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Creators	Beaver, Kinta, Campbell, M., Williamson, Susan, Procter, D., Sheridan, J., Heath, J. and Susnerwala, S.

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# An exploratory randomized controlled trial comparing telephone and hospital follow-up after treatment for colorectal cancer

K. Beaver\*, M. Campbell†, S. Williamson‡, D. Procter§, J. Sheridan§, J. Heath§ and S. Forrestal†

\*School of Health, University of Central Lancashire, Preston, UK, †School of Nursing, Midwifery and Social Work, University of Central Lancashire, Preston, UK, ‡School of Health, University of Central Lancashire, Preston, UK, §Surgical Directorate, Blackpool Teaching Hospitals NHS Foundation Trust, Blackpool, UK and ¶Rosemere Cancer Centre, Lancashire Teaching Hospitals NHS Foundation Trust, Preston, UK

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## Abstract

**Aim** Following treatment for colorectal cancer it is common practice for patients to attend hospital clinics at regular intervals for routine monitoring, although debate persists on the benefits of this approach. Nurse-led telephone follow-up is effective in meeting information and psycho-social needs in other patient groups. We explored the potential benefits of nurse-led telephone follow-up for colorectal cancer patients.

**Method** Sixty-five patients were randomized to either telephone or hospital follow-up in an exploratory randomized trial.

**Results** The telephone intervention was deliverable in clinical practice and acceptable to patients and health professionals. Seventy-five per cent of eligible patients agreed to randomization. High levels of satisfaction were evident in both study groups. Appointments in the hospital group were shorter (median 14.0 min) than appointments in the telephone group (median 28.9 min).

Patients in the telephone arm were more likely to raise concerns during consultations.

**Conclusion** Historical approaches to follow-up unsupported by evidence of effectiveness and efficiency are not sustainable. Telephone follow-up by specialist nurses may be a feasible option. A main trial comparing hospital and telephone follow-up is justified, although consideration needs to be given to trial design and practical issues related to the availability of specialist nurses at study locations.

**Keywords** XXXXXX, XXXXXX, XXXXXX

### What is new in this paper?

The study demonstrates that colorectal cancer patients do not need to attend busy hospital outpatient clinics for follow-up care. Specialist nurses can provide a quality service with high levels of patient satisfaction by telephoning patients at home and asking specific questions about physical and psycho-social function.

## Introduction

Colorectal cancer (CRC) is the third most common cancer worldwide [1]. However, mortality rates have generally declined across Europe [2], reflecting improvements in treatment, detection of early stage cancers from screening programmes and/or improved symptom recognition [3,4]. Hence, increasing numbers of people live many years beyond diagnosis and treatment and need information and support to resume normal activities. The UK's National Cancer Survivorship Initiative (NCSI) has

recognized the need to develop models of care that ensure that the needs of cancer survivors are met; improving self-care, care planning and making the best use of resources and technology [5].

Following treatment for CRC it is common practice for patients to return to hospital clinics at regular intervals over a number of years for routine monitoring aimed at detecting early recurrence. Debate has raged internationally on whether there are survival benefits to follow-up after curative CRC surgery, with little consensus on the best combination of tests/investigations to maximize outcome [6,7]. While work is ongoing to address these issues, other aspects of survivorship demand attention. Patients can be unaware that long-term side-effects are associated with treatment and they experience a host of

Correspondence to: Kinta Beaver, Professor of Cancer Nursing, School of Health, University of Central Lancashire, Preston, UK.  
E-mail: kbeaver@uclan.ac.uk

1 physical and psychological problems [8]. Stoma patients  
2 may experience particular difficulties, with a negative  
3 impact on body image and quality of life [9–11], while  
4 debilitating bowel problems are also reported by patients  
5 treated with sphincter-saving surgery [12].

