient appointments and this
396 may have biased outcomes. Given that women would have experienced at least one hospital
397 appointment prior to recruitment it is not possible to state when the introduction of TFU would be most
398 beneficial or if the findings are generalisable to the first follow-up appointment. There may also have
399 been a carry-over effect with participants reporting on a change of appointment type rather than
400 reporting purely on telephone follow-up

401

402 **Interpretation**

403 On an international level, nurse-led and TFU approaches are increasingly advocated. A recent survey in
404 South West England indicated that nurse-led TFU had similar levels of patient satisfaction to
405 conventional doctor-led follow-up, ²⁴ providing further support for a shift away from traditional
406 approaches. It may not be practical to suggest that all patients with early stage endometrial cancer are
407 followed up post treatment by specialist nurses. Resource limitations and workloads may inhibit broad
408 implementation. However, we now have increasing evidence that TFU is non-inferior to HFU and
409 patients could be offered a choice of follow-up regime. In this study we mirrored the frequency of
410 hospital appointments to enhance research rigour. In clinical practice it may be that appointment
411 frequency can be negotiated with patients based on their preferences and patients may benefit from

412 more flexible approaches to follow-up care. Patients may prefer one or two hospital appointments
413 before TFU is implemented and further research is needed to determine the most appropriate time
414 points at which to implement TFU.

415
416 Busy hospital clinics and ever increasing numbers of cancer survivors indicate that historical practices
417 need to change and nurse-led TFU may not go far enough in addressing the challenge of meeting the
418 needs of millions of cancer survivors within limited resources. Self-management approaches, where
419 patients are discharged back to primary care on completion of treatment, may become standard
420 practice in the future for low risk groups. There may be a sense of urgency to implement new
421 approaches but it is vital that we have the evidence to support these implementation decisions. A recent
422 survey on gynaecology follow-up practices in the UK found that 98% of 117 respondents indicated that
423 regular scheduled hospital follow-up was the approach most commonly implemented.²⁵ A small minority
424 reported using nurse-led and telephone approaches with none reporting GP led follow-up practices.²⁵
425 Providing the evidence that TFU is a non-inferior service could give providers and commissioners
426 confidence to implement effective approaches while more novel approaches are being evaluated for
427 quality and safety.

428
429 The recent strategy document for improving cancer outcomes in England over the next five years (2015-
430 2020) argues that stratified follow-up pathways that promote self-management offer a more effective
431 approach to follow-up than traditional medical models of follow-up¹³. Positive patient experience is
432 paramount and nurse specialists have been reported as the most important contributors to positive
433 patient experience and yet this workforce is not expanding to keep pace with the growing numbers of
434 cancer survivors. While TFU is an acceptable alternative to hospital based approaches it still has
435 workforce and cost implications. In 2006 it was reported that a study called FIGURE would investigate

436 patient initiated follow-up for endometrial cancer patients²⁶ but this trial did not open for recruitment.
437 There are trials underway in Europe exploring more minimalist approaches to endometrial cancer
438 follow-up. The TOTEM trial (Italy) compares different intensity follow-up regimes in two groups:
439 minimalist (reduced schedule of clinic visits with gynaecological examination and limited investigations -
440 chest, abdomen, pelvis CT every 12 months in minimalist/high risk group) versus intensive (regular clinic
441 visits with gynaecological examination and regular investigations - pap tests, Ca125, trans-vaginal and
442 abdominal ultrasound , and chest, abdomen, pelvis CT) based on risk of relapse (high versus low risk)
443 with overall survival as the primary outcome measure (Clinical Trials Identifier: NCT00916708). The OPAL
444 trial (Denmark) compares hospital based follow-up (including clinical examination) with a minimalist
445 approach (patient self-referral and instruction on alarm signals that warrant contact with a health care
446 professional with fear of recurrence as the primary outcome (Clinical Trials Identifier: NCT01853865)).
447 As minimalist approaches gain momentum, TFU and HFU may both be considered suitable control arms
448 for studies that investigate novel approaches to follow-up that effectively meet patient's needs and
449 provide positive experiences of care within constrained health care budgets.

