Full Study Title:

A randomised study comparing satisfaction with individualised follow-up led by a trained cancer nurse versus conventional medical follow-up after primary treatment for ovarian cancer.

Short Title:
Ovarian follow-up study

Ethics Ref: No 05 Q0505 75

STUDY PROTOCOL
Date and Version number: V3 28/07/2006

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1.0. Background

Following a diagnosis of cancer improving patients’ psychosocial wellbeing and their ability to effectively participate in treatment decisions and symptom management is a key aspect of care (NHS Centre for Reviews and Dissemination 2000). Positive mental adjustment and emotional adaptation to cancer as well as the fostering of coping and self-management skills are not only desirable outcomes for patients but for their family and carers. Such outcomes may impact on resource utilisation and demands for support from health care professionals. It may also result in better symptom management, improved physical and social functioning, and in advanced cancer a more peaceful death (National Institute for Clinical Excellence, 2004).

From diagnosis through to survival after treatment people with cancer make a series of psychological transitions in their understanding of themselves, their illness and their world (Brennan, 2001). These changes are psychologically demanding and are processes that may start with the event of the diagnosis but which may not be completed until well after that event has passed. The transitions at the end of treatment and at time of recurrence are potentially the most demanding and difficult of these transitions yet patients receive little focused help to prepare for them. Instead most patients are routinely seen in outpatient clinics despite substantial evidence that routine follow up after cancer treatment may not lead to improvements in survival (Radford, et al, 1997) or quality of life (Carlsson & Strang, 1998). It is also ineffective at detecting recurrence and costly (Moore, et al, 2002). A recent retrospective review of gynaecological cancer case notes (Olaitan, et al 2001) suggests that routine follow up hinders the diagnosis of recurrence for not only do routine visits fail to detect recurrence before symptoms develop, but symptomatic women delay seeking help until their next scheduled visit. The nature of the psychological tasks for people with cancer and the high degree of psychological morbidity among cancer patients suggests a need for more supportive models of follow-up. Though the importance to patients of seeing known and trusted health care professionals in clinic cannot be underestimated (Lanceley et al, 2004), clinicians working in busy outpatient settings often fail to detect women’s emotional distress and patients report that clinics are often overcrowded and appointments so “quick” they have little time to raise concerns (Stead, et al 2001) or gain reassurance from the encounter (National Cancer Alliance, 1996).

Despite recognition that current follow-up care provision does not fulfil its purpose or adequately meet patients’ needs only four moderate quality randomised studies have been conducted that report the effectiveness and cost effectiveness of alternative nurse-led models of follow-up care in cancer: prostate (Helgesen et al, 2000); breast (Brown et al, 2002; Koinberg et al 2004); and lung (Moore et al 2002). Results of these studies were equivocal in terms of differences in survival, recurrence, and psychological morbidity. Well conducted trials are needed to establish the effectiveness of different models of follow-up care delivery for cancer survivors.

There is compelling empirical evidence to support health care professional consultations which focus on patients’ individual needs and which encourage them to adopt a more active role in their care (Butow et al 1995; Moore, et al 2002). This study is underpinned by a model of health promoting interactions (Tones and Tilford 1994), in which communication is oriented towards the individual to improve self-efficacy and enhance a sense of personal control. Self-efficacy is defined as an individual’s belief in their capacity to execute a health–related behaviour (Bandura 1977); for instance taking steps to manage a treatment-related side effect. Self-efficacy develops through: performance accomplishment (experience of success); vicarious experience (through observation of others e.g. role modelling) and exploration and handling of emotional and physical arousal that may interfere with coping skills.

Standard follow-up for women after primary treatment for ovarian cancer is usually offered 3 monthly in the first two years after primary treatment, then 6 monthly for three years and yearly thereafter. Standard follow-up generally involves a clinical history and physical examination by a doctor, together with measurement of serum cancer antigen 125 (CA 125) tumour marker. Women may also be seen on the basis of need, and when there is a suspicion of recurrence.