6 Specialist nurses can deliver a quality follow-up service,  
7 meeting psycho-social needs and providing adequate  
8 support with high levels of patient satisfaction and no  
9 physical or psychological detriment when compared with  
10 traditional doctor-led follow-up [13–17]. A randomized  
11 controlled trial (RCT) comparing hospital and nurse-led  
12 telephone follow-up for breast cancer patients reported  
13 positive findings in terms of satisfaction with service and  
14 meeting information needs [13]. This approach could be  
15 effective for CRC as the priority information needs of  
16 patients with breast cancer and CRC are reportedly  
17 similar [18]. Nurse-led telephone follow-up may reduce  
18 the burden on busy outpatient clinics, but there is limited  
19 evidence on the efficiency of these services. Economic  
20 evaluations of telephone follow-up are few and present a  
21 complex picture. Combining telephone follow-up with  
22 an educational group programme may result in cost  
23 savings [19], although telephone follow-up for breast  
24 cancer patients can be more expensive than traditional  
25 hospital follow-up if senior nurses spend longer on the  
26 telephone than doctors in hospital clinics [20].

27 Complex interventions that evaluate psycho-social  
28 and/or information-based approaches to care are difficult  
29 to evaluate. Hence, we conducted a series of studies that  
30 followed the Medical Research Council (MRC) Frame-  
31 work for Development and Evaluation of RCTs for  
32 complex interventions in health care [21]. Phase I  
33 (theoretical) and Phase II (modelling) involved qualita-  
34 tive and quantitative approaches that explored patient  
35 views on follow-up service provision and clarified com-  
36 ponents of the intervention [22,23]. This paper reports  
37 on Phase III (exploratory trial), a crucial component prior  
38 to a definitive RCT designed to test the delivery of the  
39 telephone intervention. The aim of this exploratory trial  
40 was to evaluate telephone follow-up, using a structured  
41 intervention, in terms of psychological morbidity, meet-  
42 ing information needs and satisfaction with information  
43 and service. In addition, the study was designed to collect  
44 data to determine appropriateness of inclusion/exclusion  
45 criteria and outcome measures, the acceptability of the  
46 intervention to patients and clinicians and the likely  
47 consent rate for recruitment to a main trial.

## 48 49 Method

50  
51 This randomized pilot trial compared hospital and nurse-  
52 led telephone follow-up for patients treated for CRC. We  
53 aimed to recruit approximately 60 patients, as recom-

mended when estimating a particular parameter in a pilot study [24]. Eligible patients had a diagnosis of CRC, had completed treatment (surgery/radiotherapy/chemotherapy) with no evidence of recurrent disease, had access to a telephone, adequate hearing and were attending hospital outpatient consultations for routine monitoring. Recruitment took place at a large hospital in the north-west of England. Consecutive eligible patients were identified at the hospital clinics of four consultant surgeons and a colorectal nurse practitioner. The latter already provided a service to patients after treatment at nurse-led clinics, an expectation of the practitioner role. Clinical nurse specialists provided a service to patients at the time of diagnosis, on admission to hospital and at home following hospital discharge, and stoma care nurses attended to the needs of patients with a stoma. However, it was only the nurse practitioner who was involved in delivering the telephone intervention in this study. The study had approval from the National Research Ethics Service.

## Randomization

Consenting individuals were randomized to either hospital or telephone follow-up by a computerized system. Group allocation was stratified by age ( $\leq 60$  years,  $> 60$  years) and gender. Allocation sequences were concealed until interventions were assigned. The analyst was blind to study group allocation. Participants randomized to the hospital arm were routinely reviewed at 6-weeks posttreatment, then 6-monthly intervals for 2 years and annually for a further 3 years and discharged to the care of their general practitioner (GP) after 5 years, unless complex or unresolved problems were evident. Hospital consultations could be conducted by consultant surgeons, registrars, more junior doctors or a colorectal nurse practitioner. The content and format of appointments in the hospital control arm was unaltered and clinicians focused on routine monitoring for detection of recurrent disease.