450

451 **Conclusion**

452 ENDCAT demonstrates that nurse-led TFU can effectively replace doctor-led HFU for the routine follow-
453 up of patients treated for Stage I endometrial cancer. Patients reported greater satisfaction with some
454 aspects of the process and content of their follow up appointment.

455

456 **Acknowledgements**

457 We would like to thank all the patients who took part in the study. Administrative support was provided
458 by Simone Finley with statistical support for data entry and supervised analysis provided by Jane Burnell

459 and Laura Howell. Thanks are expressed to Bill Ryder who chaired the independent Trial Steering Group
460 for the study duration.

461 **Disclosure of Interests**

462 No conflicts of interest declared.

463

464 **Contribution to authorship**

465 PMH and KB conceived the study. All authors contributed to the overall design of the study. MA, SB, RG,
466 PK, PMH, MW and NW treated patients and liaised with treating centres. BA, KB, DC, SM, AT, and BW
467 delivered the telephone intervention. AG provided overall trial management. AG, SW and KB recruited
468 patients to the study. CJS and WH had responsibility for data analysis. All authors had a role in
469 interpreting data. KB and CJS wrote the first draft of the manuscript. All authors contributed to
470 subsequent revisions and approved the final draft for submission.

471

472 **Details of ethical approval**

473 All patients provided written consent before registration in the trial. Ethical approval was granted by the
474 National Research Ethics Service (11/NW/0648) on 3rd October 2011 and approval from the Research &
475 Development departments of all participating centres was obtained prior to recruitment.

476

477 **Funding**

478 This paper presents independent research funded by the National Institute for Health Research (NIHR)
479 under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number PB-PG-0610-22123).
480 The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the
481 Department of Health. The funder had no role in study design, data collection, data analysis, data

482 interpretation, or writing the report. The corresponding author had full access to all the data collected
483 for the study and had final responsibility for the decision to submit the manuscript.

