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Title	An exploratory randomised controlled trial comparing telephone and hospital follow-up after treatment for colorectal cancer
Type	Article
URL	https://clock.uclan.ac.uk/4761/
DOI	https://doi.org/10.1111/j.1463-1318.2012.02936.x
Date	2012
Citation	Beaver, Kinta, Campbell, M., Williamson, Susan, Procter, D., Sheridan, J., Heath, J. and Susnerwala, S. (2012) An exploratory randomised controlled trial comparing telephone and hospital follow-up after treatment for colorectal cancer. <i>Colorectal Disease</i> , 14 (10). pp. 1201-1209. ISSN 14628910
Creators	Beaver, Kinta, Campbell, M., Williamson, Susan, Procter, D., Sheridan, J., Heath, J. and Susnerwala, S.

It is advisable to refer to the publisher's version if you intend to cite from the work.
<https://doi.org/10.1111/j.1463-1318.2012.02936.x>

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

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APPROVED

Received 8 September 2011; accepted 31 October 2011; Accepted Article online XX Xxxx 20XX

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

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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 Method

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

52 mended when estimating a particular parameter in a pilot
53 study [24]. Eligible patients had a diagnosis of CRC, had
54 completed treatment (surgery/radiotherapy/chemother-
55 apy) with no evidence of recurrent disease, had access to a
56 telephone, adequate hearing and were attending hospital
57 outpatient consultations for routine monitoring. Recruit-
58 ment took place at a large hospital in the north-west of
59 England. Consecutive eligible patients were identified at
60 the hospital clinics of four consultant surgeons and a
61 colorectal nurse practitioner. The latter already provided
62 a service to patients after treatment at nurse-led clinics, an
63 expectation of the practitioner role. Clinical nurse
64 specialists provided a service to patients at the time of
65 diagnosis, on admission to hospital and at home follow-
66 ing hospital discharge, and stoma care nurses attended to
67 the needs of patients with a stoma. However, it was only
68 the nurse practitioner who was involved in delivering the
69 telephone intervention in this study. The study had
70 approval from the National Research Ethics Service.

71 Randomization

72 Consenting individuals were randomized to either hos-
73 pital or telephone follow-up by a computerized system.
74 Group allocation was stratified by age (≤ 60 years,
75 > 60 years) and gender. Allocation sequences were con-
76 cealed until interventions were assigned. The analyst was
77 blind to study group allocation. Participants randomized
78 to the hospital arm were routinely reviewed at 6-weeks
79 posttreatment, then 6-monthly intervals for 2 years and
80 annually for a further 3 years and discharged to the care
81 of their general practitioner (GP) after 5 years, unless
82 complex or unresolved problems were evident. Hospital
83 consultations could be conducted by consultant sur-
84 geons, registrars, more junior doctors or a colorectal
85 nurse practitioner. The content and format of appoint-
86 ments in the hospital control arm was unaltered and
87 clinicians focused on routine monitoring for detection of
88 recurrent disease.

89 Participants randomized to telephone follow-up
90 received telephone consultations from a colorectal nurse
91 practitioner at the same prescribed intervals as partici-
92 pants in the hospital arm. Appointments were focused
93 primarily on provision of information using a structured
94 intervention to establish patient information needs.
95 Appointment cards were sent, indicating the date and
96 time of telephone appointments. These were registered
97 on computerized hospital information systems in the
98 same way as traditional hospital appointments so that
99 medical records staff could retrieve patient notes prior to
100 telephone clinics. Thirty minutes were allocated for
101 telephone appointments (20 min consultation time,
102 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