Participants randomized to telephone follow-up received telephone consultations from a colorectal nurse practitioner at the same prescribed intervals as participants in the hospital arm. Appointments were focused primarily on provision of information using a structured intervention to establish patient information needs. Appointment cards were sent, indicating the date and time of telephone appointments. These were registered on computerized hospital information systems in the same way as traditional hospital appointments so that medical records staff could retrieve patient notes prior to telephone clinics. Thirty minutes were allocated for telephone appointments (20 min consultation time, 10 min administration), based on the mean time taken

1 to deliver the telephone intervention in a previous trial of  
2 telephone follow-up for breast cancer patients [13]. The  
3 same nurse carried out all telephone consultations. As  
4 with hospital appointments, telephone clinic appoint-  
5 ments were reimbursed to the hospital by the health  
6 authority.

### 7 8 **Telephone intervention** 9

10 The structured telephone intervention was developed  
11 from previous work [13,18]. Questions were asked  
12 relating to changes in condition, new or unresolved  
13 symptoms, information requirements about spread of  
14 disease, treatment and side-effects, genetic risk, sexual  
15 attractiveness, sexual function, self-care (diet, problems  
16 with wound/stoma, problems with bowels and urinary  
17 function, support groups, finances) and family concerns.  
18 All participants were asked if they had any other needs  
19 and concerns. Standard protocols related to routine tests  
20 and investigations (e.g. carcinoembryonic antigen blood  
21 levels, CT scan, colonoscopy) were unaltered. Four half-  
22 day sessions on the administration of the intervention  
23 were given, with regular feedback and de-briefing sessions  
24 throughout the study period. To monitor the integrity of  
25 the intervention, all telephone consultations were audio-  
26 recorded with patient consent. Any patient who pre-  
27 sented with signs of recurrent disease (symptomatic or  
28 outcome of tests/investigations) was referred back to a  
29 hospital clinic and withdrawn from the telephone arm of  
30 the study.

### 31 32 **Measures** 33

34 Primary outcomes included psychological morbidity,  
35 meeting information needs and satisfaction with infor-  
36 mation and service. Secondary outcomes related to  
37 clinical investigations ordered, time to detection of  
38 recurrent disease and costs to patients. At this exploratory  
39 stage a formal economic evaluation was not conducted,  
40 although data were collected on patient out-of-pocket  
41 expenses.

42 Psychological morbidity was measured using the  
43 State-Trait Anxiety Inventory (STAI) and the General  
44 Health Questionnaire (GHQ). The STAI comprises 40  
45 items measuring anxiety, differentiating between tempo-  
46 rary anxiety (state, Y1) and long-standing anxiety  
47 reflected as a personality trait (trait, Y2). The GHQ  
48 focuses on a wider range of issues relating to psychologi-  
49 cal morbidity; we used the shortened 12-item version  
50 (GHQ-12) to minimize patient burden. Both tools are  
51 self-administered and have been well validated [25,26].

52 Patient information needs and satisfaction levels were  
53 recorded using questionnaires adapted from a survey of

CRC patients' follow-up needs and a satisfaction measure  
used in a lung cancer follow-up trial [16,23]. The items  
comprised tick-box responses, five-point Likert satisfac-  
tion and agreement scales and one overall satisfaction  
rating scale (ranging from 1 to 10). Questions were asked  
about health-care contacts between appointments and  
out-of-pocket expenses. All questionnaires were admin-  
istered at baseline and at one additional time point,  
individually chosen to maximize the number of appoint-  
ments that patients had between completion of measures.  
To capture the benefits of immediate recall, question-  
naires were posted shortly after scheduled appointments.