484

485

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Figure 1. Trial Flow

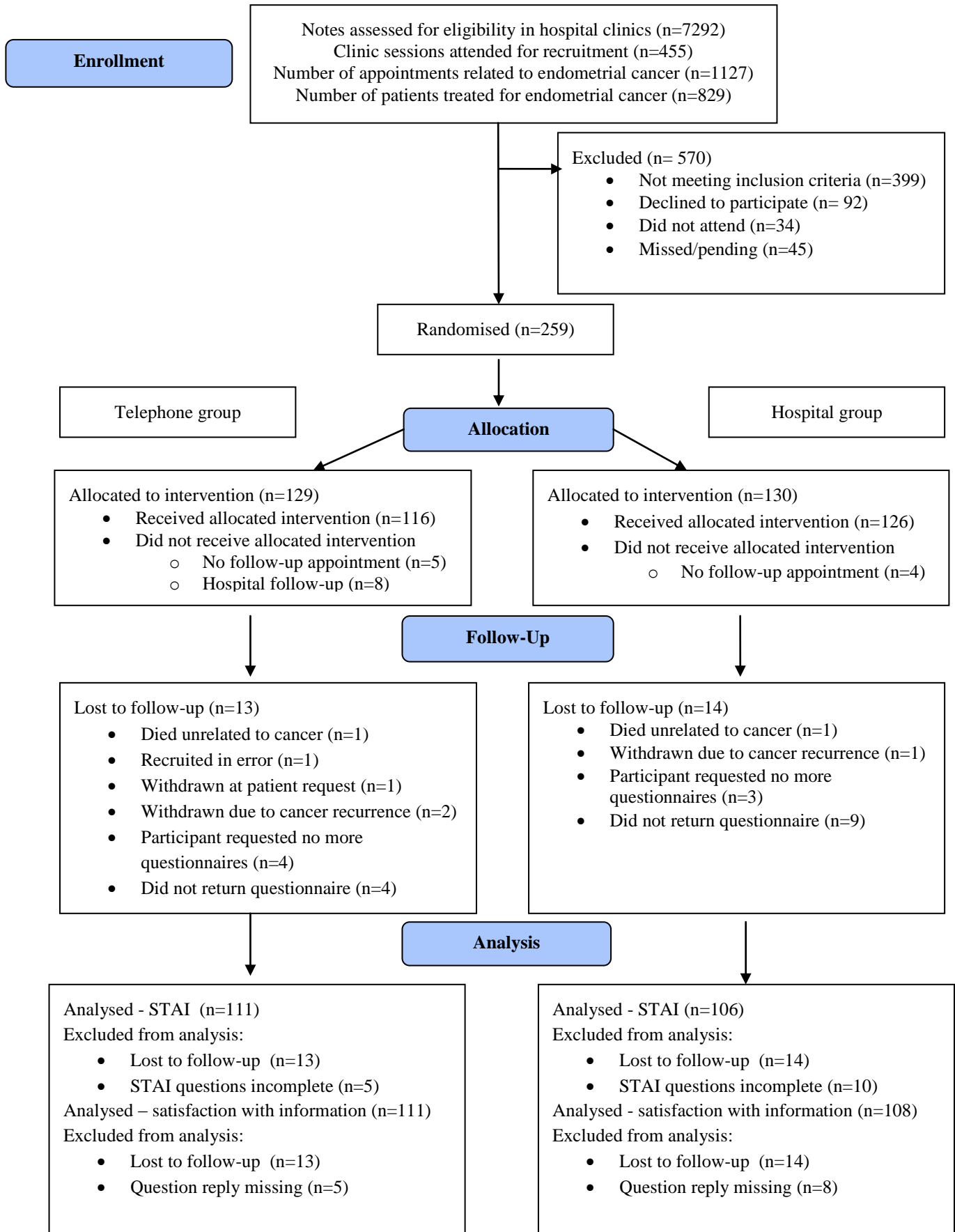


Table 1. Characteristics of the study sample. Data are n (%) unless otherwise stated.

	Total (n=259)	TFU (n=129)	HFU (n=130)
Age at recruitment			
Median (IQR)	65 (58 to 71)	66 (60 to 72.5)	64 (57.8 to 69)
Marital Status			
Married / co-habiting/civil partnership	195 (75.3%)	95 (73.6%)	100 (76.9%)
Divorced / separated	17 (6.6%)	8 (6.2%)	9 (6.9%)
Widowed	31 (12.0%)	16 (12.4%)	15 (11.5%)
Never married	16 (6.2%)	10 (7.8%)	6 (4.6%)
Educational Level			
No Formal Qualifications	43 (16.7%)	21 (16.4%)	22 (16.9%)
O-Levels, A-Levels, Vocational and Certificate/Diplomas	201 (77.9%)	99 (77.3%)	102 (78.5%)
Degree and above	14 (5.4%)	8 (6.3%)	6 (4.6%)
Current Employment Status			
Currently Working	97 (37.5%)	43 (33.3%)	54 (41.5%)
Not Currently Working	162 (62.5%)	86 (66.7%)	76 (58.5%)
Occupational Classification			
Managers, Directors and Senior Officials	19 (7.6%)	9 (7.2%)	10 (8.0%)
Professional Occupations	60 (24.0%)	31 (24.8%)	29 (23.2%)
Associate Professional and Technical Occupations	12 (4.8%)	10 (8.0%)	2 (1.6%)
Administrative and Secretarial Occupations	54 (21.6%)	25 (20.0%)	29 (23.2%)
Skilled Trades Occupations	15 (6.0%)	6 (4.8%)	9 (7.2%)
Caring, Leisure and Other Service Occupations	38 (15.2%)	20 (16.0%)	18 (14.4%)
Sales and Customer Service Occupations	17 (6.8%)	11 (8.8%)	6 (4.8%)
Process, Plant and Machine Operatives	5 (2.0%)	2 (1.6%)	3 (2.4%)
Elementary Occupations	30 (12.0%)	11 (8.8%)	19 (15.2%)
Ethnic group			
White British	256 (98.8%)	128 (99.2%)	128 (98.5%)
Indian	2 (0.8%)	1 (0.8%)	1 (0.8%)
Polish	1 (0.4%)	0 (0.0%)	1 (0.8%)
Type of surgery received			
Abdominal Hysterectomy	195 (75.3%)	97 (75.2%)	98 (75.4%)
Vaginal Hysterectomy	7 (2.7%)	6 (4.7%)	1 (0.8%)
Keyhole Surgery (LAVH)	46 (17.8%)	19 (14.7%)	27 (20.8%)
Hysterectomy - type unknown	11 (4.2%)	7 (5.4%)	4 (3.1%)
Received Radiotherapy			
Yes	11 (4.2%)	6 (4.7%)	5 (3.8%)
Time from diagnosis			
Median (IQR) (months)	12 (4 to 24)	12 (3.5 to 22)	12 (4 to 26)
Follow-up status at Recruitment			
3-4 months	163 (62.9%)	81 (62.8%)	82 (63.1%)
6 months	82 (31.7%)	44 (34.1%)	38 (29.2%)
12 months	14 (5.4%)	4 (3.1%)	10 (7.7%)