We shall conduct a randomised controlled trial using experienced clinical nurse specialists (CNSs) to deliver self-management focused individual follow-up and evaluate whether this brings about greater improvement in quality of life, is acceptable and cost saving when compared to the standard (conventional) model. Economic evaluation of the individualised model compared to the conventional treatment is important considering its psychological, health promotional component (Carlson et al 2004).
2.0. Planned investigation

2.0.1. Hypothesis:
That the nurses would provide continuity in follow-up care and instigate timely and appropriate changes in symptom management; anticipate and educate patients about potential problems arising after treatment; and equip them to know when to initiate contact and how to self-manage difficulties as appropriate. We further hypothesise that this would have a positive effect on quality of life in the intervention arm and a beneficial effect on the experience of recurrence or relapse by delaying the symptomatic presentation of this in the intervention arm.

2.0.2. Research Objectives

2.0.3. Primary:
- To determine through a randomised controlled trial the effects of individualised follow-up care compared to conventional follow-up on quality of life and mood.
- To determine if the individualised treatment is acceptable to women compared to the conventional treatment.

2.0.4. Secondary:
- To compare the total cost of follow-up between each treatment group.
- To understand the experiences of women receiving conventional and individualised follow-up.
- To understand the experiences of nurses delivering the individualised treatment.
- To provide useful information on rate of recruitment, completion rates of self-report measures, maintenance of integrity of the intervention if further enquiry on a larger scale warranted.

3.0 Methods

3.0.1. Design
Two arm randomised controlled trial.

3.0.2. Setting
Patients will be recruited from specialist gynaecological cancer outpatient services at three cancer centres, one inner city and two urban. The following sites have agreed to participate:
- University College London Hospital (UCLH) NHS Foundation Trust, Euston Road, London.
- Southend University Hospital NHS Foundation Trust, Prittlewell Chase, Westcliff-on-Sea, Essex.
- Basildon & Thurrock University Hospitals NHS Foundation Trust, Basildon, Essex.

3.0.3. Entry criteria

3.0.4. Inclusion criteria:
1. Women aged >18
2. A diagnosis of ovarian cancer (this includes fallopian tube and peritoneal cancers)
3. Within one month of completion of primary treatment including surgery and chemotherapy/radiotherapy or surgery alone, irrespective of outcome with regard to remission
4. Expected survival > 3 months
5. Agreement to be randomised
6. Agreement to give written consent to participate in the study
7. Sufficient grasp of English to engage in the self-management focused approach.

3.0.5. Exclusion criteria:
1. Clinician estimated survival of > 4 months
2. Women receiving treatment for a mental health condition or who have a learning disability.

3.0.6. Sample size
A sample size of 100 patients, randomised equally to the 2 treatment groups, has been chosen for this work. See statistical analysis section. (Medical Research Council, 2000)

3.0.7. Recruitment rate and recruitment period
There are approximately 120 new cases of ovarian cancer diagnosed each year at UCLH. However a large proportion of these women are entered into clinical trials which stipulate regular 2 monthly follow-up by a doctor who may be required to perform a pelvic examination depending on the specific trial protocol. The International Collaboration Ovarian Neoplasm ICON 7 randomised multi-centre...
Phase III trial of carboplatin & paclitaxel vs carboplatin & paclitaxel & bevacizumab in the first line treatment of patients with epithelial ovarian cancer is about to commence. A diminished pool of eligible women will be available to approach for their participation in this study and our recruitment period reflects this. Patients meeting the inclusion criteria will be recruited from 3 sites (UCLH, Southend and Basildon Hospitals) over a 1 year period. Southend and Basildon Hospitals between them have between 100-120 new cases of ovarian cancer each year. Based on previous experience of recruiting in this population where approximately 50% of women approached to take part in studies agreed, a 1 year recruitment period will be needed.