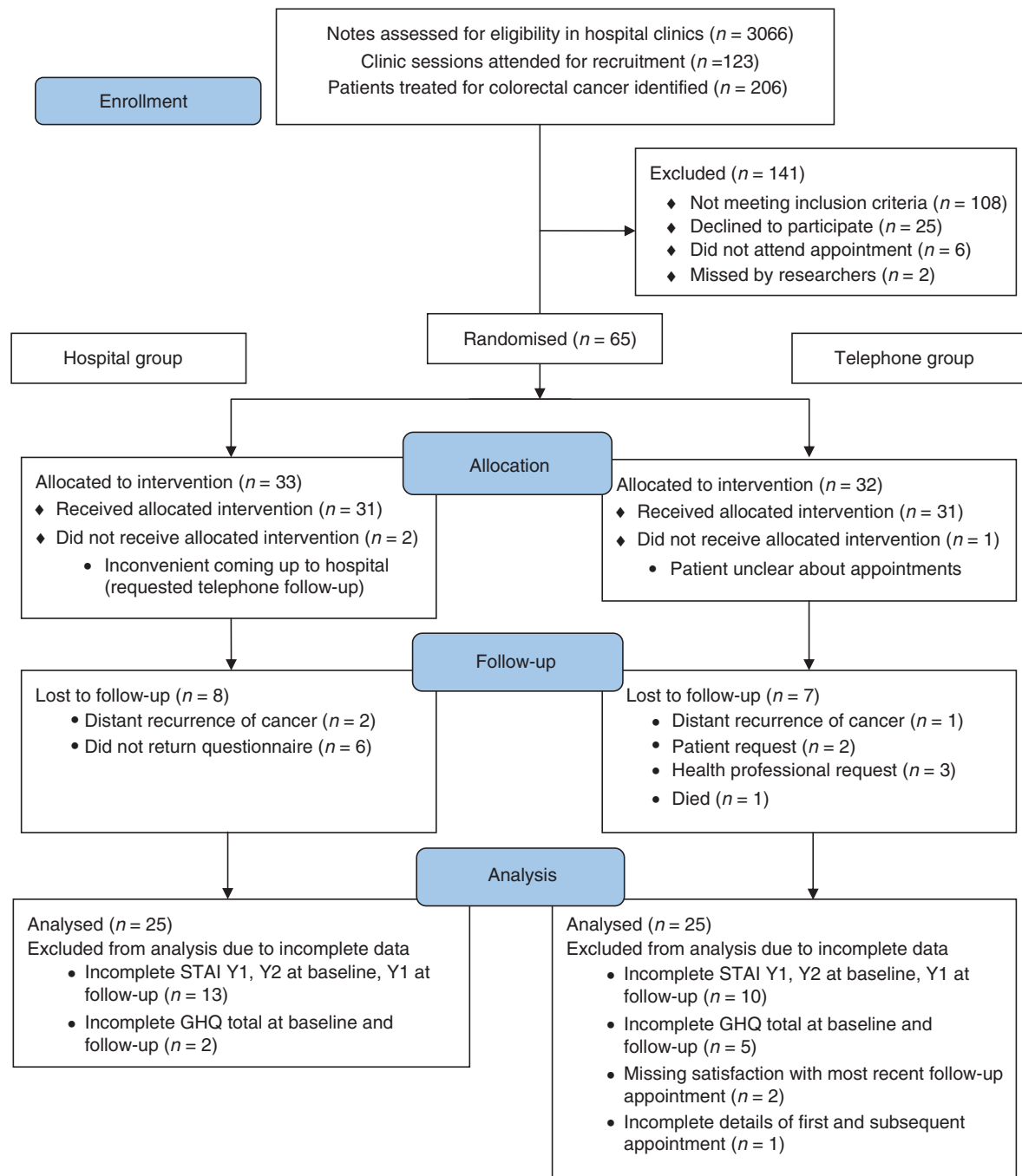
Clinical outcomes for the hospital arm were recorded  
using a 'record of visit' form, including details on  
who patients saw at consultations, tests/investigations  
ordered, referrals made, clinical examinations conducted  
and indications of recurrent disease. For the telephone  
group the nurse completed an intervention guide on  
areas of concern discussed during telephone consulta-  
tions, tests/investigations ordered, referrals made and  
any indications of recurrent disease. This information was  
cross-checked by a researcher who listened to telephone  
consultation recordings and completed a proforma sim-  
ilar to the intervention guide. Any confirmed disease  
recurrences were closely monitored through hospital  
records and consultation with clinical staff. At study end  
a retrospective examination was made of all participants'  
case notes to check the accuracy of clinical data.