Table 2. Satisfaction with aspects of service provision at follow-up by randomised group

	TFU			HFU			p
	Strongly Disagree/Disagree	Neither agree or disagree	Strongly Agree/Agree	Strongly Disagree/Disagree	Neither agree or disagree	Strongly Agree/Agree	
I was kept waiting too long for my appointment	87 (83.7%)	12 (11.5%)	5 (4.8%)	82 (73.9%)	5 (4.5%)	24 (21.6%)	0.001
The person I saw was able to deal with any problems I had	4 (3.6%)	5 (4.5%)	101 (91.8%)	4 (3.7%)	8 (7.3%)	97 (89.0%)	0.48
The person I spoke to told me all I wanted to know	2 (1.8%)	5 (4.4%)	107 (93.9%)	4 (3.6%)	8 (7.3%)	98 (89.0%)	0.26
I was not given enough information about my medication (tablets) and the side effects	21 (72.4%)	5 (17.2%)	3 (10.3%)	33 (68.8%)	12 (25.0%)	3 (6.3%)	0.88
The person I spoke to took no interest in me as a person	104 (91.2%)	3 (2.6%)	7 (6.1%)	96 (86.5%)	6 (5.4%)	9 (8.1%)	0.25
The person I spoke to gave me a chance to say what was really on my mind	2 (1.8%)	4 (3.5%)	107 (94.7%)	7 (6.5%)	6 (5.6%)	94 (87.9%)	0.07
The person I spoke to paid attention to what I was saying	2 (1.7%)	2 (1.7%)	111 (96.5%)	4 (3.5%)	7 (6.2%)	102 (90.3%)	0.042
I felt able to express myself and ask questions	0 (0.0%)	4 (3.5%)	110 (96.5%)	6 (5.4%)	6 (5.4%)	99 (89.2%)	0.016
after talking to the doctor/nurse I felt much better about my problems	1 (0.9%)	18 (17.0%)	87 (82.1%)	5 (5.0%)	23 (22.8%)	73 (72.3%)	0.66
The person I spoke to did not spend enough time talking to me	103 (91.2%)	5 (4.4%)	5 (4.4%)	99 (87.6%)	8 (7.1%)	6 (5.3%)	0.40
The person I spoke to really seemed to know about my particular case and situation	2 (1.8%)	12 (10.5%)	100 (87.7%)	13 (11.7%)	16 (14.4%)	82 (73.9%)	0.005
The person I spoke to investigated any problems I mentioned to my satisfaction	1 (1.0%)	17 (16.5%)	85 (82.5%)	5 (5.3%)	18 (19.1%)	71 (75.5%)	0.17

Table 3. Information needs at follow-up by randomised group. * P-values from Fisher's exact test reported due to low cell frequencies.

	TFU		HFU		P
	Yes	No	Yes	No	
Q17: Information about the cancer diagnosis?	6 (5.3%)	108 (94.7%)	4 (3.5%)	110 (96.5%)	0.75*
Q18: Information about the different types of treatment, including side effects? (e.g. surgery, chemotherapy, radiotherapy)	2 (1.8%)	109 (98.2%)	1 (0.9%)	110 (99.1%)	1.0*
Q19: Information about whether your children or other members of the family are at risk of getting endometrial (womb) cancer?	16 (14.3%)	96 (85.7%)	31 (27.7%)	81 (72.3%)	0.10
Q20: Information about how the treatment may have affected your feelings about your body, your sexual attractiveness and sexual function	7 (6.3%)	105 (93.8%)	12 (10.8%)	99 (89.2%)	0.80
Q21: Information about caring for yourself? (e.g. diet, support groups, finances, psychological support)	10 (8.8%)	103 (91.2%)	14 (12.4%)	99 (87.6%)	0.12
Q22: Have you had any concerns about how your family are coping with your diagnosis	4 (3.5%)	110 (96.5%)	5 (4.5%)	106 (95.5%)	0.30
Q23: Do you need information about anything else not mentioned in questions 17-22?	1 (0.9%)	111 (99.1%)	2 (1.8%)	111 (98.2%)	1.0*