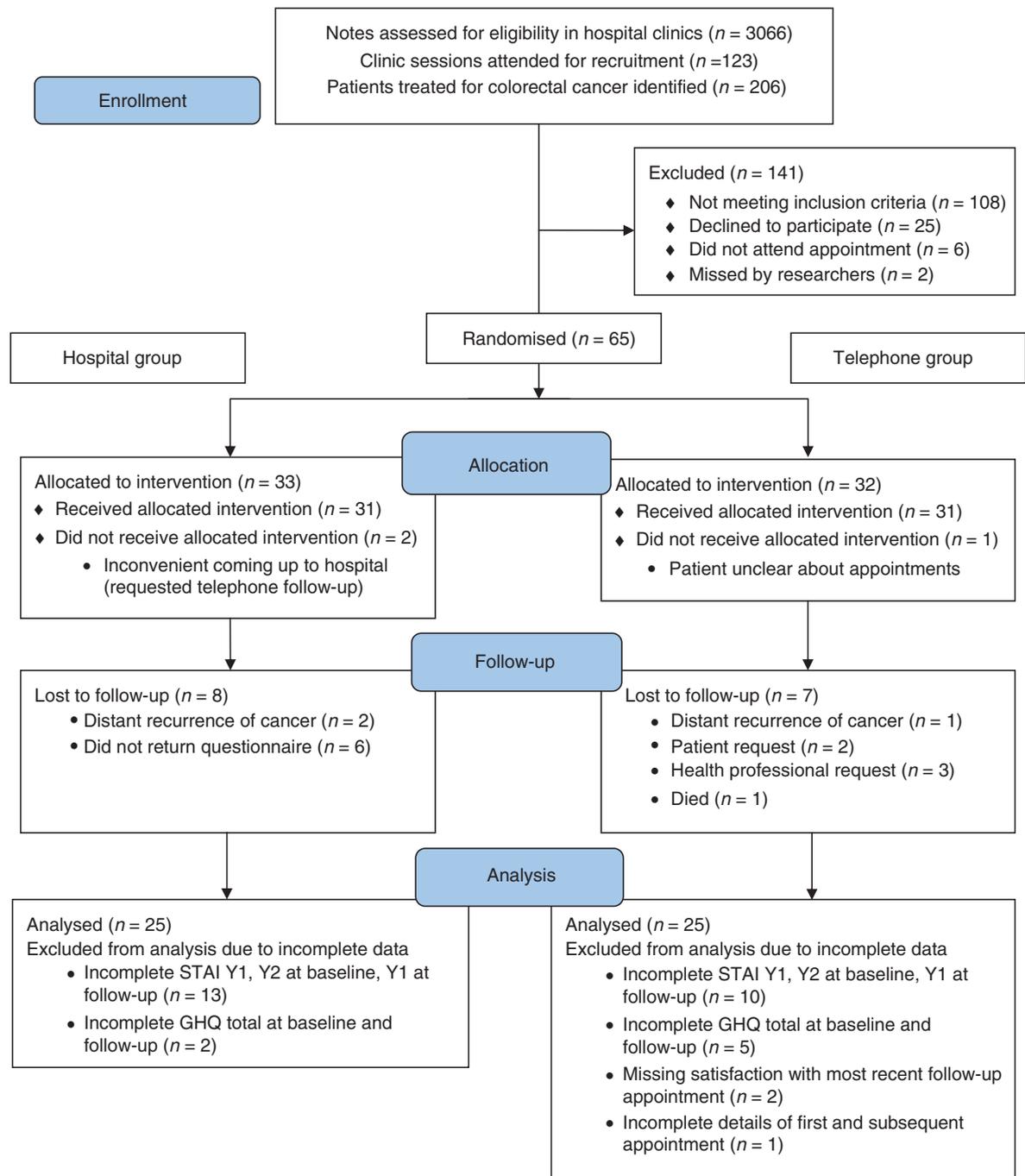


Figure 1 Flow of participants through the pilot trial [STAI, State-Trait Anxiety Inventory (Y1, temporary anxiety state; Y2, personality trait); GHQ-12, General Health Questionnaire (shortened 12-item version)].

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.

45 Acknowledgements

46 We would like to thank Sandra Foster for her assistance
 47 with data collection. Thanks are also expressed to the
 48 consultant surgeons at the study location who granted
 49 access to their clinics for the purpose of recruitment. Our
 50 thanks are also expressed to all patients who participated
 51 in this study.
 52
 53

Funding

This study was financially supported by a small project
 grant from Cancer Research UK.

Conflict of interest

The authors declare no potential conflicts of interest.

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