### 34 **Statistical analysis**

35 Analysis was by intention-to-treat. As this was a pilot  
36 study, analyses were mainly descriptive, and estimation of  
37 recruitment, protocol violation, attrition and data com-  
38 pletion rates were important. Analysis of covariance was  
39 used to compare STAI, GHQ-12 and satisfaction with  
40 appointment scores at follow-up by group adjusted for  
41 baseline scores and estimate 95% confidence intervals for  
42 differences in adjusted means. The unpaired *t*-test was  
43 also used to compare satisfaction with appointment scores  
44 at follow-up by group, given that those in the telephone  
45 group had a different kind of appointment at follow-up.  
46 Fisher's exact test was also used to compare categorical  
47 outcomes by group. The results of any inferential  
48 comparisons should be interpreted with caution given  
49 that the study was not powered to detect statistically  
50 significant differences.

### 51 **Results**

52 Figure 1 shows the flow of participants through the trial.  
53 Ninety-eight patients were eligible for inclusion although  
eight had either not attended their appointments as



**Figure 1** Flow of participants through the pilot trial [STAI, State-Trait Anxiety Inventory (Y1, temporary anxiety state; Y2, personality trait); GHQ-12, General Health Questionnaire (shortened 12-item version)].

scheduled or were missed by researchers. The study was discussed with the remaining 90 patients; 65 consented to participate (72%). Of 65 patients randomized, only three did not receive the intervention as allocated and 15 (23%) were lost to follow-up (Fig. 1). Patients remained in the study from 8 to 15 months (mean 12 months). A typical participant was male (58%), married (64%) and

retired from work (88%). Participants were a mean of 21 months from diagnosis and groups were reasonably balanced at baseline (Table 1).

Eight participants from the hospital arm (24%) and seven from the telephone arm (22%) did not provide follow-up data (Fig. 1). The four men and two women in the hospital arm who did not return questionnaires were

**Table 1** Baseline characteristics of participants.

Characteristic	Hospital group ( <i>n</i> = 25)		Telephone group ( <i>n</i> = 25)	
	Mean	SD	Mean	SD
Age (years)	72.4	8.2	73.6	7.6
	Number	%	Number	%
Aged over 60	22	88	22	88
Gender				
Male	13	52	16	64
Female	12	48	9	36
Marital status				
Married/cohabiting	17	68	15	60
Divorced/separated	2	8	4	16
Widowed	5	20	4	16
Never married	1	4	2	8
Retired from work	22	88	22	88
	Mean	SD	Mean	SD
Time from diagnosis (months)	18.7	14.4	22.4	16.1
Time from first post- treatment visit (months)	12.3	15.3	17.0	16.0
	Number	%	Number	%
Surgery	25	100	25	100
Radiotherapy	1	4	4	16
Chemotherapy	9	36	5	20
Cancer location				
Colon	17	68	12	48
Rectum	8	32	13	52
Stoma				
Permanent	5	20	9	36
Temporary	0	0	1	4
Stoma now reversed	2	8	5	20
No stoma	18	72	10	40

slightly younger (mean age 69 years) and not as far from diagnosis (mean 11 months). The one death recorded during the study was unrelated to CRC. Three participants (two hospital, one telephone) changed group during the study.

Not all participants provided complete data on the primary outcome measures. Only 12 (48%) hospital and 15 (60%) telephone participants provided complete data on the STAI at baseline and follow-up. No particular item appeared to give participants a problem. However, five hospital and one telephone participant answered at least 19 of the 20 'state' (Y1) questions but none of the 20 'trait' (Y2) questions at baseline. All but one of these participants answered at least 19/20 'state' questions at follow-up. Responses to the GHQ-12 were better: 23 (92%) hospital and 20 (80%) telephone participants provided complete data (Table 2). Mean and median scores for STAI state anxiety were appreciably higher in the hospital arm at follow-up (Cohen's *d* = 0.66), and mean GHQ-12 score was slightly higher (Cohen's *d* = 0.11). There were no significant differences between groups at follow-up in STAI (*P* = 0.297) or GHQ-12 (*P* = 0.626).

