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Control Conditions That Are Neither Usual Care Nor No Treatment in Randomized Trials of Psychoeducational Palliative Care Interventions: A Systematic Review

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Abstract

Background: Determining intervention efficacy depends as much on the control group as on the intervention, but little attention has been given to the control condition in psychoeducational trials in palliative care.

Objectives: To examine (1) research practice regarding control conditions that are neither usual care nor no-treatment controls in randomized trials of psychoeducational palliative care interventions and (2) the rationale and completeness of the descriptions of control conditions in trial reports.

Methods: PubMed, EMBASE, PsycINFO, and Web of Science were searched. After screening 1603 articles, 70 full-text articles were assessed for eligibility. The final sample included 9 trial reports. We used the Delphi list for quality assessment and the modified intervention taxonomy checklist to assess active intervention and control conditions.

Results: Four trials used an attention control designed to be equivalent to the structure of the active intervention. In another 4, the control condition included some aspects of attention control such that the mode of contact was similar to that in the active intervention, but either the amount or the intensity of attention was not similar. Only 3 trial reports explicitly stated the rationale for the choice of control condition. Although most reports contained delivery mode, materials, duration, frequency, and sequence, none described the qualifications or training required to deliver the control condition. Only 1 report mentioned the fidelity monitoring method, and none included fidelity data.

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Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Conclusion: Our review of psychoeducational trials in palliative care calls for researchers' attention to appropriate selection, design, conduct and report of control conditions.

Keywords

attention control; control group; palliative care; psychoeducation; randomized trial; systematic review

Introduction

Psychoeducation refers to an intervention that provides patients and/or their families with information and support to help them understand and manage their illnesses.¹

Psychoeducational interventions, a common type of palliative care intervention, encompass a broad range of activities that combine education and counseling delivered via provider–patient interactions, self-direction, online, or telephone.^{2,3} As the gold standard for testing the efficacy of interventions, randomized controlled trials (RCTs)⁴ are widely used to test psychoeducational interventions in the context of palliative care. In such RCTs, the effect of an active intervention is determined relative to a control condition, and thus, the evaluation of intervention efficacy inherently depends as much on the control as on the intervention.^{5,6} That is, the nature of the control condition is intimately tied to the extent to which threats to internal validity are mitigated.^{5–7} Nonetheless, attention to designing, monitoring, and reporting RCTs of psychoeducational interventions remains largely focused on the interventions rather than on both the intervention and the control.^{8,9}

Four types of control conditions are commonly used in RCTs to evaluate the efficacy of interventions: no-treatment control, care-as-usual control, waitlist control (offering the active intervention after no-treatment or care-as-usual control), and placebo control.^{5,7} A variant of placebo control in psychoeducational RCTs is the attention control in which the amount of attention (such as the duration, frequency, or amount of contact with the study team) provided to those in the intervention and control groups is equalized.¹⁰ Attention is 1 example of nonspecific factors that can have an impact on outcomes of interest. Other nonspecific factors include patient expectations for improvement, therapeutic relationships, and the interventionist's personality.¹¹ Attention control groups may be seen as more credible compared to other types of control conditions because they are thought to increase the likelihood that conclusions about intervention efficacy are not biased by lack of control for a nonspecific factor, that is, attention.^{12,13} However, the adequacy of attention controls is extremely difficult to examine empirically because it is nearly impossible to construct a psychoeducational intervention trial that is double-blind with both the interventionist and the participant in the manner seen in drug/device trials.¹⁴ In fact, there has been considerable research and debate surrounding control of non-specific effects of psychotherapy.^{5,6,14–21} Although psychoeducational palliative care interventions share many aspects of psychotherapy, little attention has been given to the use of attention control in RCTs that test psychoeducational palliative care interventions. Furthermore, studies may employ a control condition that is neither usual care nor no-treatment control but rather consists of some aspects of attention control without that term being explicitly used.^{22,23} Therefore, we conducted a systematic review to (1) examine research practice regarding control conditions

that are neither usual care nor no treatment (that is, excluding control conditions that are clearly usual care only or no treatment) in RCTs of psychoeducational palliative care interventions and (2) examine the rationale and completeness of the descriptions of those control conditions in reports of trials.