3.0.8. Process of recruitment

Women who are approaching the end of their primary treatment will be identified first from clinic lists and multidisciplinary team meeting lists by the clinical team. Individual patients will be considered for participation by the member of the clinical team primarily responsible for their care (i.e. their consultant or nurse specialist). During the course of a usual clinic appointment and if the clinician believes the patient is suitable for participation (i.e. not too ill or distressed) they will ask the patient if they would be interested to hear about the study. If so they will be introduced to the Research Associate (RA) who will attend the clinic. The RA will discuss the study, answer any questions the patient might have and provide them with the study information sheet and a consent form to take away. The RA will ensure that potential participants understand that their consent involves consent to agree to be randomised. Patients will be randomised to either conventional or individualised follow-up once they have provided written consented to take part. Eligible patients will have up to 10 days to decide if they would like to take part in the study and written consent will be obtained by the RA.

A research ethics committee will approve the detailed procedure for approaching patients. A Trial Steering Group, which includes service users and clinicians, will help the research team to approach these issues sensitively and appropriately from the start of the project.

3.0.9. Randomisation

Randomisation to either conventional follow-up (control) or individualised follow-up (experimental) will take place after eligible patients have consented to the trial and after study baseline measures have been taken. For the purposes of independent randomisation, participants will be subdivided into two groups by an experienced trials data manager, those recruited at the inner city cancer centre and those recruited at the suburban centres. Randomisation will be performed independently for both groups with participants randomly allocated to either the conventional or individualised follow-up in a 1:1 ratio. Allocation of the first participant from a pair to one of the 2 follow-up strategies will be made using randomness derived from atmospheric noise (http://www.random.org); the second participant from each pair will then be allocated to the other group.

4.0. The intervention

Trial follow-up is 2 years from baseline so that any advantages of treatment endure over time and to compare against natural recovery rates in the conventional treatment as usual group.

4.0.1. Conventional follow-up/treatment as usual

Care for patients in the conventional group will remain unchanged. This treatment as usual will involve: one post treatment appointment then appointments every 3 months at the Cancer Centre with a medical member of the gynaecological oncology team. At the routine appointment a medical history is taken and investigations to monitor disease progression including CA125 tumour marker blood test if this were raised at diagnosis. A physical examination may be performed. The appointment will sometimes involve clinical nurse specialist input and patients may contact the non-study CNS on an ad hoc basis depending on need.

4.0.2. Individualised follow-up

Nurses will be prepared for their role on the study during two half day workshops which will outline the theory underpinning the individualised follow-up and the implications of this on the interaction style and follow-up delivery model. Adherence to the individualised follow-up will be supported by the protocol and on-going engagement of the nurses by the Chief Investigator. The study will run on 3 sites with one or two CNSs at each site not versed in the intervention approach. These nurses will contribute to care in the conventional arm thus avoiding the potential for contamination. We will encourage the CNSs versed in the approach not to share details of it with their colleagues for the
duration of the study. The regular presence of the Chief Investigator at the study sites will reinforce this.

Patients randomised to individualised follow up will meet the study CNS in clinic when they attend for their 4-6 week post treatment appointment. The nurse will discuss the follow-up approach, in particular its focus on supporting and helping with adjustment to life after treatment and the management of any difficult symptoms or difficulties arising from the cancer or its treatment. The nurse will negotiate with the patient to agree follow-up arrangements best suited to their needs. This may entail patient-initiated telephone or face-to-face appointments with the nurse. There will be no limit to the number of such appointments. Patients will also have access to the nurse by telephone without an appointment. In addition, and on the basis of an assessment, the nurse may initiate an appointment in clinic or by telephone.

