

PAPER

Telephone-delivered individual cognitive behavioural therapy for cancer patients: An equivalence randomised trial

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Abstract

Objective To evaluate Telephone-Delivered Cognitive Behavioural Therapy (T-CBT) compared to CBT face to face treatment as usual (TAU-CBT), in cancer patients with high psychological needs, in terms of mental health and coping.

Method A prospective randomised equivalence trial with Patient Reported Outcome (PRO's), measured pre- and post-therapy including; Hospital Anxiety and Depression Scale (HADS), Mental Adjustment to Cancer Scale: Helpless/Hopeless subscale only (MAC H/H), Checklist of Cancer Concerns (CLCC) and the Cancer Coping Questionnaire (CCQ). A study-specific Service Evaluation Questionnaire (SEQ) was include.

Results Assessment of change scores, in $n = 118$ randomised patients referred for psychological care, indicate significant improvements ($P < 0.01$ or greater) for both therapy groups pre- and post-therapy in HADS anxiety, depression and total scores and cancer concerns (CLCC). Overall, for the groups combined, there is a significant shift towards reduction of CCQ stress ($P = 0.028$) and worry ($P = 0.003$) post-therapy when compared to baseline levels. Median number of therapy sessions was four. For cancer coping (CCQ) and for Mental Adjustment to Cancer (MAC) there were significant change scores only for Positive Focus and Helpless/hopeless scores respectively, in the TAU-CBT group. Although equivalence was not observed, the data demonstrate that T-CBT was non-inferior to TAU-CBT.

Conclusions Delivery of CBT to patients with clinician identified high need can be offered according to patient choice without loss of mental health benefit. Both TAU-CBT and T-CBT are effective at reducing mental health problems on the specific outcome measures.

KEYWORDS

anxiety, cancer, CBT, coping, depression, oncology, telephone therapy

1 | INTRODUCTION

Increasing access to high-level psychotherapies, capable of improving mental health in cancer patients, is a priority.¹ With expanding global phone access,² research is beginning to focus on telephone-delivered psychotherapies.³⁻⁶ Potential advantages include improved access where therapy is offered regardless of patients' location or level of physical functioning; the option of home-based sessions; dispensing with patients' travel time/costs to attend clinic/hospital sessions; reducing their time off work to attend; avoiding stigma associated with use of mental health services; and protecting patients' immune-suppressed status. Adaptability of a structured therapy, such as cognitive behavioural therapy (CBT), makes it appropriate for telephone

delivery.⁷ A review of telephone-delivered psychological therapies for cancer patients found only modest effect sizes.⁸ Studies on tele-based low-intensity interventions for cancer patients have generally produced low-moderate quality data, mainly attributable to lack of patient pre-selection at study enrollment based on mental health needs. Face-to-face CBT is well established and is therapy of choice in the UK National Health Service (NHS) for patients with chronic physical illness.⁹ Face-to face delivery of high-level CBT for pre-selected high-needs cancer patients already has established efficacy¹⁰ continuing beyond the therapy period.¹¹ A feasibility study of telephone-delivered CBT (T-CBT)⁷ indicated benefits requiring replication in a randomised trial. The current study assesses a telephone-delivered high-intensity CBT, provided by level 3/4 mental health professionals

in a clinically referred cohort, reflecting a real-world service model. Few studies, at inception of the intervention, have used this approach.

1.1 | Telephone-delivered CBT

A manualised therapy (T-CBT) provided by psychologists; treatment fidelity is ensured through weekly peer supervision along with peer observation of some sessions, with patient consent, then discussion at supervision meetings. Core therapy components include establishing a collaborative therapeutic relationship between patient and therapist; focusing sessions through agenda setting; use of a Socratic questioning guided discovery technique; teaching problem-focused coping; use of "homework" as a didactic method to advance coping efficacy; activity scheduling to provide positive behavioural structure and pre-selected goals in everyday life; use of relaxation to assist in management of worry; teaching patients to use distraction/thought-stopping to limit negative mood; and teaching monitoring/re-scripting/challenging of unhelpful negative automatic thoughts. Graded goal-setting, within realistic limits, is central. Ventilation of concerns is encouraged. The aim is to facilitate coping, to increase patients' self-efficacy and problem-solving skills, and to reduce anxiety, depression, helplessness, and cancer concerns. A Therapists' manual is available, and a patient workbook (based on the prior feasibility study) is provided¹ along with a standard relaxation Compact Disc (CD) for each participant. Telephone-specific elements include using more verbal communication to compensate for lack of non-verbal cues in therapy interactions (see Therapists' manual). Patients are telephoned at pre-arranged times and sessions scheduled. The same requirements of confidentiality, professional conduct, and ethics within routine face-to-face therapy are used in T-CBT. Based on the feasibility study data, up to 8 sessions can be offered and therapy is delivered over an approximate 12-week period.⁷