Methods

We used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement and checklist²⁴ to organize and report this systematic review. The process of study selection and review involved at least 2 authors throughout.

Eligibility Criteria

The inclusion criteria were studies that (1) used an RCT design in which participants were prospectively randomized to 1 of 2 or more groups, (2) targeted patients and/or family caregivers, (3) evaluated a psychoeducational palliative care intervention, (4) included a control condition that was neither usual care nor no treatment (eg, attention control or a condition that includes more than usual care or no treatment), and (5) were written in English. We excluded articles that (1) did not report the main findings of the RCT, such as those reporting protocols, baseline data only, or secondary analyses of RCT data; (2) targeted health-care providers or trainees to improve their outcomes; and (3) reported comparative effectiveness research (CER) trials as opposed to efficacy trials.

Search Strategy

We consulted an experienced librarian to determine a comprehensive search strategy to obtain as many articles as possible. Four electronic databases, PubMed, EMBASE, PsycINFO, and Web of Science, were searched for articles published up to July 31, 2017. Search strategies to identify randomized trials of psychoeducational interventions in the context of palliative care were as follows: *for PubMed*, (“Randomized Controlled Trial” [Publication Type] AND [“Palliative Care” (Mesh) OR “Terminal Care”(Mesh) OR “Terminally Ill” (Mesh) OR “Critical Illness” (Mesh) OR serious illness]) AND (“Psychotherapy”[Mesh] OR “Patient Education as Topic”[Mesh] OR “Decision Making” [Mesh] OR “Advance Care Planning”[Mesh] OR “Decision Support Techniques”[Mesh] OR “Patient Care Planning”[Mesh] OR “Communication”[Mesh]) filter: (English); *for EMBASE*, “randomized controlled trial”/exp AND (“palliative therapy”/ exp OR “terminal care”/exp OR “terminally ill patient”/exp OR “critical illness”/exp) AND (“psychotherapy”/exp OR “patient education”/exp OR “interpersonal communication”/ exp OR “decision making”/exp OR “advance care planning”/ exp OR “decision support system”/exp OR “patient care planning”/exp) filter: (English); *for PsychInfo*, (randomized controlled trial) AND (palliative care OR terminal care OR terminally ill OR critical illness OR serious illness) AND (psychotherapy OR patient education OR communication OR decision making OR advance care planning OR decision support OR patient care planning); and *for Web of Science*, (TOPIC: [randomized controlled trial]) AND (TOPIC: [palliative care] OR TOPIC: [terminal care] OR TOPIC: [terminally ill] OR TOPIC: [critical illness] OR TOPIC: [serious illness]) AND (TOPIC: [psychotherapy] OR TOPIC: [patient education] OR TOPIC: [communication] OR TOPIC: [decision making] OR TOPIC:

[advance care planning] OR TOPIC: [decision support] OR TOPIC: [patient care planning])
Filter: article and English. In addition, we searched the databases using 2 key words, “psychoeducation*” and “psychosocial*,” to identify additional articles.

Study Selection

The search strategy yielded 1968 articles. After removing duplicates, the remaining 1603 articles were divided among the 5 authors. All authors independently reviewed the titles and abstracts to screen for relevance and then cross-validated the screening results with a second author. After excluding 1533 articles that were clearly ineligible, 2 groups of the authors ([MKS and HK] and [SEW, EMP, and CH]) reviewed full texts of 70 articles and categorized as “eligible” or “unsure.” Any discrepancies and “unsure” articles were discussed by all authors (see Figure 1). Of the 70 articles, 9 trial reports met the inclusion criteria (Table 1).

Data Extraction

We used the guidelines discussed in the Cochrane Handbook for Systematic Reviews of Intervention.³³ For quality assessment of RCTs, we used the Delphi list³⁴ that included 9 criteria on key elements of an RCT (Table 2). Each criterion included 3 response options, yes/criterion met, no/criterion not met, and don’t know/not stated. The options of no and don’t know were combined because we focused solely on the primary RCT reports and did not rely on other sources (eg, protocol papers) or on contacts with the authors. This decision was based on the Consolidated Standards of Reporting Trials guideline,³⁵ which recommends that a primary RCT report clearly states how the trial was conducted with respect to the key elements of RCTs.