The nurse will assess the patient during appointments. The assessment will aim to identify patient problems, symptoms warranting intervention, symptoms indicative of disease progression, or serious complications. The nurse will offer psychologically sensitive advice on symptom management tailored to each patient’s particular concerns and needs. Although the follow-up will be individualised, the nurse will use an assessment proforma (See Appendix 1) for the integrity of the follow-up approach. Essential aspects of the individual follow-up are as follows:

- Detailed assessment of patient’s physical status by oral history taking (not physical assessment) and identification of factors that ameliorate or exacerbate symptoms of treatment morbidity or recurrence
- Monitoring CA 125 if this was raised at diagnosis, including addressing women’s concerns about these levels
- Information about ways of relieving symptoms
- Advice and support for patients and their families that respect their choices and ways of managing illness related problems
- Exploration of the meaning of patient’s illness, and thoughts and feelings about the future
- Providing support to women in ‘watch and wait’ when it is known the cancer has relapsed or recurred but the optimal time for re-treatment has not been reached.

The nurse will be responsible for the care of patients receiving individualised follow-up unless the patient has worsening symptoms needing further treatment. The nurse will then discuss the patient with the relevant consultant and arrange any necessary investigations for example a CT scan prior to a clinic appointment with the doctor (See Appendix 2).

5.0. Study measures
We will seek empirical evidence that the intervention positively impacts patients’ quality of life; does not have a negative effect on mood and length of progression free interval; is acceptable to women; and is cheaper or cost neutral to deliver.

5.0.1. Quantitative measures
We will administer three validated self-report instruments at baseline, 3, 6, 12, 18 and 24 months.

5.0.1. a. Quality of life
The European Organisation for Research and Treatment of Cancer (Aaronson et al, 1993) core quality of life questionnaire (QLQ-C30) is a 30-item questionnaire assessing five 5 functional domains (physical, role, cognitive, emotional and social), 3 symptom domains (nausea/vomiting, fatigue and pain), and a number of specific symptoms (dyspnoea, appetite loss, sleep disturbance, constipation, and diarrhoea) as well as the perceived financial impact of the disease and treatment. We will use the core scale with the site specific ovarian cancer module Ov-28 (Greimal, et al 2003) which consists of 28 items which are factor analysed into six factors: abdominal/gastrointestinal symptoms, peripheral neuropathy, other chemotherapy side effects specific to ovarian cancer treatments, hormonal symptoms, body image and sexuality, and attitude to disease/treatment. Higher scores for functioning subscales indicate better functioning. Higher scores in symptom subscales indicate worse symptoms.

5.0.1. b. Mood
Hospital Anxiety and Depression Scale (HADS): Anxiety and depressive symptoms will be assessed with this 14-item self-rated scale designed for use in the medically ill. (Zigmond & Snaith, 1983)
5.0.1. c. Patient satisfaction  
We will use the Ware Patient Satisfaction Questionnaire (PSQ-III) to measure patients’ perceptions of care (Ware et al., 1978). This provides a summary measure, general satisfaction, as well as six aspects of health care: technical competence, interpersonal manner, communication, time spent with clinician, financial aspects, and access to care. In the version we will use the financial items will be left out because these are not appropriate for the UK national socialised health system.

6.0. Use of services  
Data will be entered on a ‘Patient events’ database and then extracted for all patients for the following types of service use during the two-year follow-up period: clinic appointments with the CNS; CNS visits while the patient was an inpatient; telephone consultations with the CNS; email consultations with the CNS; clinic appointments with the consultant gynaecological oncologist; clinical appointment with other types of consultant; clinic appointment with clinical psychologist; clinic appointment with complementary medicine team; and inpatient stays. We will also record primary care contacts and the reasons for these with a questionnaire to General Practitioners (Appendix 3).

7.0 Patient disease and demographic information  
We will collect the following demographics at baseline: ethnicity, current relationship status, occupation, education. We will also collect ovarian cancer disease information as follows: treatment modalities; stage of disease at diagnosis; disease status at end of primary treatment.