Questions on information needs were answered by the majority at baseline and follow-up. Information about genetic risk and self-care were the most common information needs in each group at baseline (Table 3). By follow-up, this was still true for the telephone arm and at the same level. However, in the hospital arm information about genetic risk and sexual attractiveness were the most common needs but at a reduced level. The most noticeable difference between groups was the number of information needs raised by participants: in the telephone arm, 33 needs were raised at baseline and 30 at follow-up; in the hospital arm 32 were raised at baseline but only 16 were raised at follow-up. Only three

**Table 2** Psychological morbidity by randomization group.

Measure	Hospital group ( <i>n</i> = 25)					Telephone group ( <i>n</i> = 25)				
	No.	Mean	SD	Median	Range	No.	Mean	SD	Median	Range
Baseline										
STAI Y1	12	29.0	8.9	25	20–47	15	28.5	8.1	27	20–42
STAI Y2	12	35.9	13.2	32	22–63	15	31.3	10.8	29	20–53
GHQ-12 total	23	1.4	1.8	1	0–6	20	1.5	2.3	0	0–6
Follow-up										
STAI Y1*	12	36.0	17.4	31	20–73	15	27.9	9.8	24	20–50
GHQ-12 total†	23	1.3	2.7	0	0–10	20	1.0	2.9	0	0–12

STAI, State-Trait Anxiety Inventory (Y1, temporary anxiety state; Y2, personality trait); GHQ-12, General Health Questionnaire (shortened 12-item version).

\*Analysis of covariance: *F* = 1.14, d.f. = 1 and 23, *P* = 0.297; 95% CI for difference between adjusted means –3.5 to 11.1

†Analysis of covariance: *F* = 0.24, d.f. = 1 and 40, *P* = 0.626; 95% CI for difference between adjusted means –1.1 to 1.8

**Table 3** Information needs by randomization group.

	Baseline						Follow-up					
	Hospital group (n = 25)			Telephone group (n = 25)			Hospital group (n = 25)			Telephone group (n = 25)		
	No. of responses	No. with need	%	No. of responses	No. with need	%	No. of responses	No. with need	%	No. of responses	No. with need	%
Information about the disease and whether it had spread	24	4	17	21	4	19	23	1	4	21	3	14
Information about the different types of treatment, including side-effects	24	4	17	21	4	19	23	2	9	24	3	13
Information about whether children or other family members are at risk	23	10	43	21	8	38	23	5	22	24	7	29
Information about how treatment may have affected feelings about body and sexual attractiveness	23	4	17	20	6	30	22	5	23	23	4	17
Information about caring for self	23	9	39	21	8	38	23	3	13	24	8	33
Concerns about how family are coping with diagnosis	24	0	0	21	2	10	23	0	0	23	3	13
Other information required	21	1	4	17	1	6	22	0	0	22	2	10

participants reported 'other' information needs. One participant wanted information about bowel function, which was included in the intervention, and two did not specify information needed.

Satisfaction with the most recent appointment was scored by all 50 participants at baseline and by all those in the hospital arm and 23 of those in the telephone arm at follow-up (Table 4). The mean score for satisfaction with

**Table 4** Satisfaction with service and information provision by randomization group.

	Baseline						Follow-up					
	Hospital group (n = 25)			Telephone group (n = 25)			Hospital group (n = 25)			Telephone group (n = 25)		
	No. of responses	Mean	SD	No. of responses	Mean	SD	No. of responses	Mean	SD	No. of responses	Mean	SD
Satisfaction with most recent appointment*,†	25	9.0	1.1	25	8.7	1.8	25	9.5	0.8	25	9.8	0.5
		<i>n</i>	%		<i>n</i>	%		<i>n</i>	%		<i>n</i>	%
Received all/most information needed	23	22	96	22	21	95	25	25	100	23	23	100
Had concerns or problems	24	7	29	23	8	35	23	3	13	25	5	20
Mentioned concerns	10	8	80	11	7	64	7	3	43	10	9	90
Very satisfied/satisfied with way concerns were addressed	12	11	92	14	13	93	11	11	100	18	17	94

\*At follow-up, unpaired *t*-test:  $t = -1.66$ , d.f. = 39.6,  $P = 0.104$ ; 95% CI for difference between means  $-0.7$  to  $0.7$ .