To review the descriptions of both the intervention and the control conditions, we used Schulz et al’s intervention taxonomy to describe essential features of interventions.³⁶ We added 2 items, whether the overall procedure of the intervention or control condition (eg, sequencing of techniques) was described,³⁷ and whether intervention or control fidelity data that were monitored during the trial were actually presented in the report.

The authors first reviewed 3 randomly selected articles independently using these checklists and compared the reviews. Any discrepancies among the authors were discussed for resolution and decision rules were developed. The remaining 6 articles were divided between the 2 groups of authors for review. The authors in each group independently reviewed the assigned articles using the checklists. Any discrepancies in assessment within each group were discussed with the group members first, and any unresolved discrepancies were discussed with all authors for final resolution. Descriptive statistics were used to summarize the review results.

Results

Of the 70 reports reviewed in full texts, we excluded 61. The most common reason ($n = 31$) for exclusion was that the trial’s control condition was usual care or was not a control condition but rather was an alternate intervention as in CER. However, we included 1 report³² that described the trial as CER with an active intervention as a control condition. We made this decision because during the process of search and selection of trial reports, 2

nonprimary reports^{38,39} of the same trial were found that referred to the study as an efficacy trial. To resolve the discrepancy, we turned to clinicaltrials.gov, wherein the study was described as an efficacy trial with 2 groups, an intervention and a control condition, “to determine the efficacy” of the test intervention. One group of investigators tested 1 intervention in 2 different trials.^{28,29} The final sample thus contained 8 interventions from 9 trials and reports. Table 1 summarizes the trial purpose, sample, and intervention and control conditions.

Study Characteristics and Quality Assessment

Of the 9 studies, 7 were designed to test an advance care planning intervention or an intervention to clarify goals of care for individuals with advanced dementia.^{23,26,28–32} One study evaluated a patient navigator intervention to improve “palliative care outcomes,” for example, completion of an advance directive and documentation of pain management discussion,²² and 1 study tested a brief educational intervention to improve layperson’s knowledge about palliative care.²⁷ Three studies were pilot RCTs, assessing the feasibility and preliminary effects of the intervention.^{22,28,31}

Quality assessment of the 9 trial reports is summarized in Table 2. While all reports stated that randomization was performed, with or without clearly describing the specific method used, only 1 report²² provided information about the method by which allocation was concealed before assignment. As expected in psychoeducational trials, no studies were double-blind with the interventionist and the participant knowing whether they were participating in the active intervention or the control condition. Only 4 reports clearly stated that an intention-to-treat analysis was performed.^{26,28,29,32}

Rationale for the Choice and Design of Control Condition

Eight studies’ control conditions^{22,23,26–31} were either an attention control, or had some aspects of attention control with or without the rationale for the choice provided or the term, attention control, being used. Of the 8, 3 reports^{28,30,31} explicitly stated the rationale, eg, “to control for the Hawthorne effect,” “to demonstrate that the effects of treatment were not simply a result of greater attention.” One RCT report²⁹ called the attention control “an active control” instead.

Four of the 8 trials’ control conditions^{27–29,31} were attention controls designed to be equivalent to the structure of the active intervention with respect to the amount and intensity of attention/time, delivery setting, and the mode of interventionist–participant interactions, while not containing an active ingredient. In the other four,^{22,23,26,30} the control condition included some aspects of attention control such that the mode of interactions was similar to the active intervention but the amount or intensity of attention was not or vice versa. Finally, in 1 report,³² the control condition could be seen as an active intervention because it (a paper handout regarding advance directives) had previously been shown to have a positive effect on the study’s primary outcome (advance directive completion rate).

Completeness of Intervention and Control Descriptions

Figure 2 shows the number of intervention descriptions that contained each of the checklist items in the trial reports. These primary reports contained intervention delivery mode, materials, setting, and frequency. However, duration, interventionist qualifications, and method of fidelity monitoring were often omitted. Only 1 report²⁶ presented intervention fidelity monitoring data.