8.0. Qualitative interviews  
8.0.1. Patient interviews  
Findings from the questionnaires at 6 and 18 months will be used to purposively select a sub-sample of 10-12 women from each arm of the study for in-depth interview. Women will be selected to maximise variation in terms of quality of life scores, patient satisfaction and HADS scores in each arm of the study. Care will also be taken to include women of different ages and ovarian cancer stage. Patients’ experiences of follow-up and their preferences for follow-up care will be elicited in one-to-one semi-structured interviews which will be conducted by the clinical psychologist, a co-investigator to the project. See Appendix 4 for the interview schedule.

8.0.2. Nurse interviews  
Nurses’ experiences of delivering the follow-up care will be elicited in one-to-one semi-structured interviews to be conducted by the clinical psychologist, a co-researcher to the project. See Appendix 5 for the interview schedule.

9.0. Data collection  
9.0.1. Quantitative data  
The EORTC QLQ C30 and Ov-28, plus HADS and PSQ-III will be administered at baseline, 3, 6, 12, 18 and 24 months. The baseline questionnaires will be provided by the RA at the time of written consent and completed and returned prior to disclosure of randomisation. Subsequent self-report questionnaires will be posted to participants with a reply paid envelope. If the questionnaires are not returned within 2 weeks the RA will telephone to remind the participant to complete and return the questionnaires. A maximum of two reminders will be given 2 weeks apart.

9.0.2. Qualitative data  
9.0.2 a. Patient interviews  
Patients will take part in a 45-60 minute one-to-one interview with a clinical psychologist at a location convenient to them. The interview will be audio-recorded following consent and anonymised to maintain confidentiality. A semi-structured interview guide will be used to ensure all important topic areas are covered (Appendix 4).

9.0.2 b. CNS interviews  
CNSs will be interviewed in a quiet room away from their clinical area at a time convenient to them. The interview will be audio-recorded following consent and anonymised to maintain confidentiality. A semi-structured interview guide will be used to ensure all important topic areas are covered (Appendix 5).
10.0. Data Analysis

10.0.1. Quantitative data

Differences in mean patient satisfaction (Ware’s scale) and quality of life (HAD’s anxiety and depression measures; and the QLQ-C30 along with the ovarian cancer specific QLQ-OV28 scale) between the two groups will be assessed by 2 sample t-tests. Assuming a two-sided significance level of 5% with 40 in each sample, to achieve 80% power any differences will have to be quite large to be detectable. For the Ware’s scale (0-100), where the estimated common standard deviation ($\sigma = 14.7$ (de Bock et al (2004)), a difference between the two groups of 9.3 would be detectable with 80% power. For the HAD’s anxiety (0-13) and depression (0-14) measures ($\sigma=2.75$ in both cases (de Bock et al 2004)), such a difference would need to be 1.74 in both cases. We may be able to detect smaller differences with our planned sample size when we take into account adjustment for baseline values in the sample size calculation comparing our randomised groups (analysis of covariance).

For the QLQ-C30 and OV-28 scales there are various sub-scales (0-100) and the evidence from various literature sources suggest that for most scales the standard deviation is approximately 20-25 (Greimel et al 2003; Arndt et al 2004; Davidson-Homewood et al 2003). Using such a value then, a difference in means, detectable with 80% power, would be between 12.7 and 15.9.

These values are perhaps relatively large compared to the respective scale ranges, and it is apparent that the sample sizes here affect the power of the tests. However, even if the ensuing results are not able to detect clinically important differences between the two groups, the scale scores will still provide useful information on the ovarian cancer population regarding patient satisfaction and quality of life, and may justify further inquiry on a larger scale. The results will also inform the design of a future study, where, for example, standard deviation estimates will be more accurate.

10.0.2. Economic analysis

The total cost of follow-up for each patient will be calculated by multiplying service use by unit costs obtained from relevant NHS Reference Costs and summing across all types of use. Unadjusted service use and total costs will be compared between each group using Mann-Whitney two-sample statistics.