†At follow-up, analysis of covariance:  $F = 5.08$ , d.f. = 1 and 45,  $P = 0.029$ ; 95% CI for difference between adjusted means  $-0.8$  to  $-0.04$ .

1 the most recent appointment was higher in the telephone  
2 arm (Cohen's  $d = 0.45$ ). Unadjusted for baseline scores,  
3 there was no evidence of a difference in satisfaction  
4 between groups at follow-up ( $P = 0.104$ ); adjusted for  
5 baseline scores, satisfaction was higher in telephone  
6 follow-up ( $P = 0.029$ ). The most noticeable difference  
7 between the groups was in the mentioning of concerns at  
8 the follow-up appointment: 3/7 hospital participants  
9 who answered the question did so compared with 9/10  
10 telephone participants, although the difference was not  
11 statistically significant (Fisher's exact  $P = 0.101$ ).

12 The two groups were similar at baseline in terms of  
13 numbers of contacts between appointments with health  
14 professionals in the previous 6 months. The groups were  
15 also similar at follow-up, with fewer contacting a GP or  
16 hospital doctor. In the hospital arm, nine had contacted a  
17 GP, ten a colorectal nurse and one a hospital doctor; in  
18 the telephone arm the numbers were eight, thirteen and  
19 three respectively. There were no noticeable differences in  
20 the numbers of participants in the two groups in terms of  
21 blood tests or colonoscopies ordered, although CT scans  
22 were more likely to be ordered in the hospital (14/25,  
23 56%) than the telephone (10/24, 42%) arm. The  
24 difference was not statistically significant but the sample  
25 size was small.

26 There was a clear difference between groups for  
27 duration of appointment. The median duration of hospital  
28 appointments was 14.0 min (range 2.3–58.0) compared  
29 with a median of 28.9 min (range 6.1–48.3; Mann-  
30 Whitney  $U = 136.0$ ,  $P = 0.001$ ) for telephone appoint-  
31 ments. Within the hospital arm, a nurse conducted 12 of  
32 the face-to-face appointments (median 24.0 min, range  
33 8.8–33.0) and two telephone appointments (34.6 and  
34 58.0 min); the other 11 appointments were with hospital  
35 doctors (median 4.0 min, range 2.3–13.8).

36 Two hospital participants and one telephone partici-  
37 pant had a recurrence during the study. All three  
38 occurred in asymptomatic male patients and were  
39 detected by routine investigations ordered at hospi-  
40 tal/telephone appointments (CT scan in all cases). Time  
41 to detection of recurrence was estimated based on  
42 the date on which the scan showed an abnormality to  
43 the date the patient was informed of the diagnosis of  
44 recurrence. For the telephone participant (age 72 years) it  
45 was 8 weeks to confirmation of metastases in a retrocaval  
46 node. For the two hospital participants, time to detection  
47 of recurrence was 7 weeks for one individual with lung  
48 metastases (81 years) and 8 weeks for an individual with  
49 liver metastases (59 years).

50 At baseline, patients reported that it took a median of  
51 22.5 min (range 10–60) to get to the hospital appoint-  
52 ment from home. For the hospital arm this was similar at  
53 the follow-up time point (median 30 min). The majority

reported travelling to hospital appointments in their own  
car or a friend's/relative's car (63.1% at baseline, 65.2%  
for the hospital arm at follow-up). Other forms of  
transport included bus, taxi and hospital transport. For  
those who used public transport the cost was reported as  
a median of £3 (€3.42) at baseline (range £1–18, €1.14–  
20.51) and £8 (€9.11) at follow-up (range £5–11, €5.70–  
12.53). Only four participants reported having to take  
time out of work for their hospital appointments at  
baseline and one at the follow-up time point. However,  
the majority reported being accompanied to hospital  
appointments by a relative/friend at baseline (73.9%),  
slightly reduced at follow-up (56.5%).

