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

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Short running title:

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

ABSTRACT

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

Design Multicentre, randomised, non-inferiority trial

Setting Five centres in the North West of England

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

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

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

Results STAI-S scores post-randomisation were similar between groups (mean [SD] TFU 33.0 [11.0], HFU 35.5 [13.0]). The estimated between group difference in STAI was 0.7 (95%CI -1.9 to 3.3); the CI lies above the non-inferiority limit (-3.5) indicating non-inferiority of TFU. There was no significant difference between groups in reported satisfaction with information (OR 0.9, 95% CI 0.4 to 2.1, p=0.83). The HFU group were more likely to report being kept waiting for their appointment (p=0.001), that they did not need any information (p=0.003) and were less likely to report that the nurse knew about their particular case and situation (p=0.005).
Conclusions TFU provides an effective alternative to HFU for Stage I endometrial cancer patients, with no reported physical or psychological detriment. Patient satisfaction with information was high, with similar levels between groups.

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

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Tweetable abstract (108 characters with spaces)
ENDCAT trial shows effectiveness of nurse-led telephone follow-up for Stage I endometrial cancer patients.
INTRODUCTION

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

UK Department of Health (DoH) guidance suggests that women treated for endometrial cancer should be informed about the lack of known benefit of follow-up, although retaining some degree of support post treatment. The National Cancer Survivorship Initiative (NCSI) was key to the Cancer Reform Strategy, aiming to improve services for cancer survivors in England and advocating supported self-management approaches to follow-up, accompanied by risk stratification (based on clinical and individual need). Current follow-up practice does not meet cancer survivors’ full range of needs. A recent rapid review of service provision following cancer treatment concluded that addressing the needs of cancer survivors, particularly with the predicted increase in numbers, requires new models of follow-up. There are also increasing financial pressures to devise more efficient care pathways. Alternative strategies include nurse-led and supported self-management approaches. A systematic review of nurse-led versus conventional physician-led follow-up for patients with cancer concluded that patients are generally satisfied with nurse-led follow-up, and a meta-analysis concluded that nurse-led telephone follow-up (TFU) services were acceptable, appropriate and effective. Patients with early stage cancers at low risk of recurrence could be empowered to take responsibility for their care if sufficiently
supported, with rapid access back to secondary care if needed. Individual responsibility and self-management have been highlighted as central principles for successful implementation of the 2015-2020 strategy for improving cancer outcomes, empowering individuals to manage their own health care needs. However, the NCSI reported that these models needed further testing and evaluation. The model we proposed for Stage I endometrial cancer follow-up built on previous studies of nurse-led TFU for breast and colorectal cancer patients, demonstrating that specialist nurses can meet the information needs and concerns of people treated for cancer, with no physical or psychological detriment. We therefore designed a trial to test for non-inferiority of nurse-led TFU relative to traditional hospital based follow-up (HFU) following treatment for Stage I endometrial cancer.

**METHODS**

**Study design and sample**

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

**Randomisation and masking**

Patients were randomly assigned (1:1) to HFU or TFU using a computer based system. Randomisation was performed using permuted blocks, with randomly varying block sizes, within 10 strata defined by the combinations of the five hospitals and follow-up duration (less than 1 year or 1 year or more post diagnosis). The trial statistician was masked to group allocation. It was not possible to mask clinical staff.
or participants as they would have been aware that follow-up care was being delivered over the telephone or in hospital clinics.

Outcomes

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

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

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

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

Sample size

The sample size was based on a pre-stated margin of non-inferiority (3.5) for the intervention effect on the STAI-S and data (SD 10) from a previous trial of TFU for breast cancer patients.\textsuperscript{14} We planned for 80% power, a 5% significance level, and allowed for 20% attrition; the target sample size was 128 participants per group. For the co-primary outcome of ‘satisfaction with information’ it was calculated that this sample size would provide 80% power to detect an OR of at least 2.25 using ordinal regression techniques (5% significance level) based on control percentages of: ‘very satisfied’ 54%, ‘satisfied’ 39%
and ‘not very satisfied’ or ‘very unsatisfied’ 7%, approximate values from our previous trial; however the phrasing of the question was subsequently changed for use in ENDCAT. 14

Statistical methods

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

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

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

RESULTS

We recruited 259 participants; 129 were randomised to TFU and 130 to HFU (Figure 1). As patients had repeat visits in outpatient clinics, some patients declined consent on one occasion but asked to be
considered at subsequent appointments. It was challenging to obtain accurate data on the numbers of such individuals; some will have subsequently consented but many will have remained as ‘pending’.

Figure 1 contains accurate data on number of appointments but, in attempting to avoid double counting, the number of known refusers (n=92) may reflect an under-estimate as it excludes any remaining as ‘pending’ or ‘missed’. Nine randomised women did not have subsequent follow-up appointments (Figure 1) due to non-attendance (n=5), illness (n=2) and death (n=2).