Table S1. Satisfaction with information received post-randomisation by randomised group

	TOTAL (n=219)	TFU (n=111)	HFU (n=108)
I got all the information I needed	137 (62.6%)	75 (67.6%)	62 (57.4%)
I got most of the information I needed	30 (13.7%)	20 (18.0%)	10 (9.3%)
I got some of the information I needed	6 (2.7%)	1 (0.9%)	5 (4.6%)
I got none of the information I needed	1 (0.5%)	0 (0.0%)	1 (0.9%)
I did not need any information	45 (20.5%)	15 (13.5%)	30 (27.8%)

Table S2 EORTC QLQ-C30 subscales by randomised group.

* Hospital group mean minus telephone group mean, adjusted for age, level of education, occupational group, centre, baseline EORTC C30 score and post-operative follow-up status (<1 year; ≥1 year).

	Mean (SD) Baseline Total	Mean (SD) Telephone group Baseline	Mean (SD) Hospital clinic group Baseline	Mean (SD) Telephone group First Post- randomisation Appointment	Mean (SD) Hospital clinic group First Post- randomisation Appointment	P	Adjusted mean difference (95% CI) *
Global health status QoL (revised)	72.9 (19.8)	72.8 (20.0)	73.0 (19.8)	71.6 (19.8)	73.2 (21.5)	0.31	2.1 (-2.0 to 6.2)
Physical functioning (revised)	76.1 (25.3)	73.6 (27.0)	78.5 (23.3)	76.5 (24.3)	78.5 (24.9)	0.50	-1.3 (-5.0 to 2.4)
Role functioning (revised)	75.5 (32.2)	72.5 (33.2)	78.5 (31.0)	76.9 (32.6)	82.0 (29.4)	0.44	2.4 (-3.7 to 8.4)
Emotional functioning	83.3 (19.7)	85.3 (18.2)	81.4 (21.0)	84.6 (19.5)	80.8 (24.0)	0.73	0.8 (-3.7 to 5.3)
Cognitive functioning	84.6 (19.6)	84.6 (20.3)	84.7 (19.0)	87.0 (16.0)	83.8 (21.4)	0.41	-1.5 (-5.1 to 2.1)
Social functioning	83.2 (26.8)	83.1 (27.0)	83.3 (26.8)	86.6 (24.7)	85.1 (26.0)	0.82	-0.6 (-6.1 to 4.8)
Fatigue	27.9 (24.0)	29.6 (25.7)	26.2 (22.3)	29.2 (28.3)	24.9 (25.7)	0.23	-3.2 (-8.4 to 2.0)
Nausea and vomiting	3.6 (11.4)	2.4 (10.6)	4.7 (12.1)	3.5 (9.7)	4.6 (12.8)	0.83	0.3 (-2.6 to 3.2)
Pain	21.4 (28.8)	21.3 (28.8)	21.5 (29.0)	21.5 (29.8)	20.1 (30.1)	0.56	-1.8 (-7.8 to 4.3)
Dyspnoea	14.6 (22.8)	16.4 (24.3)	12.9 (21.1)	17.5 (28.5)	13.2 (23.7)	0.50	-1.9 (-7.4 to 3.6)
Insomnia	32.1 (32.2)	31.4 (31.7)	32.8 (32.8)	27.3 (31.1)	32.2 (31.8)	0.26	3.5 (-2.5 to 9.5)
Appetite loss	7.3 (17.8)	7.3 (17.9)	7.2 (17.8)	4.4 (11.3)	4.2 (13.5)	0.60	-0.8 (-3.9 to 2.2)
Constipation	14.8 (25.8)	13.1 (24.1)	16.5 (27.3)	10.4 (20.9)	15.9 (25.2)	0.035	5.0 (0.4 to 9.6)
Diarrhoea	5.9 (17.0)	4.1 (13.9)	7.7 (19.5)	3.2 (9.9)	4.4 (13.0)	0.98	0 (-2.7 to 2.8)
Financial difficulties	7.5 (20.1)	5.0 (14.7)	10.0 (24.0)	4.7 (13.9)	6.5 (20.1)	0.31	-1.8 (-5.3 to 1.7)