## Discussion

This study demonstrates that telephone follow-up by  
specialist nurses is an acceptable and feasible approach to  
providing follow-up care for CRC patients and inclusion  
criteria appear appropriate. The intervention was relevant;  
no questions were considered redundant or unsuitable.  
Early indications are that telephone follow-up can be  
successfully incorporated into clinical practice within  
current resources. While the best combination of tests  
and investigations for maximizing patient outcomes  
remains unclear, telephone follow-up is one means of  
meeting psycho-social needs and providing patients with  
the information and support they need to live well  
following diagnosis.

Although it is unlikely that specialist nurses could  
provide follow-up care for all patients on completion of  
treatment, they could take responsibility for a significant  
cohort who had a preference for being telephoned at  
home. In this study 75% agreed to randomization,  
indicating that patients were agreeable to their consulta-  
tion being carried out by a specialist nurse rather than a  
doctor. A recent study comparing nurse- and doctor-led  
follow-up after rectal cancer surgery found that patient  
satisfaction was equally as high for nurses and doctors  
[27]. If telephone support is equivalent to hospital  
support, with no physical or psychological detriment,  
then a negotiated approach offering patients a choice of  
follow-up care provision could be introduced.

Outcome measures appeared to be appropriate,  
although there were missing data for 'trait' (Y2) ques-  
tions on STAI. We are not clear why this was the case and  
may have resulted from administrative error; more  
detailed records would need to be kept in any future  
trial. Participants did not have raised anxiety levels if they  
were telephoned, foregoing face to face contact with a  
hospital doctor. This would justify a RCT with a non-  
inferiority or equivalence design in future research.  
Telephone participants raised more concerns. Arguably,



1 information needs were met at hospital visits and there-  
 2 fore patients did not have any concerns. Alternatively,  
 3 patients may not have been comfortable raising concerns  
 4 in busy hospital clinics. If clinicians rely on patients to  
 5 initiate discussion of psycho-social issues then problems  
 6 may not be addressed [28].

7 Appointments with a nurse were longer than appoint-  
 8 ments with a doctor, irrespective of study group. Appoint-  
 9 ments with hospital doctors were of short duration (mean  
 10 9 4.8 min). This clearly has cost implications. Although  
 11 patients in the telephone group saved time and travelling  
 12 costs, more evidence is needed on whether this is a cost-  
 13 effective approach for the health service. It was more likely  
 14 that patients would mention their concerns during tele-  
 15 phone consultations, probably as a result of being asked  
 16 specific questions, and this may have extended consulta-  
 17 tions. As this was a pilot study, patients were not followed  
 18 up over an extended time period, and we are uncertain if  
 19 appointment duration reduces over time once nurses are  
 20 familiar with the intervention and initial concerns and  
 21 information needs are addressed.

22 A limitation of the study was that the same nurse  
 23 conducted some of the hospital appointments and all the  
 24 telephone appointments. Although the nurse only used  
 25 the structured telephone intervention with patients ran-  
 26 domized to the telephone arm, contamination is possible  
 27 and would need to be avoided in a main trial. Resources  
 28 were not available to carry out a multicentre study with a  
 29 number of different specialist nurses. However, there was  
 30 value in one nurse being involved in both arms of the  
 31 study at the pilot stage in providing useful feedback on  
 32 the two approaches and training requirements to inform  
 33 the main study. A design that involves sequential rollout  
 34 of the intervention may be a suitable and practical design  
 35 if there is a shortfall in the number of nurses required to  
 36 eliminate contamination between study groups.

37 In the current economic climate it is unlikely we can  
 38 sustain historical approaches to follow-up that are not  
 39 supported by evidence of effectiveness and efficiency. The  
 40 telephone intervention was acceptable to both patients  
 41 and health professionals and was deliverable in practice. A  
 42 main trial of the intervention is justified with an economic  
 43 evaluation, preferably with an equivalence or non-inferi-  
 44 ority design.

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## Conflict of interest

The authors declare no potential conflicts of interest.

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