Figure 3 shows the number of control group descriptions that contained each of the checklist items. Overall, descriptions of control conditions were substantially shorter than that of the active intervention. Most reports contained some information about delivery mode, materials, duration, frequency, and sequence. However, none described the qualifications or training required to deliver the control condition. Only 1 report²⁸ mentioned the method of fidelity monitoring (for 1 of the 3 sessions), and no report included control group fidelity monitoring data.

Discussion

In this review focused on control conditions of RCTs of psychoeducational palliative care interventions that are not usual care nor no-treatment groups, we found that research practice regarding designing and reporting control conditions varied considerably across studies. Only 4 of the 9 trials used attention controls that were structured to attain equipoise with respect to attention and the type of contact between the groups. The rationale for the choice and design of the control condition was rarely provided in trial reports, and most reports downplayed the description of the control condition in general, including the implementation of the control condition during the trial.

We also observed a lack of equivalence in intervention and control condition provider qualifications and required training. For example, although the intervention was delivered by an interventionist who had years of clinical experience and underwent extensive training and certification process for the intervention delivery, the control condition was delivered by a “trained” research assistant with no information about qualifications and training required to deliver the control condition. These imbalances between groups fail to serve the purpose of using an attention control, making the trial more vulnerable to threats to internal validity, even when the gold standard, RCT designs, are used. Only 1 trial report stated that the study employed fidelity monitoring for both the active intervention and the control condition. No trial reports provided fidelity data for the control condition (including whether the control condition was manualized) and only 1 trial report presented intervention fidelity data. Consequently, even if the trial used a well-designed attention control to equalize attention between the 2 groups, the extent to which this goal was achieved is unknown. These findings indicate less than optimal design and conduct of attention control in current research practice. It should be acknowledged, however, that it is difficult to evaluate whether an attention control is well designed and executed because there is no “gold standard” for the construction of attention control groups in RCTs of psychoeducational interventions.⁴⁰

Taken together, evidence of investigators’ efforts to carefully define, design, and implement control conditions in RCTs of psychoeducational palliative care intervention was rarely seen

in the trial reports. Our results echo those of Hoffman et al³⁷ who found that omission of essential information about nonpharmacological interventions is a frequent, substantial problem and referred to this problem as a contributor to the worldwide research waste because if trial reports do not have a sufficient description of interventions, other researchers cannot build on the findings, and clinicians cannot reliably implement useful interventions. As noted in the PRISMA statement,²⁴ the conduct and reporting of a study are distinct but closely intertwined concepts by nature, and thus the failure to report both the intervention and control conditions adequately may be seen as a poor conduct and likely raise questions about the trial's internal validity. One may argue that one of the major barriers to describing both the intervention and the control conditions sufficiently is the stringent word limits set by most biomedical journals. As Hoffman et al³⁷ argue, journal editors and reviewers have a responsibility to be aware of the importance of sufficient reporting of the intervention as well as the control condition and institute policies to improve quality of reporting.

Several authors^{5,7,14} caution that attention controls should not be chosen as a default in RCTs of psychoeducational interventions; rather, the purpose of the trial needs to be taken into consideration when designing a control condition in such trials. Baskin et al¹⁴ suggested that if research is focused primarily on determining the efficacy of an intervention rather than on theoretically dismantling specific ingredients, then no treatment or usual care only is an appropriate control condition. Mohr et al⁵ argued that control of attention or other nonspecific factors may be unnecessary or even inappropriate for early stage trials (phase I or II).

Our study has limitations. Despite our effort to identify eligible trial reports with various types of psychoeducational palliative care interventions using several search strategies (eg, using a Boolean and OR), the sample is small and mainly includes trials that tested interventions focused on communication, advance care planning, and decision-making. Although initial searches included interventions focused on other areas, such as a cancer caregiver support intervention or multicomponent palliative care interventions, these studies were excluded during the screening process because they did not meet all of the inclusion criteria (eg, a usual-care control). Another reason for the small sample size is that we did not expand our criteria to include studies addressing pain and symptom management because a separate review focusing on pain and symptom management in palliative care would be needed to address that large body of literature.

Nevertheless, our findings may help draw palliative care researchers' attention to the critical role of the choice, design, and implementation of control conditions with respect to inferences drawn from the trial, the level of bias, and the scientific credibility of the trial findings. Our findings highlight the importance of providing sufficient descriptions of both the intervention and control conditions in trial reports. The choice of control condition must be justified based on the nature of the intervention being tested and on the specific study purpose (eg, determining efficacy vs dismantling specific ingredients). A control condition that is well conceptualized and implemented is an essential component of solid evidence, and without sufficient details about both the intervention and the control conditions, such evidence may not be useful to guide palliative care practice and policy.

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Figure 1.
Flow of article inclusion.

Figure 2.
Description of active intervention ($N=9$).

Figure 3.
Description of control condition ($N=9$).

Table 1.

Study Purpose, Sample, and Intervention and Control Conditions.^a

Study	Study Purpose	Sample	Intervention Condition	Control Condition
Bravo et al ²³ (2016)	To test an intervention designed to motivate older adults to document their health-care preferences and to guide proxies in making decisions that match those preferences	235 dyads of older community-dwelling adults and their surrogate (proxy) decision makers	Three monthly sessions—2 were 1-hour sessions with each dyad separately at home before and after 1 session in subgroups of 6 to 20 dyads lasting 1½ hours at the research center. At-home sessions were led by a senior social worker who had had a full-day training, whereas the subgroup session was led by a retired teacher. Materials included an interview guide, a chart illustrating baseline level of concordance on end-of-life preferences, and the “My Preferences” booklet.	“Control intervention.” Three monthly 2¼-hour health promotion workshops adapted from Viens et al ²⁵ in subgroups of 4 to 22 dyads led by a retired nurse using PowerPoint presentations and group discussion at a meeting room in the research center.
Fischer et al ²² (2015)	To determine whether a patient navigator intervention is feasible to improve palliative care outcomes	64 Latino adult patients with serious illnesses	A packet of written information including a booklet about advance directives, hospice care, and pain management. Plus, 5 home visits from a patient navigator to review the educational packet and discuss advance care planning (ACP), hospice utilization, and pain management.	“Control condition” A packet of written information including a booklet about advance directives (ADs), hospice care, and pain management.
Hanson et al ²⁶ (2017)	To test whether a goals of care (GOC) decision-aid intervention improves quality of communication and quality of palliative care for nursing home residents.	302 dyads of nursing home residents with advanced dementia and their family decision-makers.	One 18-minute GOC video shown to family decision-makers addressing end-of-life goals such as prolonging life and comfort care. Plus, a 1-hour structured discussion with nursing home providers who also received a written discussion guide and reminders to meet with family decision-makers. Providers were nurses, social workers, therapists, and nutritionists. Fidelity was monitored and achieved for 90% of participants	“Attention control” One informational video regarding how to interact with someone with dementia as well as usual care planning from nursing home staff.
Kozlov et al ²⁷ (2017)	To determine whether a web-based self-administered video or a written information page can improve knowledge about palliative care.	152 community dwelling adults age 18 to 89 who volunteered through research registries to participate in this web-based study.	Two interventions were tested. A 3-minute video (About.com) and an information page from Vanderbilt Health, both of which contained the same information about what palliative care is, who provides it, who can receive it, and where one can get it. Three weekly 60–90-minute semi-structured interview sessions held in 2 hospital-based outpatient clinics with a trained facilitator. Sessions held 1 week apart and included the (1) Lyon ACP survey; (2) respecting choices interview; and (3) documentation of end-of-life wishes using the 5 wishes AD document. Session 2 fidelity monitored through video/audiotapes.	Two control groups, one a 3-minute video (“control video”) and the other an information page about the Mediterranean diet and health
Lyon et al ²⁸ (2009)	To test the feasibility and acceptability of an ACP intervention to increase adolescent-surrogate congruence in end-of-life treatment preferences.	38 dyads of adolescents with HIV/AIDS and their surrogate decision-makers.	Three weekly 60–90-minute semi-structured interview sessions held in 2 hospital-based outpatient clinics with a trained facilitator. Sessions held 1 week apart and included the (1) Lyon ACP survey; (2) respecting choices interview; and (3) documentation of end-of-life wishes using the 5 wishes AD document. Session 2 fidelity monitored through video/audiotapes.	“Healthy living control” Three weekly 60– to 90-minute sessions held in 2 hospital-based outpatient clinics with a trained facilitator. Sessions held 1 week apart and included (1) development history surveys, (2) discussion about health and safety, and (3) school and career planning.
Lyon et al ²⁹ (2017)	To test the efficacy of an ACP intervention to increase adolescent-surrogate congruence in end-of-life treatment preferences.	105 dyads of adolescents with HIV/AIDS and their surrogate decision-makers.	Three weekly 60–90-minute semi-structured interview sessions held in a hospital-based outpatient clinic with a trained facilitator who was a research psychologist. Sessions held 1 week apart and included (1) the Lyon ACP survey, (2) respecting choices interview, and (3) documentation of end-of-life wishes using the 5 wishes AD document. AD shared with health-care providers and placed in medical record. Session 2 fidelity monitored through video/audiotapes.	“Active control” Three weekly 60– to 90-minute structured interview sessions held in a hospital-based outpatient clinic with a trained facilitator who was a research assistant. Sessions held 1 week apart and included (1) developmental history surveys, (2) counseling on safety information, and (3) counseling on nutrition and exercise. Session 2 fidelity monitored through video/audiotapes.

Study	Study Purpose	Sample	Intervention Condition	Control Condition
Reinhardt et al ³⁰ (2014)	To assess the effect of information and support provided to family members about the pros and cons of treatment decisions that may arise as their relative's severity of dementia increases	110 surrogate decision-makers for nursing home residents with advanced dementia.	One 47-minute, face-to-face meeting with a palliative care physician and social worker to discuss resuscitation, hospitalization, artificial nutrition and hydration, and pain and symptom management for the patient. Three 10-minute follow-up phone calls spaced 2 months apart with palliative care social worker.	"Comparison group" Three 10-minute social phone calls with a research assistant, on the same schedule as the intervention group
Steinhauser et al ³¹ (2008)	To test an intervention designed to promote discussions of end-of-life (EOL) preparation and completion.	82 hospice-eligible patients aged 28 to 96 years	Three, weekly, 45 to 60 minutes, interview sessions held at home to discuss life completion and preparation including life review, accomplishment, forgiveness, and legacy ("Outlook").	Two control groups, 1 receiving 3 weekly 45-minute sessions with nonguided relaxation meditation held at home ("attention control group") and the other receiving no contact ("no-intervention group").
Sudore et al ³² (2017)	To determine the efficacy of an interactive patient-centered ACP website (PREPARE) plus an easy-to-read AD.	414 veterans with at least 2 chronic conditions	A 1-hour, 5-step computer learning module, resulting in printed "Summary of My Wishes" and a commitment to do 1 ACP step. Computer module was completed at the study office. Also an easy-to-read AD (the same as control condition), PREPARE website login, and DVD to take home, and instructions to take the PREPARE printout to the next primary care visit.	"AD-only intervention" Participants reviewed the easy-to-read AD for 5 to 20 minutes at research office.

^a N = 9.

Table 2.Quality Assessment of the Included Studies.^a

Criterion	No of Studies	
	Met	Not Met or Not Stated
Method of randomization	9	0
Allocation concealment	1	8
The groups similar at baseline regarding the most important prognostic indicators	5	4
Eligibility criteria specified	8	1
Blinding of outcome assessment	6	3
Blinding of the care provider/interventionist	0	9 ^a
Blinding of participants	0	9
Point estimates and measures of variability for the primary outcome measures	9	0
Intention-to-treat analysis	4	5 ^b

^aIncluding 2 studies^{27,32} for which the criterion was not applicable because the intervention did not require interactions with an interventionist (eg, self-directed, written materials only).

^bIncluding 1 study³¹ that did not perform hypothesis testing but estimated effect sizes only.