Table S3. EORTC QLQ-EN24 subscales by randomised group.

* Hospital group mean minus telephone group mean, adjusted for age, level of education, occupational group, centre, baseline EORTC score and post-operative follow-up status (<1 year; ≥1 year).

	Mean (SD) Baseline Total	Mean (SD) Telephone group Baseline	Mean (SD) Hospital clinic group Baseline	Mean (SD) Telephone group First Post- randomisation Appointment	Mean (SD) Hospital clinic group First Post- randomisation Appointment	P	Adjusted mean difference (95% CI) *
Sexual interest	17.5 (25.0)	14.5 (24.6)	20.5 (25.0)	16.7 (24.6)	21.4 (24.6)	0.41	-2.1 (-7.0 to 2.9)
Sexual activity	12.8 (21.6)	12.2 (21.8)	13.3 (21.5)	13.1 (24.3)	18.0 (23.6)	0.13	4.0 (-1.1 to 9.0)
Sexual enjoyment	53.3 (34.3)	51.3 (35.6)	54.9 (33.7)	56.8 (31.8)	61.0 (29.7)	0.20	-7.4 (-18.7 to 3.9)
Lymphoedema	14.2 (23.5)	17.8 (25.3)	10.6 (21.0)	16.8 (23.7)	11.4 (20.2)	0.47	-1.6 (-6.0 to 2.8)
Urological symptoms	22.4 (21.1)	23.3 (22.2)	21.6 (20.1)	20.4 (22.0)	18.4 (18.6)	0.64	-0.9 (-4.9 to 3.0)
Gastrointestinal symptoms	14.5 (17.0)	15.0 (17.7)	14.0 (16.4)	11.3 (12.9)	11.1 (14.6)	0.58	0.8 (-2.0 to 3.5)
Body image problems	13.1 (25.4)	11.6 (23.5)	14.7 (27.2)	8.0 (16.9)	11.5 (25.3)	0.35	1.9 (-2.1 to 5.9)
Sexual/vaginal problems	32.4 (29.8)	32.5 (29.8)	32.4 (30.3)	25.9 (28.7)	24.7 (30.8)	0.37	5.0 (-6.0 to 15.9)
Back/pelvis pain	28.0 (31.3)	27.2 (29.7)	28.8 (32.7)	27.1 (32.1)	24.8 (31.4)	0.13	-4.9 (-11.2 to 1.4)
Tingling/numbness	15.1 (25.3)	15.9 (27.2)	14.4 (23.4)	16.2 (26.8)	12.6 (21.9)	0.31	-2.8 (-8.2 to 2.6)
Muscular pain	37.2 (32.8)	37.4 (31.7)	36.9 (34.0)	36.6 (33.2)	31.3 (30.8)	0.11	-5.7 (-12.7 to 1.3)
Hair loss	4.5 (14.9)	5.2 (16.6)	3.8 (12.9)	5.3 (15.1)	5.3 (14.4)	0.60	0.9 (-2.6 to 4.5)
Taste change	5.6 (16.3)	6.9 (19.2)	4.3 (12.7)	3.2 (11.7)	1.5 (6.9)	0.29	-1.4 (-3.9 to 1.2)

Note: EORTC QLQ-C30 and QLQ-EN24 have both function and symptom subscales. For function subscales a higher score indicates a better performance in this subscale, so a positive difference in means implies a higher function in the hospital group. For symptom subscales a higher score indicates a higher level of symptoms in this subscale, so a positive difference in means implies a higher level of this symptom in the hospital group.