10.0.3. Qualitative data

10.0.3. a. Patient interviews

The qualitative interviews will be fully transcribed and analysed according to principles of grounded theory (Strauss and Corbin, 1990). Data will be analysed line-by-line using the constant comparative method and annotating paper copies with ‘memos’ on initial codes. Initial codes will be amended and revised after discussion between the RA and a senior researcher external to the project. Once the coding is agreed the RA will review the coded manuscripts and confirm themes and sub-themes in the margins (Glaser & Strauss, 1967; Glaser, 1992). Data relating to each case and theme will be extracted and tabulated, in particular, the challenges faced by women both in their lives and within the health care system, on how they are responding to these in terms of self-management and on their experiences of care and relationships with health care staff. Finally findings will be summarised in a table by case/study arm and theme in order to facilitate comparison across individual cases and within and across different arms of the study.

10.0.3.b. CNS interviews

These interviews will also be fully transcribed and analysed according to principles of grounded theory (Strauss and Corbin, 1990). Data will be analysed line-by-line using the constant comparative method and annotating paper copies with ‘memos’ on initial codes. Initial codes will be amended and revised after discussion between the senior researcher external to the project and the RA. Once the coding is agreed the RA will review the coded manuscripts and confirm themes and sub-themes in the margins (Glaser & Strauss, 1967; Glaser, 1992).

11.0 Ethical issues

Approval of the National Research Ethics Service (NRES) will be obtained. As this is a vulnerable group, and patients may tire easily, interviews will kept short and the administration of self-report questionnaires handled sensitively.

If patients choose to come to the hospital for their qualitative research interview travel costs will be met by the project funding. An expert Trial Steering Group will monitor the progress of the study according to UCL research governance procedures.
Regular clinical supervision mechanisms are already in place in the host academic department in UCL to support field researchers working with people with advanced progressive and life limiting conditions.

12.0 Timescale
The study will run for 3 years (December 2005 to December 2008). Time will be spent initially briefing involved gynaecological oncologists and surgeons at the study sites, and finalising practical arrangements for the individualised follow-up. Recruitment into the study will run for 1 year (December 2005- 2006) with a 2-year follow-up ending in October 2008. The final 5 months of the study will be devoted to analysing the data, writing up summary findings for participants, and preparing papers for publication.

13.0. References


Appendix 1

ASSESSMENT PROFORMA FOR INDIVIDUALISED OVARIAN CANCER FOLLOW-UP

PATIENT’S NAME:
CONSULTANT:
OVARIAN CANCER TREATMENT:

<table>
<thead>
<tr>
<th>Date</th>
<th>Follow up to meet individual need.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>General Health</strong></td>
</tr>
<tr>
<td></td>
<td>Any recent changes to general health/condition:-</td>
</tr>
<tr>
<td></td>
<td>Current medication:-</td>
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<tr>
<td></td>
<td><strong>Assessment of pelvis and related bodily changes/symptoms</strong></td>
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<tr>
<td></td>
<td>Pain</td>
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<tr>
<td></td>
<td>Abdominal distension</td>
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<td></td>
<td>Urinary problems</td>
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<td></td>
<td>Bowel problems</td>
</tr>
<tr>
<td></td>
<td>Appetite/weight maintenance concerns</td>
</tr>
<tr>
<td></td>
<td>Any other symptoms/problems (e.g. lymphoedema)</td>
</tr>
</tbody>
</table>
| Date | **Psychological wellbeing**  
Any difficulties expressed or identified |
| --- | --- |
|  | **Sexuality / Psycho-sexual Assessment**  
Any concerns or problems identified |
|  | Sexual health |
|  | **Social Issues**  
Any problems identified |
|  | Additional information |
|  | **Negotiated self-management plan** |
|  | Type and date of next contact |
|  | Signature |
Appendix 2

Outline plan: follow up for women after first line treatment for ovarian cancer.
Appendix 3

Questionnaire

Thank you for helping us with this research.

We would be grateful if you could answer the following questions concerning your Patient............................................................., DOB................................................who gave written consent to participate in the Ovarian Follow-up Study.

