



## Review

## Recruitment and retention rates in behavioral trials involving patients and a support person: A systematic review



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## ABSTRACT

**Background:** Recruitment and retention challenges impede the study of behavioral interventions among patient-support person dyads.

**Purpose:** The aim of the study was to characterize recruitment and retention rates of behavioral interventions involving dyads.

**Methods:** Using PRISMA guidelines and with the guidance of a medical librarian, we searched Medline, EMBASE, Cochrane Controlled Trials, PsycInfo, and CINAHL from inception until July 2011. Eligible articles involved RCTs of behavioral interventions targeting adult patients with a non-psychiatric illness and a support person. Sample and study characteristics, recruitment and retention strategies, and recruitment and retention rates were abstracted in duplicate. Quality of reporting was determined on a 5-point scale. Due to the heterogeneity in data reporting and missing data, a narrative synthesis was undertaken.

**Results:** 53 unique studies involving 8081 dyads were included. 9 studies were ascertained to have a “high quality” of reporting. A majority of the studies did not report target sample size, time to complete recruitment, and sample sizes at each follow-up time point. Strategies employed to recruit support persons were rarely reported. 16 studies did not report the number of dyads screened. The mean recruitment rate was 51.2% (range: 4.3%–95.4%), and mean retention rate was 77.5% (range: 36%–100%).

**Conclusions:** Details regarding recruitment and retention methodology were sparse in these interventions. Where available, data suggests that resources need to be devoted towards recruitment of sample but that retention rates are generally adequate.

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## 1. Introduction

Engaging family members is one of the six dimensions of patient-centered care [1]. Proponents of patient-centeredness have critiqued existing medical practices for excluding family members [2,3]. Recent reviews and meta-analyses across health conditions indicate efficacy of behavioral interventions involving a support person when compared to usual care or patient-alone interventions [4–6]. Although much of this research has focused on patients with Alzheimer's disease or other dementias [7,8], a growing number of studies address cancer, osteoarthritis, and other chronic diseases.

Despite the potential positive impact of involving support persons in interventions to improve patient outcomes, researchers may shy away from conducting such studies due to inherent difficulties in conducting them. Two significant challenges in conducting trials of interventions involving patients and their support persons are the recruitment and retention of such dyads. Although recruitment and retention present significant challenges for trials in general [9], the challenges for dyads are multiplied because both persons must meet eligibility criteria and be willing and able to participate [10]. Once a dyad is enrolled, time burden and logistical difficulties may preclude participation of support persons and patients alike [11].

When planning trials involving the participation of both patients and their support persons, it would be helpful to know the number of dyads that need to be screened (i.e., the recruitment rate) to achieve target sample size, and the number required to sustain sufficient statistical power (i.e., retention rate). Furthermore, it would be important to identify the recruitment and retention strategies that are most likely to yield the required sample size. Yet, no recommendations or strong examples exist as to the optimal approaches to recruiting and retaining dyads. Therefore, the goals of this systematic review were to characterize recruitment and retention rates of behavioral interventions involving patients and their support persons, and to characterize successful recruitment and retention strategies.

## 2. Methods

We searched published literature using Medline, PsycInfo, EMBASE, CINAHL, and Cochrane Registry for Controlled Trials. Articles were searched based on: 1) terms that captured dyads (e.g., couples, partners, caregivers, family); 2) behavioral interventions (e.g., behavioral, psychosocial); and 3) study design (e.g., randomized clinical trial). Final searches were developed in close collaboration with a medical librarian who had familiarity with the search strategies of each database. Sources were searched from database inception to July 2011.

We reviewed article bibliographies from selected articles to confirm that no relevant studies were missed. The review protocol is available from the corresponding author. A sample search from one of the databases is provided in Appendix A. The literature review was guided by PRISMA guidelines; the PRISMA checklist is provided in Appendix E.

Eligible articles involved a randomized clinical trial testing a behavioral intervention targeting patients with a non-psychiatric medical condition. Behavioral interventions that only provided educational materials as their intervention or were medication-focused were not eligible. Studies had to require participation of both a patient and a support person, broadly defined to include spouse/significant other, family member, or friend, who were both 18 years or older. However, simultaneous participation in intervention sessions was not a requirement, nor did the primary outcome have to be obtained from both members of the dyad, nor did patient and support person have to be cohabitating. Although studies could have been conducted in any country, articles that were not in English were excluded.

Results from all searches were combined in EndNote X5®, and duplicates were eliminated. Because it was not possible to exclude psychiatric illnesses at the search level, and because two databases did not allow restrictions for age  $\geq 18$  years, one author manually excluded articles of interventions targeting psychiatric illnesses and those that involved children. After this step, trained reviewers (RT, CV, AS, WY) independently reviewed citations identified through the literature search. Initially, two reviewers reviewed titles and abstracts for eligibility criteria; an article was excluded if both reviewers independently ascertained that it did not meet inclusion criteria. If either reviewer ascertained that the article met inclusion criteria or that the title/abstract did not provide sufficient information to exclude the article, then the article was retained. All retained articles were subjected to full text review. At this stage, articles were excluded if both reviewers independently ascertained that they did not meet inclusion criteria, and at least one reason for exclusion was noted. Any disagreements were resolved through discussion between the assigned reviewers; if necessary, a third reviewer (RT or CV) was designated as a tiebreaker. In this way, full consensus was achieved for all articles that were included in the final analyses. Where multiple articles referred to the same trial, we used the article that included the most information regarding recruitment and retention. All review and subsequent data abstraction activities were overseen by two researchers experienced with systematic reviews (RT and CV).

### 2.1. Data abstraction

Study details were abstracted in duplicate by 4 co-authors (JG, KB, KB, and EN) and verified by RT and CV. Abstracted

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