1.2 | Coping mechanisms

While CBT is well established, the mechanisms by which this brings improvements are unclear within cancer care. Little attention within the psycho-oncology literature has focused on which coping strategies mediate therapeutic outcomes. One review suggests that interventions need to be firmly based on an understanding of change mechanisms and promising options include "self-efficacy" coping strategies.¹² The importance of assessing coping strategies is that it enables a better understanding of how therapy technique and the affective outcome are related. Assessing coping strategies provides information on therapy methods more likely to help patients achieve improvement in mental health. Data from our feasibility study confirmed changes in coping consistent with a therapy approach that targets use of "positive focus" and "planning" as mechanisms for improvement.⁷ Further assessment within the current Randomised Clinical Trial (RCT) is indicated.

1.3 | Study aims and hypotheses

Using an equivalence design, CBT Face-to-Face Treatment As Usual (TAU-CBT) is compared with telephone-delivered CBT (T-CBT). The primary end point is change in Hospital Anxiety and Depression Scale

(HADS) anxiety and depression after treatment compared to baseline. The aim is to test if T-CBT has equivalent efficacy to TAU-CBT. The trial was approved by the Royal Marsden NHS Foundation Trust Ethical Committee NHS/HSC R&D (Protocol REC 09/H0801/60). All participants provided written informed consent.

2 | METHOD

2.1 | Design

Prospective randomised equivalence trial comparing TAU-CBT with T-CBT.² A no-treatment control group was not used given prior data indicating efficacy of standard care CBT for cancer patients.^{9,10} CONSORT principles¹³ and requirements of the UK Medical Research Council¹⁴ on assessment of complex psychological interventions were applied.

2.2 | Participant recruitment

A consecutive series of patients referred to the Royal Marsden Hospital's Psychological Care Service over an 18-month period by clinical staff (predominantly medical consultants and specialist cancer nurses not necessarily trained in psychological screening or assessment) was approached. Clinicians considered these patients to have high psychological needs, and eligible patients, consenting to the referral, were invited to participate.

2.3 | Eligibility criteria

The criteria are the following: patients aged 18 years or older with a cancer diagnosis (except non-melanoma skin cancer), aware of their cancer diagnosis, greater than 8 weeks post-diagnosis with a minimum disease prognosis greater than 3 months (clinician judged), no psychotic symptoms or suicide risk at baseline,³ no communication or cognitive problems, not previously seen in our service, not receiving other formal psychological therapy at recruitment, currently an out-patient with access to a telephone, and able to complete a study questionnaire.

2.4 | Measures

2.4.1 | Patient-reported outcomes

Patient-reported outcomes (PROs) were self-assessed by postal questionnaire issued by an independent research manager. The questionnaires (all pre-validated) were scored using standard procedures. Patient-reported outcomes assessed pre-therapy (baseline) and at cessation of therapy (post-therapy) were (1) anxiety and depression on the HADS with cases defined as "borderline" (8-10) or "clinical" (11 or above)¹⁶; (2) Mental Adjustment to Cancer: helpless/hopeless (MAC-H/H) subscale only¹⁷; and (3) Cancer concerns using the 14-item checklist of cancer concerns (CLCC).¹⁸ Post-therapy, a study-specific service questionnaire, evaluated patient-perceived satisfaction, benefits, or disadvantages of the therapy with additional questions, for T-CBT patients only, on receiving telephone therapy.⁴ Use of the patient workbook and relaxation CD was assessed.

Coping was assessed pre- and post-therapy using the cancer coping questionnaire (CCQ) designed to measure coping skills taught in CBT as applied to cancer patients.¹⁹ This 21-item measure covers general coping strategies, positive focus, diversion, planning, interpersonal skills, and a total coping score. The interpersonal skills subscale (items 15-21) relates only to patients in a partnership. Ratings are from 1 = "not at all" to 4 = "very often." The measure has 2 items assessing levels of stress (from 1 = "not at all stressful" to 4 = "very stressful") and worry (from 1 = "none of the time" to 4 = "most of the time").

2.5 | Sociodemographic and medical data

Baseline data included gender, age, marital status, ethnicity, occupational status, occupational change as a result of cancer, educational level, cancer diagnosis, disease stage, and type and number of cancer treatments received within the previous 6 months.

2.6 | Procedure

Eligible patients were invited via an opt-in letter from an independent administrator, which included an information sheet, consent form, and contact details for the psychological service. The option for therapy outside the study was provided for patients declining participation. Where no reply was received within 2 weeks, the invitation letter⁵ was re-issued. Randomisation to T-CBT or TAU-CBT was by independent statistician and stratified by therapist. Patients were offered up to 8 sessions; any requiring more, continued in therapy outside the trial following a post-therapy assessment.

2.6.1 | Sample size and power calculations

An earlier study¹⁰ indicated a reduction in anxiety and depression following TAU-CBT on the HADS. The average change was 1.8 for anxiety (SD = 4.1) and 1.3 for depression (SD = 3.6). Total change in HAD = 3.1. In the feasibility study,⁷ a similar reduction was seen: average change anxiety 2.1 (SD = 4.0); depression 1.3 (SD = 2.6); and total score 3.4 (SD = 6.0), (expected reduction for TAU-CBT = 3.1; equivalence limit = 1.6; common SD = 6.0, alpha = 5%; power = 80%). The study was initially powered to recruit 124 patients to each group based on the primary end point of the combined change in anxiety and depression score compared to baseline.

2.7 | Statistical method

Patient's demographic and medical details were compared between groups using the chi-squared, Fishers exact, or Mann-Whitney tests to check balance between therapy groups. Analysis was on an intention to treat basis. For follow-up assessments, change score from baseline was calculated and formed the basis for treatment comparisons. The t-test or Mann-Whitney test compared change from baseline between the treatment groups. The influence on the study outcome of disease stage (early/locally advanced/advanced), cancer treatment within the previous 6 months (surgery/chemotherapy/radiotherapy/hormone therapy) and anti-depressant therapy (Yes/No), was controlled by analysis of covariance. As an equivalence trial, all treatment comparisons are 2 sided; a 5% level of significance was used.

3 | RESULTS

A CONSORT diagram shows the flow of patients through the study (see Figure S1); 118/400 (30%) eligible patients were randomised. Patients declined participation either because they did not want any therapy 58/400 (15%) or because they wanted therapy but declined trial participation 183/400 (46%). A further 41/400 (10%) failed to reply to the opt-in letters. Sixty patients were randomised to T-CBT and 58 to TAU-CBT with 43 and 35 providing complete analysable data, respectively. No other psychological intervention was provided during the trial.

3.1 | Sociodemographic, medical, and PRO data at baseline

Median age of the 118 participants at baseline was 51 (range: 18-79), and 72% were female (other details are summarised in Table 1). The therapy groups are balanced for baseline attributes/scores and were not significantly different (all $P > .1$). There were no significant differences between those randomised and decliners for median age ($P = .656$), gender ($P = .806$), cancer diagnosis ($P = .257$), and cancer stage ($P = .322$).

3.2 | Number of therapy sessions

Median number of sessions for the whole sample was 4 (min: 1; max: 8⁶), and distribution by number of session across groups was equivalent (Mann-Whitney U test $P = .813$). Median number of sessions attended in the 2 groups was equivalent (4 sessions) range 1-8 for TAU-CBT and 2-9 for T-CBT. The proportion of patients overall who attended 1-4 sessions was 43/78 (55%). The proportions of attendance in the 2 groups was not significantly different (Chi-square $P = .553$). The mean change scores of patients who had either 1-4 or 5-9 sessions was not significantly different for all questionnaire domains with t-test P -values ranging from 0.130 to 0.846. Costs of therapist time were equivalent between the 2 treatment arms. Therapist effects between the 3 psychologists were compared; there were no significant differences on the PROs.

3.3 | Telephone-delivered CBT and TAU-CBT equivalence

To demonstrate full equivalence, the difference between the 2 groups should be around zero and the 95% confidence interval of the difference should also be within the limit of 1.6 in both directions. Equivalence was not achieved as per the data reported in Table 2.

3.4 | Between and within group comparisons

The primary analysis compared T-CBT and TAU-CBT on HADS anxiety, depression, and total score; MAC-H/H; CLCC; and CCQ stress and worry scores, pre- to post-therapy for each treatment group and patients overall. The paired scores at baseline and post-therapy (Table 3) indicate significant improvements ($P < .01$ or greater) on HADS anxiety, depression, and total scores and for cancer concerns (CLCC). There was a positive change ($P = .015$) in MAC-H/H scores but only for TAU-CBT.

TABLE 1 Baseline sociodemographic/medical data and patient-reported outcomes (PROs)

SocioDemographic/ Medical Data	T-CBT N = 60 (%)	TAU-CBT n = 58 (%)	P Value
Gender			
Female	44(73)	41 (71)	0.749
Male	16 (27)	17 (29)	
Age			
Mean (SD)	48.5 (13.3)	52.4 (13.1)	0.883
Median (Range)	47 (20-74)	52 (18-79)	
Disease diagnosis			
Breast	24 (40)	23 (40)	0.722
Gastro-intestinal (GI)	7 (12)	9 (16)	
Gynae	4 (7)	2 (3)	
Leukaemia	5 (8)	2 (3)	
Lung	1 (2)	1 (2)	
Lymphoma	5 (8)	3 (5)	
Prostate	3 (5)	1 (2)	
Sarcoma	2 (3)	5 (9)	
Teratoma	0	1 (2)	
Other	9 (15)	11 (19)	
Disease stage			
Early	22 (37)	20 (35)	0.970
Locally advanced	21 (35)	21 (36)	
Advanced	17 (28)	17 (29)	
Currently receiving a cancer treatment			
No	9 (15)	13 (22)	0.301
Yes	51 (85)	45 (78)	
Cancer treatment received at baseline			
Surgery	29 (48)	25 (43)	
Chemotherapy	27 (45)	22 (38)	
Radiotherapy	15 (25)	16 (28)	
Hormone therapy	7 (12)	8 (14)	
Other treatments	5 (8)	7 (12)	
Ethnicity: n = 109			
White British	51 (96)	49 (88)	0.098
Others	2 (4)	7 (13)	
Marital status: n = 115			
Married	28 (49)	38 (66)	0.327
Single	18 (32)	12 (21)	
Widowed	4 (7)	2 (3)	
Divorced / separated	7 (12)	6 (10)	
Education level: n = 102			
University graduate or equivalent	19 (37)	23 (45)	0.764
College or specialized training	15 (29)	10 (20)	
Secondary education	14 (28)	16 (31)	
Left school before 15 y	2 (4)	1 (2)	
Other	1 (2)	1 (2)	
Currently employed: n = 112			
Yes	26 (47)	31 (54)	0.375
No	18 (33)	12 (21)	
Retired	11 (20)	14 (25)	

TABLE 1 (Continued)

Patient-Reported Outcomes	n = 55 Mean (SD)	n = 53 Mean (SD)	P Value
HADS anxiety	9.60 (10.17)	10.17 (3.92)	.443
HADS depression	7.89 (4.63)	7.81 (3.75)	.922
MAC helpless/hopeless	12.53 (4.26)	13.02 (4.00)	.538
Checklist of cancer concerns	20.87 (8.97)	22.13 (9.17)	.472
Cancer coping questionnaire (CCQ)			
Coping	9.62 (3.20)	10.15 (3.41)	.404
Positive focus	7.62 (2.35)	7.06 (2.00)	.189
Diversion	7.31 (2.15)	6.94 (2.13)	.377
Planning	7.73 (2.62)	7.19 (2.25)	.261
Total scores	32.27 (7.91)	31.35 (7.19)	.528
Interpersonal subscale (n = 68) ^a	16.54 (5.20) n = 31	15.00 (4.61) n = 37	.127
HADS cases			
Anxiety			
Not a case (scores ≤11)	31 (56)	29 (55)	.863
Clinical case (scores >11)	24 (44)	24 (45)	
Depression			
Not a case (scores ≤11)	41 (75)	42 (79)	.563
Clinical case (scores >11)	14 (25)	11 (21)	

^aCompleted only by patients currently in a partnership.

Abbreviations: MAC, Mental Adjustment to Cancer; HADS, Hospital Anxiety and Depression Scale; T-CBT, telephone-delivered cognitive behavioural therapy; TAU-CBT - face-to-face treatment as usual.

Cancer coping questionnaire levels of stress and worry are equivalent and not significantly different between the 2 treatment groups at baseline and post-therapy (Chi-square): see Table S1 for group CCQ scores separately. Overall, for the groups combined, there is a significant shift towards ($P = .028$) and reduction of stress/worry ($P = .003$) post-therapy compared to baseline levels: see Table S2.

3.5 | Hospital Anxiety and Depression Scale clinical cases

Overall, the proportion of patients changing from case to no-case for HADS anxiety and depression improved post-therapy, and the differences were significant based on the McNemar test ($P < .005$). For TAU-CBT and T-CBT, there are similar effects to those of patients overall but only anxiety change was significantly improved: TAU-CBT ($P = .021$) and T-CBT ($P = .039$); this is likely due to larger number of anxiety cases compared to depression in the whole sample.

3.6 | Coping response

For CCQ, there were no significant change scores except for positive focus in the TAU-CBT group ($P = .003$): see Table 4.

TABLE 2 Questionnaires change score comparisons between groups

Change Scores (Pre and Post)				
	n	Mean change	SD	Mean diff (Tel–F-F) (95% CI of diff)
Anxiety				
Telephone	43	2.02	3.54	–0.09 (–1.91: 1.73)
Face to face	35	2.11	4.54	
Depression				
Telephone	43	1.86	3.29	–0.45 (–2.19: 1.28)
Face to face	35	2.31	4.40	
HADS: Total score				
Telephone	43	3.88	6.23	–0.55 (–3.83: 2.74)
Face to face	35	4.43	8.32	
MAC: Helpless/Hopeless				
Telephone	43	1.26	5.33	–0.74 (–3.02: 1.53)
Face to face	35	2.00	4.60	
Checklist of Cancer Concerns				
Telephone	43	4.67	8.95	–1.58 (–5.56: 2.40)
Face to face	35	6.26	8.55	
Cancer Coping Questionnaire (CCQ)				
CC General Coping				
Telephone	43	–0.44	3.35	–0.53 (–2.09: 1.03)
Face to face	35	0.09	3.55	
CC Positive Focus				
Telephone	43	–0.51	2.12	0.831 (–0.21: 1.88)
Face to face	35	–1.34	2.51	
CC Diversion				
Telephone	43	0.16	2.50	0.42 (–0.73: 1.57)
Face to face	35	–0.26	2.57	
CC Plan				
Telephone	43	0.05	2.56	0.48 (–0.70: 1.65)
Face to face	35	–0.43	2.60	
CC TOTAL				
Telephone	43	–0.74	8.33	1.20 (–2.36: 4.76)
Face to face	35	–1.94	7.21	
CC Interpersonal (n = 51)				
Telephone	26	0.62	3.31	0.91 (–1.81: 3.62)
Face to face	25	1.52	5.99	

Abbreviations: CCQ, cancer coping questionnaire; CI, confidence interval; HADS, Hospital Anxiety and Depression Scale; MAC, Mental Adjustment to Cancer.

3.7 | Study specific service evaluation

The groups were similar in their evaluation of the service. However, 7 of the T-CBT group would have preferred TAU-CBT (i.e., face to face care) if available, and 3 of the TAU-CBT would have preferred T-CBT (telephone) if available. For the TAU-CBT and T-CBT groups, respectively, 31 (94%) and 36 (90%) indicated the service had helped, 28 (85%) and 27 (68%) used the patient workbook, and 17 (52%) and 17 (43%) used the relaxation CD. Full descriptive data on service evaluation are given in Appendix S1.

4 | DISCUSSION

The 2 therapy methods were equally effective in reducing mental health outcomes assessed by HADS anxiety and depression, cancer

TABLE 3 Baseline and post-therapy paired t-test comparisons for PROs

Change Scores	n	Mean	SD	P Value
HADS: Anxiety				
T-CBT				
Baseline	43	9.81	3.55	<.001
Post-therapy	43	7.79	3.64	
TAU-CBT				
Baseline	35	9.66	3.23	.009
Post-therapy	35	7.54	4.76	
HADS: Depression				
T-CBT				
Baseline	43	7.37	4.15	<.001
Post-therapy	43	5.51	4.22	
TAU-CBT				
Baseline	35	7.63	3.98	.004
Post-therapy	35	5.31	4.34	
HADS: Total score				
T-CBT				
Baseline	43	17.19	6.68	<.001
Post-therapy	43	13.30	7.20	
TAU-CBT				
Baseline	35	17.29	6.04	.003
Post-therapy	35	12.86	8.56	
MAC: Helpless/Hopeless				
T-CBT				
Baseline	43	12.26	4.04	.130
Post-therapy	43	11.00	4.47	
TAU-CBT				
Baseline	35	12.57	4.22	.015
Post-therapy	35	10.57	4.55	
Checklist of Cancer Concerns				
T-CBT				
Baseline	43	20.67	8.36	<.001
Post-therapy	43	16.00	9.16	
TAU-CBT				
Baseline	35	20.71	8.59	<.001
Post-therapy	35	14.46	10.00	

Abbreviations: HADS, Hospital Anxiety and Depression Scale; MAC, Mental Adjustment to Cancer; T-CBT, telephone-delivered cognitive behavioural therapy; TAU-CBT, CBT face-to-face treatment as usual.

concerns, and cancer coping (CCQ) stress and worry. Although equivalence was not observed, the data demonstrate that T-CBT was non-inferior to TAU-CBT. In HADS clinical caseness, there were reductions in anxiety and depression for the groups combined. Level of stress and worry on the CCQ are equivalent between groups at both baseline and post-therapy, with a shift towards reduction of stress and worry post-therapy compared to baseline. There were no therapist effects within the trial, and all were mental health professionals. For coping response, assessed using the CCQ, the only pre- and post-therapy change was increased use of positive focus in the TAU-CBT group. This sub-scale includes 3 items: "Made sure you thought of some of the positive aspects of your life," "Reminded yourself of what things you have in life in spite of cancer," "Made definite

TABLE 4 Baseline and post-therapy paired t-test comparisons for coping

CCQ	n	Mean	SD	P Value
General Coping Strategies				
T-CBT				
Baseline	43	9.81	3.27	0.392
Post-therapy	43	10.26	2.99	
TAU-CBT				
Baseline	35	10.63	3.65	0.887
Post-therapy	35	10.54	3.22	
Positive Focus				
T-CBT				
Baseline	43	7.79	2.32	0.121
Post-therapy	43	8.30	2.47	
TAU-CBT				
Baseline	35	6.97	2.02	0.003
Post-therapy	35	8.31	2.22	
Diversion				
T-CBT				
Baseline	43	7.26	2.15	0.671
Post-therapy	43	7.09	2.61	
TAU-CBT				
Baseline	35	7.00	2.26	0.558
Post-therapy	35	7.26	1.74	
Planning				
T-CBT				
Baseline	43	7.95	2.61	0.906
Post-therapy	43	7.91	2.52	
TAU-CBT				
Baseline	35	7.71	2.07	0.337
Post-therapy	35	8.14	2.34	
Total Score				
T-CBT				
Baseline	43	32.81	7.77	0.561
Post-therapy	43	33.56	8.53	
TAU-CBT				
Baseline	35	32.31	7.20	0.120
Post-therapy	35	34.26	7.14	
Interpersonal				
T-CBT				
Baseline	26	16.65	4.82	0.352
Post-therapy	26	16.04	6.12	
TAU-CBT				
Baseline	25	15.48	4.72	.217
Post-therapy	25	13.96	5.53	

Abbreviations: CCQ, cancer coping questionnaire; T-CBT, telephone-delivered cognitive behavioural therapy; TAU-CBT, CBT face-to-face treatment as usual.

plans for the future."¹⁹ We previously reported significant changes on all CCQ dimensions except the interpersonal scale.⁷ The greatest change in the feasibility study and the current trial data was on positive focus suggesting tailoring of therapy to stimulate this coping strategy is helpful. More research on coping is indicated.

There are some potential disadvantages to telephone-delivered therapy. Control of the therapeutic environment is more difficult with

interruptions possible in the home environment. It can be more difficult for therapists interpreting pauses and a moderate to high level of clinical experience may be required to successfully implement the telephone approach. This requires investigation.

Recent reviews have shown modest effect sizes for psychological therapies with cancer patients.⁸ This has been linked to insufficient high-needs patients; this creates a floor effect on outcome data. Use of screen-identified moderate- to high-needs patients is linked to clearer efficacy data. While evidence on therapy type providing clearest efficacy has been lacking, a recent review indicated the best evidence was for CBT.²⁰ Development of different delivery options for CBT with cancer patients is a priority. Use of CBT in the UK Improved Access to Psychological Therapies programme has accelerated over recent years, as efficacy data in clinically depressed groups and cost-benefits to the health system have emerged.^{21,22} The present study indicated benefits to cancer patients using both traditional face-to-face therapy and telephone-delivered therapy. It opens up the options to provide CBT via flexible delivery methods that can improve access to those in need who want therapy.

4.1 | Study limitations

Equivalence was not achieved due to participant under recruitment; the majority wanted therapy but declined the trial. This was a clinical sample not routinely screened using standard methods but referred to the service because clinicians judged patients had high psychological needs. Although within the current trial this likely introduces bias, as clinician judgement may not be empirically robust, it reflects how referrals are made in a real-life setting. Hospital Anxiety and Depression Scale baseline scores indicated clinical cases of depression and anxiety were 29% and 54%, respectively. This may be interpreted in a number of ways; that clinicians inaccurately judged psychological symptoms; or symptoms remitted over the 2 to 4 weeks from point of referral to trial entry. These issues might be resolved through using standardised screening methods ascertaining high psychological needs in patients being offered high-level psychological therapies. Issues relating to study uptake continue to be a challenge. Brebach et al²³ highlighted that mean study uptake rates are about 60%. In the present study, uptake was (30%) and attributed to patients wanting to have psychological care but declining the randomised clinical trial (46%). Clinical trial uptake rates frequently do not reflect a real world therapy uptake rate, which could be higher. These problems are not confined to psychosocial therapy trials. A review of medical and surgical RCTs indicated that 21% failed to achieve adequate numbers at randomisation and 48% at outcome assessment.²⁴ In the current study, we did not systematically collect data on reasons for non-uptake by eligible patients. Anecdotally, many patients expressed a preference for mode of therapy and did not want to be randomised. Reasons might be explicated using qualitative interview methods.

4.2 | Clinical implications and conclusions

The present study differs from most others,^{23,25} as it specifically assesses a high-intensity high-level intervention in a clinician-referred sample of patients being treated for cancer at the same hospital where

the psychological care service is situated. It represents a model of cancer care in a real-world service. There is ecological validity in the method, as this is the approach often taken in cancer and mental health services more generally. There is probably not equity of service access, which is something that needs to be addressed more broadly. However, this is the reality of many psycho-oncology services at present.

The results indicate that both treatment groups improved regardless of type of delivery method for CBT. This suggests that patient's choice and convenience will be important determinants of therapy delivery method, with no disadvantages to patients in mental health benefits. Costs of resource usage would be useful to ascertain given both methods delivered mental health benefits.

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CONFLICT OF INTEREST

The authors have declared no conflict of interest.

NOTES

¹ The Therapists' manual and patient workbook are available from the corresponding author. Watson M & White, C. (2009) Coping with Cancer. A Patient Workbook. Royal Marsden Hospital, internal publication. Watson, M, White, C, Lynch A. (2014) A Brief Manual for CBT Therapists working in Oncology, internal publication.

² Only patients with identified psychological care needs, referred by their clinicians to the Psychological Care Service, were included. In this way, the study provides a more ethical trial design.

³ The SCID-I/NP¹⁵ was used by a member of the Psychological Medicine Service clinical team to assess possible symptoms of psychotic illness and suicide risk at baseline for study exclusion purposes.

⁴ See Appendix S1 for more details.

⁵ If no response after 2 weeks, a letter was sent reminding patients that, as they consented to a referral, we invite them to contact us if they want access to care outside of the study. To comply with standard Duty of Care, a letter was sent to the referring clinicians making them aware that the patient had not been seen by the Psychological Service.

⁶ One patient receiving 9 sessions was included in the analysis.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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