Insert Figure 1 here

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

Insert Table 1 here

STAI-S scores at baseline (mean [SD] TFU 33.5 [11.3], HFU 35.9 [12.4]) were similar to scores post randomisation (mean [SD] TFU 33.0 [11.0], HFU 35.5 [13.0]). Using ‘adjusted for treatment received’ the estimated between group difference in STAI was 0.7 (95%CI -1.9 to 3.3); the CI lies above the non-inferiority limit (-3.5) indicating non-inferiority of TFU (Figure 2). Sensitivity analysis using alternative
‘analysis sets’ (‘as treated’, ‘as randomised’ and ‘per protocol’) all showed very similar results, supporting the conclusion of non-inferiority of TFU (Figure 2).

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

Regardless of group allocation, participants were highly satisfied with the service they had received and there were no significant differences between groups (mean [SD] TFU 9.2 [1.5], HFU 8.9 [1.7], p=0.58, 95%CI adjusted mean difference -0.5 to 0.3). Overall, participants considered that their appointments had been ‘about right’ in terms of both frequency and duration, with no significant differences between randomised groups (p=0.76 for frequency, p=0.20 for duration). Participants in the HFU arm were more likely to indicate that they had been kept waiting for their appointments (p=0.001). Participants in the TFU arm were more likely to indicate that the person they spoke to paid attention to what they were saying (p=0.042), that they could express themselves and ask questions (p=0.016) and that the person they spoke to knew about their particular case (p=0.005) (Table 2). Information needs did not differ
significantly between groups for any item (Table 3). Overall, information about familial risk, self-care, and sexual attractiveness and sexual function were the most prevalent information needs reported.

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

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

For the five planned subgroup analyses on the two primary outcomes, there was no significant subgroup effect on the STAI, nor on satisfaction with information received except work status at recruitment (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
less satisfied with information received than those in work in the TFU arm but this pattern was not
observed amongst those not working.

DISCUSSION

Main Findings

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

Strengths and Limitations

Our study is the only trial of nurse-led telephone follow-up for endometrial cancer patients that has
been published to date. The study was conducted in the North West of England, although we see no
reason why the findings should not be generalisable to other NHS regions. The geographical locations
were diverse in terms of populations and ethnic diversity, although this was not represented in the
sample, which was predominantly white British. Although ethnic group was associated with refusal to
participate, numbers of eligible women from minority ethnic groups was low overall. This may reflect a
more international problem of under-representation of minority groups in cancer clinical trials.\textsuperscript{21,22}

Although more white women are diagnosed with endometrial cancer in England than other ethnic minority groups, age standardised incidence rates are similar for white and South Asian women and are higher for black and Chinese women.\textsuperscript{23} Hence, the low numbers of women from ethnic minority groups eligible for recruitment cannot be readily explained and can be considered a limitation. For practical reasons, and limitations to the funding period, it was not possible to recruit all participants immediately after their first post-treatment outpatient appointment. Although 51\% of women were less than one year post surgery, many would have experienced a number of hospital outpatient appointments and this may have biased outcomes. Given that women would have experienced at least one hospital appointment prior to recruitment it is not possible to state when the introduction of TFU would be most beneficial or if the findings are generalisable to the first follow-up appointment. There may also have been a carry-over effect with participants reporting on a change of appointment type rather than reporting purely on telephone follow-up.

**Interpretation**

On an international level, nurse-led and TFU approaches are increasingly advocated. A recent survey in South West England indicated that nurse-led TFU had similar levels of patient satisfaction to conventional doctor-led follow-up,\textsuperscript{24} providing further support for a shift away from traditional approaches. It may not be practical to suggest that all patients with early stage endometrial cancer are followed up post treatment by specialist nurses. Resource limitations and workloads may inhibit broad implementation. However, we now have increasing evidence that TFU is non-inferior to HFU and patients could be offered a choice of follow-up regime. In this study we mirrored the frequency of hospital appointments to enhance research rigour. In clinical practice it may be that appointment frequency can be negotiated with patients based on their preferences and patients may benefit from
more flexible approaches to follow-up care. Patients may prefer one or two hospital appointments before TFU is implemented and further research is needed to determine the most appropriate time points at which to implement TFU.

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

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

There are trials underway in Europe exploring more minimalist approaches to endometrial cancer follow-up. The TOTEM trial (Italy) compares different intensity follow-up regimes in two groups: minimalist (reduced schedule of clinic visits with gynaecological examination and limited investigations - chest, abdomen, pelvis CT every 12 months in minimalist/high risk group) versus intensive (regular clinic visits with gynaecological examination and regular investigations - pap tests, Ca125, trans-vaginal and abdominal ultrasound, and chest, abdomen, pelvis CT) based on risk of relapse (high versus low risk) with overall survival as the primary outcome measure (Clinical Trials Identifier: NCT00916708). The OPAL trial (Denmark) compares hospital based follow-up (including clinical examination) with a minimalist approach (patient self-referral and instruction on alarm signals that warrant contact with a health care professional with fear of recurrence as the primary outcome (Clinical Trials Identifier: NCT01853865)).

As minimalist approaches gain momentum, TFU and HFU may both be considered suitable control arms for studies that investigate novel approaches to follow-up that effectively meet patient’s needs and provide positive experiences of care within constrained health care budgets.

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

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Disclosure of Interests

No conflicts of interest declared.

Contribution to authorship

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

Details of ethical approval

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

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