We are interested in the period your patient was a participant on the follow-up study From.......................to.....................

During this period:

1. How many times did the patient attend your surgery to see a doctor in relation to her gynaecological cancer? ☐

2. How many times did the patient attend your surgery to see the practice nurse in relation to her gynaecological cancer? ☐

3. If the practice provides a counselling service, how many times did the patient attend to see the counsellor in relation to her gynaecological cancer? ☐

4. Did a doctor perform a pelvic examination at any of these appointments? Yes/No
   If yes, on how many occasions? ☐

5. Did a doctor perform an abdominal examination at any of these appointments? Yes/No
   If yes, on how many occasions? ☐

6. If your patient came to see you for reasons related to her cancer disease, please indicate the main reason by ticking the relevant box(es)
   a) Physical problems ☐
   b) Reassurance ☐
   c) Other - please describe below ☐

7. Are there any other relevant details? Please describe below.

☐
Appendix 4

A randomised study comparing satisfaction with follow-up led by a trained cancer nurse versus conventional medical follow-up after primary treatment for ovarian cancer

One-to-one Interview Schedule with Patients

V2 28/04/06

These questions aim to broadly address the follow-up care experiences of individual women, so that satisfaction, preferences and needs for follow-up care can be heard in this bigger picture. It is anticipated that questions will be refined as interview data is collected and analysed concurrently.

1. How have things been for you since you finished your ‘first line’ treatment?
2. What aspects of your follow-up care have helped you and made things easier for you?
3. What aspects of your follow-up care have made it more difficult for you? Can you tell me what were the things you didn’t like, or things that could have been better?
4. (If intervention arm) How did you decide either to telephone or see your nurse?
5. Did you perceive you had more care choices when you were part of the study? If so what were they?
6. What sort of things did you talk about when you had your follow-up appointment while on the study? Is that different to occasions before you entered the research study?
7. In what ways did the health professional try to help you?
8. Do you think you benefited from your follow-up care, and if so can you tell me how? Prompts:
   - Has the follow-up care you have received had an impact on your feelings or how you have responded to things emotionally since finishing treatment?
   - Has your follow-up care had an impact on how you feel you have coped day-to-day with physical problems after your treatment ended?
9. What thoughts do you have about your future care?
10. What are your feelings about your future care?
Appendix 5

A randomised study comparing satisfaction with follow-up led by a trained cancer nurse versus conventional medical follow-up after primary treatment for ovarian cancer

One-to-one Interview Schedule with Nurse Specialists

V1 02/05/2006

These questions aim to broadly address the experiences of individual nurses involved in the care of women in the intervention and control arms of the ovarian follow-up study, so that experiences and support and educational needs can emerge. It is anticipated that questions will be refined as interview data is collected and analysed concurrently.

1. Before you began the study, what did you expect the nurse led follow up to be like? How did you feel about taking on this role? In what ways do you think you were prepared for the role? In what ways do you think you were unprepared? Have your feelings about your preparedness changed as you have followed women up?

2. What do you think the general aim of the study was?

3. What was your experience of doing the study as a nurse? Experiences of care and negotiating with patients Women’s’ responses to you Particular concerns/difficulties in relation to the follow-up care you provided? What do you think may have helped you? Education, training & support needs – met and unmet?

4. Has working to deliver the follow-up study been different to the way you usually work as a CNS? If so in what ways?

5. In what ways do you think you made a connection with the patient? What was negotiated? What was left open? Was there any pattern to who initiated contact? How did patients decide either to telephone or see you face-to-face? Did you experience any difficulties in meeting patients’ expectations for care? Did you feel they talked about different sorts of things, or more things?

6. What strategies did you use to support women to self-manage their cancer related problems? Did you experience difficulties in doing this? If so what were they? How do you think things might be different/better in this respect?

7. Would you say that this sort of follow up was a satisfying experience for you and if so, can you say how?