TELEPHONE INTERVENTION (ENDCAT TRIAL)

Questions to be asked by Gynaecology Oncology Clinical Nurse Specialist (CNS) at telephone consultation

nb Please re-check patient consent for audio recording

Patient Name: _____

Hospital Number: _____

Date of Birth:

CNS Initials:

Date:

Follow-up telephone call (please tick)

3 months 4 months 6 months 12 months

Other (please state) _____

Hello, this is <name of specialist nurse> phoning for our month follow-up appointment.

1. How are you doing with (issues related to previous hospital visit/telephone appointment)?

CNS - please tick one box

Issues remain a problem

Issues partly resolved

Issues fully resolved

No problems recorded

2. Since your last follow-up appointment has anything changed?

Yes No

If yes, what has changed?

CNS – If yes, was this change in condition addressed over the phone?

Yes (fully) Yes (partly) No

Was further action indicated? Yes No

If yes, what was the course of action?

3. Since your last appointment have you noticed any of the following:

- Bleeding Yes No
- Unusual discharge Yes No
- Unusual aches and pains Yes No

CNS – if yes to any of the above what was the course of action indicated?

I have a list of things that other people have said they'd like to have information about following treatment. Obviously, not all of them will apply to you, but do you mind if we work through the list anyway and you can tell me if you need information (or have any concerns) about any of these areas?

4. Do you need information about the operation you had?

Yes No

CNS - If yes, what information was needed?

If yes, was the information need met over the phone?

Yes (fully) Yes (partly) No

Was further action indicated? Yes No

If yes, what was the course of action?

5. Do you need more information about your cancer diagnosis?

Yes No

CNS - If yes, what information was needed?

If yes, was the information need met over the phone?

Yes (fully) Yes (partly) No

Was further action indicated? Yes No

If yes, what was the course of action?

6. If applicable. Do you need information about the other types of treatment you had, including side effects (i.e. chemotherapy, radiotherapy)?

Yes No Not applicable

CNS - If yes, what information was needed?

If yes, was the information need met over the phone?

Yes (fully) Yes (partly) No

Was further action indicated? Yes No

If yes, what was the course of action?

7. Do you have any concerns about whether your children or other members of the family are at risk at getting endometrial (womb) cancer?

Yes No

CNS - If yes, what concerns were expressed?

If yes, was the concern dealt with over the phone?

Yes (fully) Yes (partly) No

Was further action indicated? Yes No

If yes, what was the course of action?

8. Do you need information about how the treatment may affect your feelings about your body and your sexual attractiveness?

Yes No

CNS - If yes, what information was needed?

If yes, was the information need met over the phone?

Yes (fully) Yes (partly) No

Was further action indicated? Yes No

If yes, what was the course of action?

9. Do you need information about your sexual function?

Yes No

CNS - If yes, what information was needed?

If yes, was the information need met over the phone?

Yes (fully) Yes (partly) No

Was further action indicated? Yes No

If yes, what was the course of action?

10. Do you need information about caring for yourself? (e.g. diet and appetite, exercise, problems with bowel and urinary function, support groups, complementary therapy, finances, psychological support)

Yes No

CNS - If yes, what information was needed?

If yes, was the information need met over the phone?

Yes (fully) Yes (partly) No

Was further action indicated? Yes No

If yes, what was the course of action?

11. Do you have any concerns about how your family have coped with your diagnosis?

Yes No

CNS - If yes, what concerns were expressed?

If yes, was the concern dealt with over the phone?

Yes (fully) Yes (partly) No

Was further action indicated? Yes No

If yes, what was the course of action?

12. Is there anything else concerning you?

Yes No

CNS - If yes, what concerns were expressed?

If yes, was the concern dealt with over the phone?

Yes (fully) Yes (partly) No

Was further action indicated? Yes No

If yes, what was the course of action?

13. CNS – Please arrange next appointment

The next telephone follow-up call will be due in months.

Date of next appointment Time

Please check that patient has contact numbers for gynaecology oncology nursing service.

14. CNS – were any tests/investigation requested? Yes No

If yes, what tests/investigations were requested?

If yes, why were the tests /investigations requested?

15. CNS – were any referrals made?

Yes

No

If yes, what referrals were requested?

If yes, why was a referral necessary?

16. CNS - Additional Comments:
