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# **Review**

# Psychosocial telephone interventions for patients with cancer and survivors: a systematic review

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#### **Abstract**

*Objective*: Over one third of patients with cancer experience elevated psychosocial distress. As screening for distress becomes more common, the number of patients referred for psychosocial care will increase. Psychosocial telephone interventions are recommended as a convenient and exportable alternative to inperson interventions addressing psychosocial distress. This study reviews the efficacy of randomized controlled trials (RCTs) of psychosocial telephone interventions for patients with cancer.

Methods: We conducted a systematic review of peer-reviewed RCTs evaluating telephone interventions in adult patients with cancer across the survivorship continuum.

Results: Through a database search, 480 articles were identified. After manual review, 13 were included, with 7 additional studies identified by back citation, totaling 20 studies. Participants were largely Caucasian, highly educated, with mean age ranging from 49 to 75 years. Most participants were patients with breast cancer (n = 13 studies). Sample sizes were generally small, with most patients recruited from large medical centers. Only one screened for psychosocial need. Interventions varied greatly in length and intensity. Eight studies reported significant effects post-intervention in the hypothesized direction on at least one psychosocial outcome measure. Of these eight studies, four included more than one follow-up assessment; of these, only one reported significant effects at last follow-up. No clear commonalities were found among studies reporting significant effects.

Conclusions: Methodological concerns and lack of consistency in adherence to CONSORT reporting guidelines were identified. This body of research would benefit from well-designed, theory-based RCTs adequately powered to provide more definitive evidence for intervention efficacy. This will probably require multi-institutional collaborations, guided by intervention and research methodology best practices.

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# **Background**

Cancer diagnosis and treatment constitute a major life disruption that brings unique challenges throughout the survivorship continuum, resulting in elevated levels of psychosocial distress in more than one third of patients [1–3]. This distress is not limited to the initial diagnosis and active-treatment phases but is also prevalent post-treatment [4]. Elevated psychosocial distress is associated with poor health status, low adherence to treatment recommendations, increased reports of pain and fatigue, as well as anxiety and depression [5–8]. Given the magnitude of patients with cancer and survivors in the USA alone [9–12], the psychosocial concerns associated with cancer diagnosis, treatment and survivorship constitute a major challenge.

In response to the burden of distress experienced by many patients with cancer and survivors, the American College of Surgeons (ACoS) Commission on Cancer has mandated distress screening and referral to psychosocial care as a condition of cancer program accreditation starting in 2015 [13]. It is

anticipated that this ACoS mandate will substantially increase the number of patients with cancer who will be referred for psychosocial care. Accordingly, there is an urgent need to assess the science of evidence-based psychosocial oncology programs that will respond to the identified elevated distress.

Recognized for their efficacy in improving quality of life and ameliorating distress in patients with cancer, psychosocial oncology interventions have been the subject of several meta-analyses and systematic reviews [3,14–21]. In the most recent one, Faller *et al.* included 198 randomized controlled trials (RCTs) covering 22,238 patients. This meta-analysis was limited to in-person psychosocial interventions, where small to medium effects on emotional distress, anxiety, depression and health-related quality of life (HRQOL) were found. The observed benefits for some were sustained in medium and long-term follow-up, particularly for longer duration of interventions. Unfortunately, all reviews agree about similar shortcomings in this area of research—that they are mostly concentrated in the active treatment phase with a disproportionate focus

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on breast cancer and limited by poor reporting, low methodological quality and measurement challenges [3,19,20,22].

Evidence also suggests that psychosocial interventions delivered through the telephone, a recommended modality for psycho-educational support to patients with cancer and survivors for over 25 years, may be efficacious [7,14–18,23–25]. Telephone counseling interventions have been found to improve health behaviors such as physical activity, dietary behavior change and smoking cessation [26–29]. Convenient and exportable, telephone interventions transcend geographic barriers and do not require a return visit to the treatment institution [7]. Because one third of patients or more decline to participate in in-person interventions, telephone interventions may be an appropriate alternative [18]. This modality may provide a costeffective way to deliver psychosocial care in compliance with the ACoS mandate [7,17]. The present study is the first review to solely examine the efficacy of telephone interventions in over a decade. A 1998 review of telephone psychosocial support in patients with cancer reported that telephone interventions are feasible and acceptable but that too few studies had been conducted to report generalizable results (only three eligible studies were randomized controlled trials) [18].

This review examined all published RCTs of psychosocial telephone interventions tested in patients with cancer throughout the cancer care continuum [7,30–48]. Each RCT is described in terms of its research setting, populations studied, research and intervention methodology, as well as the main findings obtained from the primary end points in each trial. Finally, based on this review, recommendations for future research are provided to advance the science of telephone interventions in psychosocial oncology.

#### **Methods**

Methods reported herein are in accordance to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [49]. Inclusion criteria and analysis were specified and agreed upon in advance.

# Eligibility criteria

Following the participants, interventions, comparators, outcomes, and study design (PICOS) framework [50], the following eligibility criteria were considered:

#### **Patient population**

Adults age 18 or older with a cancer diagnosis at any point across the cancer survivorship continuum, including diagnosis, in-treatment, immediately post-treatment and long-term survivorship.

#### Intervention

Telephone psychosocial intervention, defined as a nonpharmacologic intervention, where the description of the intervention included at least some evidence of interactive counseling techniques, approaches or protocols to help patients normalize and/or cope with and respond to their psychosocial sequelae, including anxiety, distress, depression, feelings of uncertainty and fear of recurrence, as well as other related psychosocial concerns. The intervention structure is briefly described, but the reader is encouraged to refer back to the original citation for more specific details, such as the theory underlying the intervention. Studies in which the intervention was not explained enough to ascertain whether counseling, as defined in the preceding texts, was provided were excluded [51]. Otherwise, studies were included if intervention staff provided interactive social support to normalize the psychosocial concerns of patients with cancer and survivors. Studies that used a combination of a primarily in-person or multimedia (such as CD-ROM) counseling intervention, and those studies that used the telephone only as an adjunct for follow-up or reinforcement and not as primary mode of intervention delivery, were excluded [52–54]. Telephone interventions that focused mainly or exclusively on promoting medical follow-up or clinical case management were excluded [55,56]. Although few in number, such studies shared a different research or service-delivery objective, that the telephone intervention did not specifically or directly address the psychosocial concerns of patients with cancer. In addition, telephone intervention studies that focused mainly on promoting physical activity, healthy diet and nutrition practices or other healthy lifestyle behaviors among patients with and survivors were similarly excluded [57-60].

#### Comparator group

Comparator group could be usual care, attention control or other psychosocial counseling or intervention modalities.

#### **Outcomes**

Primary outcomes evaluated in this review included global assessments of HRQOL, if such assessments also included psychosocial functioning, as well as content-specific psychosocial assessments. Subscales that assessed psychosocial functioning were also abstracted and reported. Statistically significant changes were defined by a p-value of p < 0.05. Many of the studies included in this review also reported differences by experimental condition on selected intermediate outcomes or mediator variables (e.g. use of different coping strategies). However, as noted above, this review focuses only on the primary or secondary psychosocial or HRQOL end points, as identified by the authors. Similarly, this review does not include or

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summarize findings related to patient-reported satisfaction or other non-psychosocial end points such as symptoms.

#### Study design

Only RCTs published in peer-reviewed journals from 1966 until March 2013 were included. Abstract-only reports were excluded. Several studies produced multiple publications that reported the same data or outcomes from the same study. When this occurred, only one of these studies was included in this review [48,61–63].

#### Information sources and search

Studies were initially identified by electronic database search, including PubMed, CINAHL, PsycINFO and Web of Science. Keywords included were 'hotline, telephone counseling, telecare, cancer, neoplasm', and excluded 'smoking, tobacco' in order to avoid retrieval of the numerous telephone smoking cessation interventions published. The search was last updated on March 18, 2013. The study author S.O. performed all searches.

In addition to the database search, studies were subsequently identified by scanning reference lists, and finally by consultation with experts in the field. Retrieval of missing data was obtained by email contact to the corresponding author [64].

# Study selection

All study titles and abstracts were reviewed by one of the authors, excluding those that were clearly not relevant. Remaining studies' full-text publications were obtained and discussed as a group. Disagreements about a study's inclusion or exclusion were discussed as a group, and decisions were made based upon consensus.

#### Data collection process

We developed a data abstraction form based on the information of interest to be extracted. This form was pilot-tested with five randomly selected studies and was refined accordingly. Data was extracted as a group during in-person meetings in order to promote discussion and learning. Any disagreements were resolved by group discussion.

#### Data items

The information extracted from each study included the following: (1) setting or environment from which participants were recruited, (2) general study design, (3) number of participants in intervention and comparator groups, (4) participation (based on eligible patients) and retention rates, (5) eligibility criteria for study participation, (6) description of the telephone intervention(s), including who delivered it, duration, number and frequency of sessions, length of calls, (7) description of the comparator condition(s), (8) primary psychosocial outcome measures, (9)

timing of outcome assessments related to the intervention, (10) summary of primary psychosocial outcome findings.

#### Assessment of risk of bias

To ascertain the validity of eligible randomized trials, the study authors as a group evaluated each study according to the CONSORT 2010 guidelines [50].

#### Results

A total of 20 studies were identified for inclusion in this review, covering 3848 patients. The search of PubMed provided a total of 480 citations. Other databases queried did not provide any additional citations to the ones previously identified. Of these, 447 citations were excluded based on the evaluation of titles and abstracts because they were clearly not relevant. Thirty-three full-text articles were assessed in further detail. Twenty did not meet inclusion criteria as described in Figure 1. Scanning reference lists of included studies and review articles subsequently identified seven additional studies.

Characteristics of the study designs, participants and interventions for each of the 20 RCTs can be found in Table 1. Over half of the RCTs featured usual care (including enhanced usual care) as the comparator group. Other studies used attention control or telephone education as a comparison. Participants were largely Caucasian, highly educated, married, and the mean age of participants in each study ranged from 49 to 75 years of age. Most participants were patients with breast cancer (n = 13 studies), newly diagnosed with early stage disease and were recruited from large hospitals including multi-site clinics and academic medical centers. Other cancer types included prostate (n=3), cervical (n=2) and a combination of cancers (n=2). Eligibility criteria typically included no major comorbidities (including but not limited to psychiatric conditions), ability to speak English, early stage disease and recent diagnosis (or, in a smaller number of studies, recent completion of treatment). Three studies focused on the re-entry phase alone [7,31,44] while one focused on watchful waiting for prostate cancer [35] and another on long-term survivorship [43]. Only one screened on the basis of psychosocial need, showing positive intervention effects [31].

Most studies reported a guiding theoretical framework and/or specific counseling technique (n=18) such as uncertainty in illness theory, the stress and coping model, interpersonal psychotherapy or cognitive behavioral therapy. Only two interventions did not specify a theory or technique. Interventions were largely delivered by nurses (n=11) but also included graduate psychology students, social workers, trained oncology counselors and cancer survivors as peer counselors. Interventions were mainly delivered during treatment (n=8) or during

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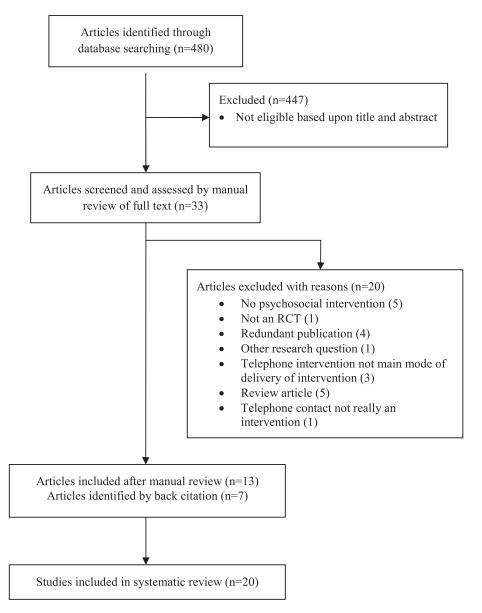


Figure 1. Flow diagram depicting the systematic review process

treatment and/or re-entry (n=7). Duration of counseling varied from two telephone sessions to 20 calls over 13 months, with over half (n=12) falling into the 5 to 8 call range. Total dose ranged from 65 to 720 min. Frequency of calls was weekly for nearly half of the studies, while others featured other intervals. Sample sizes were generally small, ranging from 23 to 571 participants overall and from 8 to 209 individuals per intervention arm. Nearly half of studies (n=9) had an overall sample of 100 or less. A wide variety of end points were used, most common including quality of life (FACT-G, QOL-CS, QOL-BC, CARES-SF, EORTC QOL-C30, QOL-BR23) and mood/affect (POMS, POMS-SF, PANAS), depression (CES-D, HADS) and anxiety (STAI, HADS). Other end points included social

support (IPRI-SF, PSS-FA), stress (ICS, PPS), distress (IES), physical and mental health (SF-12), psychological growth (GTUS), psychosocial adjustment (PAIS-SR), fear of recurrence (FR), and resource use (RU).

Nine studies had a statistically significant effect on at least one psychosocial outcome measure at any time point in the hypothesized direction (main effect or other measure), eight of which had a significant effect when measured after completion of the intervention [7,30–32,35,44–46]. Four of these eight studies measured outcomes beyond the immediate post-intervention, and only one demonstrated sustained significant effects at the end of the follow-up period [7]. No commonalities were identified for the nine studies with significant findings.

(Continues)

Table 1. Descriptive summary of included studies by author

			Telephone		Primary outcomes,	
	Study design		psychosocial	(	timing of	Primary psychosocial
Allard 2007	Two-group RCT, intervention $(n = 61)$ versus control $(n = 56)$	Breast cancer diagnosis/ suspected lesion, scheduled to undergo outpatient breast surgery, French speaking	Two calls, I week apart over 3 weeks, delivered by nursing professor	Usual care, additional call by research assistant, call length; not specified	POMS total score and anger, depression, confusion and anxiety subscales	Significant group differences favoring intervention group for POMS total score in hypothesized direction at T1 but not T2
	Five regional medical centers, urban and rural, Quebec, Canada		Call length: variable depending on patient needs  Duration: 2–3 weeks		Assessments: TO: baseline (2–3 days after surgery), T1: 9–10 days after surgery, following the first session, and T2: 17–18 days after surgery, following second session	No significant group-by-time interaction
Ashing-Giwa 2008	64% PR, RR not reported Two-group RCT, intervention (n = 15) versus, control (n = 8)	Latina women 1–3 years after completion of cervical cancer treatment (stage I-III), self-identified as Latina, at least moderate concerns on FACT-Cx emotional wellbeing subscales	Six total calls, 1–2 week intervals, initial call 1 h, all others 30–40 min, delivered by graduate psychology students	Survivorship kit	FACT-G total score, and physical, social/family, emotional, and functional well-being subscales	No direct comparison between groups
	Selected from previous cohort study from state and hospital cancer registries PR not reported, 100% RR		Duration: 3 months		Assessments: TO: baseline, T1: immediately post- intervention	Significant improvements in intervention group for FACT physical and overall scores No significant differences for the control group
Badger 2007	Three-group RCT of patient/partner dyads to two interventions; telephone interpersonal counseling (TP-C, n = 38), self-management exercise intervention (El n = 23); versus, attention control (AC, n = 37).	Breast cancer, stages I–III, undergoing adjuvant treatment, available partner	TP-C: six weekly calls, mean 34 min, delivered by psychiatric nurse with oncology expertise	El: self-managed exercise protocol, six weekly calls encouraging exercise, mean 11 min	CES-D, composite anxiety score based on items from PANAS, SF-12, ICS	No significant group-by-time interaction for CES-D. Significant group effect for TP-C and El over the course of the study
	Academic cancer center, private oncology offices		Duration: 6 weeks	AC: printed breast cancer information, six weekly calls without counseling, mean 7 min	Assessments: TO: baseline, T1: immediately post- intervention, T2: 1 month post-intervention	Significant group by time interaction for composite anxiety score in the hypothesized direction for TIP-C and El, compared

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Reference	Study design setting	Eligibility criteria	Telephone psychosocial intervention	Comparator	Primary outcomes, timing of measurements	Primary psychosocial outcome findings
						with AC; Post hoc analyses revealed group-by-time interaction confined to the TO-TI comparisons for TIP-C and EI
Badger 2011	84% PR, 94% RR Two-group RCT of patient/ partner dyads, intervention $(n = 36)$ versus control $(n = 35)$	Males with prostate cancer, undergoing or completed treatment within 6 months, available partner	Eight weekly calls, mean 31 min, delivered by master's prepared nurse or social worker	Health information without counseling, eight weekly calls, initial call mean 59 min, all other calls mean 28 min, delivered by paraprofessionals or research assistant students	CES-D, PANAS, PSS, QOL-CS social well-being subscale, PSS-Fa, QOL-BC, spiritual well-being subscale	Significant group differences favoring attention control group in four psychosocial outcomes: depression, negative effect, perceived stress and spiritual wellbeing, over the course of the study
	Recruitment from VA regional cancer center, cancer support groups and oncology offices 39% PR, 90% RR		Duration: 8 weeks		Assessments: T0: baseline, T1: immediately post- intervention, T2: 8 weeks post-intervention	
Badger 2012	Two-group RCT of patient/ partner dyads, intervention $(n = 45)$ versus control $(n = 45)$	Latina women, stage I-III breast cancer, receiving adjuvant treatment, English or Spanish speaking, available partner	Eight weekly calls (four biweekly calls for partners) mean 29 min, delivered by bilingual, bicultural master's-level social worker	Mailed health education materials reviewed via telephone, eight biweekly calls (four biweekly calls for partners) mean 29 min, delivered by bilingual, bicultural paraprofessionals	CES-D, PANAS, PSS, STAI	No significant differences between groups, with both groups showing significant improvement over time
	Cancer center, oncologists' offices, support groups, self-referral 50% PR, 78% RR		Duration: 8 weeks		Assessments: T0: baseline, T1: immediately post- intervention,T2: 8 weeks post-intervention	
Bailey 2004	Two-group RCT, intervention $(n = 20)$ versus control $(n = 19)$	Stages B1, B2, or C1 prostate cancer, who elected watchful waiting	Five weekly calls, mean 13 min, delivered by nurse interventionist	Usual care	GTUS, POMS-SF, Cantril's ladder	Significant differences in the intervention group in the hypothesized direction for the GTUS subscale hew view of life, and OOL at TI
Crane-Okada 2012	Central North Carolina hospital urology practice 75% PR, 95% RR Three-arous block	New clianosis of state	Duration: 5 weeks	UC usual care. No peer	Assessments: T0: baseline, T1: 5 weeks post-intervention HADS, IPRI-SF FOR RU	No significant main or
	randomized design, immediate contact (IC, $n = 50$ ), delayed contact	breast cancer, scheduled for surgery, age 50+	surgery—week 5 post-	counseling unless requested. If requested, re-assigned to IC or DC depending on timing	(assessed at 6 months only)	interaction effects (time or intervention) for HADS, IPRI-SF

			No significant group differences			9	No significant group differences		No significant group by time interaction for overall QOL	Significant group by time interaction for total mood disturbance (POMS) albeit not in the hypothesized direction		No significant group differences
T)	Assessments: TO: baseline, TI: immediately post- intervention, T2: 6 months post-baseline		CES-D, PAIS-SR	: :- :- :- :-	Assessments: 10: baseline, T1: 5 months post- intervention		CARES-SP psychosocial scale, CES-D	Assessments: T0: baseline, T1: 3 months post-intervention	QOL-BC (modified scale), POMS-SF	Assessments: TO: baseline (4 days before first session). TI: immediately post-intervention, T2: 3 months post-intervention	EORTC QOL-C30, QOL- BR23	Assessments: T1: 4 weeks after radiotherapy or
of request. Analysis proceeded 'as treated'.			Usual care			-	Usual care		Usual care		Usual care	
	DC:Five calls, week 6–10 post-surgery	Mean 15 min, delivered by trained volunteer peer counselors Call length: not specified by group	Duration: roughly 5 weeks Five or more calls, no set interval between calls, delivered by trained nurses		Call length; not specified	Duration: 3 months	Four to eight weekly calls, total call mean 128 min, delivered by trained breast cancer recurrence survivors	Duration: I month	Six weekly conference calls, each 90 min, delivered by two experienced group	therapists Duration: 6 weeks	One call, 10–18 days after final radiotherapy visit, mean 10–30 min, delivered by oncology nurses	Duration: one call
			Newly diagnosed lung, breast or prostate cancer, age 50+, surgery within	past 3 months, inning within 200 km of clinic, no chemotherapy		·	hirst recurrence after surgery for stage I-lla breast cancer, recurrence diagnosed within previous 56 days		Stage I–II breast cancer, diagnosis in past 6 months, under age 65		Female, recent breast cancerdagnosis, lumpectorny or mastectorny, receiving radiotherapy, Danishspeaking	)
(DC, $n = 46$ ) or control (UC, $n = 46$ )	Community, hospital-based breast surgical oncology practice affiliated with cancer research institute, Los Angeles, CA	,	44% PR, 98% RR Two-group RCT, intervention ( $n = 89$ ) versus control ( $n = 86$ )	-	Canadian academic medical center, private offices of surgeons	66% PR, 85% RR	Iwo-group KC.1, intervention ( $n = 153$ ) versus control ( $n = 152$ )	Southwest Oncology Group cooperative group PR not reported, RR 81%	Two-group RCT, intervention ( $n = 33$ ) versus control ( $n = 33$ )	Two private oncology practices in South Carolina	Two-group RCT, intervention $(n = 50)$ versus control $(n = 50)$	
			Downe-Wamboldt 2007				Gotay 2007		Heiney 2003		Hoyer 2011	

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Reference	Study design setting	Eligibility criteria	Telephone psychosocial intervention	Comparator	Primary outcomes, timing of measurements	Primary psychosocial outcome findings
	Hospital-based radiotherapy ward, Denmark 83% PR 99% RR				10–18 days after intervention; no baseline	
Livingston 2010	Three-group block randomized design: active referral—4 outcalls (AR4, n = 209), active referral—1 outcall (AR1, n = 197), passive referral to cancer helping (PR n = 167)	Male, prostate or colorectal cancer with prognosis more than 52 weeks	AR4: four total outcalls, I week, 6 weeks, 3 months, 6 months post-diagnosis, mean 15–19 min, delivered by cancer helpline nurses	PR (participant-initiated calls): cancer helpline usual service, mean 23 min $(n = 29, 18\% \text{ of group})$	HADS, composite cancer wory/distress scale	AR4 showed statistically significant improvement in mean depression scores from TI to T2, compared eith PR. No significant effects at T3
	Referring specialists (urologists for prostate cancer and surgeons for colorectal cancer-CRC)		AR1: one total outcall, 1 week post-diagnosis, mean 19 min, delivered by cancer helpline nurses		Assessments: TO: baseline (diagnosis), T1: 4 months post-diagnosis, T2: 7 months post-diagnosis, T3: 12 months post-diagnosis	
Marcus 2010	88% PR, 89% RR Two-group RCT, intervention ( $n = 152$ ) versus control ( $n = 152$ )	Immediately following last treatment visit for stage HIIA breast cancer	Duration: 6 months 16 total calls, 6 calls— 2 weeks apart, then 10 calls-1 month apart, mean 45 min, delivered by psychosocial oncology	Usual care, literature, resource guide tailored by geographic area	IES intrusion subscale, CES-D, composite personal growth scale	No significant group differences for IES or CES-D Significant intervention effects for personal growth at T1 and T2
	Multi-site: 21 medical centers and hospitals				Assessments: TO: baseline, T1: immediately post- intervention, T2: 6 months post-intervention	
Mishel 2002	80% PK, 80% KK 3 × 2 randomized block RCT, three treatment arms: uncertainty management (UM) direct, UM supplemented to spouse, and control; crossed by race (Caucasian, African American), n = 252 (unspecified number per	African American and Caucasian men, localized prostate carcinoma, 2 weeks post-catheter removal after surgical treatment and/or within 3 weeks into radiation therapy, available partner	Duration: 1.2 months UPt: eight weekly calls, delivered by nurse matched on ethnicity and gender	Usual care, printed health information unrelated to prostate cancer	MUIS assessments: TO: baseline, T1: 2 months post-intervention months post-intervention	No significant group differences
			Call length: not specified UM supplemented to spouse: same as above but adds eight weekly calls to spouse Duration: 2 months			

	No significant effects			Significant group differences favoring the intervention group		Significantly higher mood disturbance in the education-only group than the other groups at TI, T2 and T3	
	POMS-SF	Assessments: T0: baseline, T1: 9 months post- intervention		FACT-Cx	Assessments: T0: baseline, T1: 2 weeks post-intervention	VAS-W, EWBS, POMS	Assessments: T0: baseline, T1: end of phase 1 (8–10 weeks post-baseline), T2: end of phase 2 (8-weeks after T1), T3: end of phase 3 (8 months after T2)
	Usual care			Usual care		Education-only (least intensive): mailed resource kit	
	Four weekly calls, delivered by nurses	Call length: not specified	Duration: I month	Six total calls, five weekly calls, one booster call 1 month later, mean 45–50 min, delivered by psychologist	Duration: 2 months	In-person and telephone (most intensive): 19–21 total calls, phase 1: 8–10 weekly telephone social support and education, phase 2: 8 weekly inperson support and education, phase 3: 3 months of twice-monthly telephone social support and education, then 5 monthly telephone social support and education, then 5 monthly telephone social support and education and education.	
	African-American and Caucasian breast cancer survivors, 5–9 years post-treatment, no concurrent treatment for another cancer, recurrence free			Completion of treatment for stage I-III cervical cancer, English and Spanish speaking, 9-24 months post-diagnosis		Women who had surgery for stage 0-III breast cancer 4 weeks prior to study	
Nine facilities in North Carolina 77% PR, 95% RR	2 × 2 randomized block RCT, intervention (n = 244) vs. control (n = 265); crossed by race (Caucasian, African American) 13 institutions in North Carolina (8 comprehensive cancer centers, and regional and local hospitals). Additional recruitment of African American survivors via radio, newspapers and community volunteers		55% PR. 89% RR	Two-group RCT, intervention $(n = 27)$ versus control $(n = 23)$	Regional cancer registries	Three-group RCT, combined individual telephone and inperson group sodal support and education ( $n = 34$ ).  versus telephone-only social support and education ( $n = 48$ ).  versus education-only group (one-time mailing, $n = 43$ )	
	Mishel 2005			Nelson 2008		Samarel 2002	

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	Study design		l elephone psychosocial		Primary outcomes, timing of	Primary psychosocial
Reference	setting	Eligibility criteria	intervention	Comparator	measurements	outcome findings
Sandgren 2000	Physician offices, hospitals, cancer support organizations in northern and central New Jersey  PR not reported, 68.3% RR Two-group RCT, intervention $(n=24)$ versus control $(n=29)$	Stage 1–2 breast cancer diagnosis in past 3–4 months	Telephone-only: 27–29 total calls, phase 1: 8–10 weekly telephone social support and education, phase 2: 8 weekly calls, phase 3: twice-monthly calls for 3 months, then monthly for 5 months, mailed resource kit Duration: 13 months Up to 10 total calls (mean 9 calls), 4 weekly calls, biweekly for 12–weeks, mean 20–25 min, delivered by clinical psychology master's candidates	Usual care	POMS, composite distress measure derived from POMS stress questions	No significant group by time interactions for all POMS subscales at T1 and T2
	Tertiary cancer treatment center		Duration: 4 months		Assessments: T0: baseline, T1: immediately post- intervention, T2: 6 months post-intervention	Significant group by time interaction for distress with intervention group reporting less stress at T1 but slightly increased at T2
Sandgren 2007	78.5% PR, 85.5% RR 2.2:1 ratio RCT, two interventions: health education (HE, $n = 76$ ), emotional expression (EE, $n = 89$ ) versus control n = 49).	Stage I-III breast cancer, I-3 months post-diagnosis, undergoing adjuvant treatment	EE: six total calls, five weekly calls, sixth follow-up call approximately 3 months later, mean 30 min, delivered by certified oncology nurses trained by a clinical passible distributed by a clinical passible distributed.	HE: reviewed six relevant topics, no counseling, calls were of similar length and frequency as EE	FACT-G, POMS, PSS	No significant EE intervention effects
	(v = +7) Two cancer treatment clinics 74% PR, 92% RR		transcript a minimal psychologist.  Duration: 6 months	Control: usual care	Assessments: TO: baseline, T1: immediately post- intervention,T2: 7 months post-intervention	Significant time effects from T1-T2 for all three conditions for FACT-G and POMS Significant group differences for PSS, not in the hypothesized direction, with HE participants showing less stress than EE or
Sherman 2012	Four-group RCT of patient-partner dyads to standard care/disease management (DM, $n = 59$ ), standardized video psychoeducation (SE, $n = 66$ ), telephone	Early stage breast cancer, available partner	TC: four phase-specific calls, delivered by nurse	SE + TC four phase-spedific psychoeducation videos, four phase-spedific calls, delivered by nurse. Call length; not spedified	PAL-C, BCTRI side effect distress, and severity subscales, SRHS, PAIS	control participants TI No significant effects

Assessments: T0: baseline, post-surgery, T3: adjuvant T1: diagnosis, T2: 2 days treatment, T4: on-going recovery phase psychoeducation videos SE: four phase-specific DM: usual care Call length: not specified Duration: not specified Three major medical centers, one community hospital in counseling (TC, n = 66), SE + TC (n = 58)New York City

Early, randomized control trial; PR, participation rate; RN, retention rate; POMS, profile of mood states; FACT-G, Functional Assessment of Cancer Therapy-General; CES-D, the Center for Epidemiologic Studies-Depression Scale; PANAS, the positive and negative affect schedule; SF-12, short form-12 health survey; ICS, index of clinical stress; PPS, perceived stress scale; QOL-CS, quality of life-cancer survivors; PSS-FA, perceived social support-family scale; QOL-BC, quality of life-breast cancer; STAI, State-Trait Anxiety Inventory; GTUS, Growth Through Uncertainty Scale; POMS-SF, profile of mood states-short form; HADS, hospital anxiety and depression scale; IPRI-SF, interpersonal relationship inventory. short form; FOR, fear of recurrence scale; RU, resource use scale; PAIS-SR, psychosocial adjustment to illness scale-self-report; CARES-SF, Cancer Rehabilitation Evaluation System-short form; EORTC QOL-C30, European Organization for Research and Treatment of Cancer, Quality of Life Questionnaire-Cancer-specific 30 questions; QOL-BR23, Quality of Life-Breast Cancer 23 questions; IES, impact of event scale; MUIS, managing uncertainty in illness scale; FACT-Cx. Functional Assessment of Cancer Therapy-for patients with cancer of the Cervix; VAS-W, the visual analogue scale—worry; EWBS, existential well-being scale; PAL-C, the profile of adaptation to life-clinical scale; BCTRI, breast cancer reatment response inventory; SRHS, self-report health scale; PAIS, Psychosocial Adjustment to Illness Scale

#### **Conclusions**

There have been numerous previous reviews of the literature summarizing the state of the science of intervention research in psychosocial oncology [3,14-16,19,20]. Although these reviews are generally supportive of psychosocial interventions for patients with cancer and survivors, a number of methodological concerns have been noted, including poor reporting, insufficient internal validity and measurement limitations [3,19,20]. This review is among the first to summarize the literature involving telephone intervention trials in psychosocial oncology. Although limited to a single intervention modality, we also found many of the same methodological concerns noted in these earlier reviews, with most of the RCTs characterized by small sample sizes, samples that were mainly non-Hispanic white and disproportionately focused on a single cancer site, typically breast cancer, and with limited follow-up for evaluation (most studies included outcome assessments limited to 6 months or less post-intervention). In addition, as noted in these previous reviews, there was substantial variability across studies in the primary end points that were examined, ranging from global assessments of HRQOL to more targeted assessments of depression, anxiety, cancer-specific distress, and uncertainty. Lacking more standardization in these outcome assessments, comparisons across RCTs and drawing informed inferences from this research can be especially challenging.

Also complicating this review, which has likewise been noted in previous reviews of intervention research in psychosocial oncology [3,19,20], is the lack of consistency in adhering to the CONSORT reporting guidelines for intervention trials [65]. For example, among the most frequent omissions in this regard were dates of recruitment and follow-up, how sample size was determined and results for each group including effect size for each primary and secondary outcome. Given that adherence to these CONSORT guidelines represents a best practice when reporting results from intervention trials, investigators as well as scientific journals should be especially attentive to this problem.

In terms of assessing telephone intervention efficacy in psychosocial oncology, this review indicates that while 9 of 20 studies reported statistically significant or marginally significant effects, these were typically not robust across multiple end points within the same study nor were these effects robust across studies that shared the same or similar end points. In addition, most of these effects appear to be modest in magnitude, although very few of these studies (as noted in the preceding texts) reported effect sizes in adherence with the CONSORT reporting guidelines for intervention trials. Also noteworthy is that among the RCTs showing significant or marginally significant effects, few commonalities could be identified that would separate these studies from those not reporting such

effects. For example, these studies do not appear to be distinctive in citing a guiding theoretical framework, utilizing larger sample sizes or relying on a particular subset of primary end point assessments, nor were they distinctive in the duration or intensity of telephone intervention exposure. However, it is instructive to note that most of the studies reporting significant or marginally significant effects were distinctive in their use of intervention staff with backgrounds in psychology or professional psychosocial counseling [7,31,44,47], as opposed to training medical staff (e.g. nurses) or peer counselors to deliver psychosocial interventions by telephone. While high psychosocial distress has been correlated with reported effects in some studies [3], only one study in the present review screened on the basis of psychosocial need [31]. Low baseline levels of distress could potentially have influenced the modest effects seen in the studies in this review.

Given that telephone interventions in psychosocial oncology hold promise for extending the reach of psychosocial support programs for patients with cancer and survivors, more research seems indicated to further establish the efficacy of this intervention modality. Underscoring the urgency of such research is the 2015 ACoS accreditation requirements for cancer programs [13], psychosocial telephone interventions can offer a viable programmatic option for providing exportable and sustainable service to those patients reporting elevated distress during a pivotal patient encounter. However, to avoid the limitations that characterize the current body of research, the next generation of research should implement protocols and procedures to address the methodological concerns and problems noted in the preceding texts.

Given that the current body of science includes several studies that provide proof of concept in reporting significant intervention effects for telephone interventions in psychosocial oncology, [7,44,66,67] we would also argue for a timely and fundamental shift in the funding paradigm for such research. The vast majority of psychosocial oncology research to date has been conducted on breast cancer survivors [4]. Because such findings may not generalize to other cancer diagnoses, greater diversity in diagnoses is needed in future research. What this body of research needs is several well-designed, theory-based RCTs that will have sufficient statistical power and extended follow-up to provide more definitive evidence for intervention efficacy among diverse patient with cancer populations and across the cancer care continuum. Such

research would likely require multi-institutional collaborations and centralized data coordinating centers, guided by intervention and research methodology best practices. Such studies should likewise be designed and conducted to enhance future dissemination and implementation research that could subsequently produce exportable and sustainable standard service programs in psychosocial oncology. They should therefore also identify and measure implementation barriers as well as cost-effectiveness parameters. This vision for the future is compelling and represents the next logical step for this field of research, which would be greatly accelerated with dedicated funding opportunities to encourage such research.

Finally, as in any systematic review, several key limitations should be acknowledged. As noted earlier, this review was limited to RCTs, thus excluding studies that were qualitative or quasi-experimental in design, both of which can also be instructive when assessing telephone interventions in psychosocial oncology. Similarly, this review did not include assessments of intermediate end points or mediator variables (e.g. coping self-efficacy) or process evaluations of telephone interventions (e.g. perceived utility and satisfaction), which can likewise be highly informative even though such evidence cannot be used to establish intervention efficacy. This review also excluded studies that were not published in English or Spanish in a peer-reviewed scientific journal up until March 2013. In addition, while a rigorous protocol was implemented to identify eligible studies, it is possible that studies relevant to this review were inadvertently missed. Although this possibility must be acknowledged, in our view, it is doubtful that the dominant pattern of results and the observations inferred from this review would be substantially amended if such studies were indeed excluded, including the over-arching conclusion that while the findings from this review were mixed in terms of intervention efficacy, proof of concept has been sufficiently established to allow for more definitive larger scale trials with dedicated funding opportunities to support such research.

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#### **Conflict of interest**

The authors have declared no conflicts of interest.

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