

Original article

Non-participants and reasons for non-participation in a pragmatic trial of energy healing as cancer rehabilitation

Marzcia Techau^{a,1}, Anita Lunde^b, Christina Gundgaard Pedersen^c, Anders Green^d,
Helle Johannessen^a, Nina Nissen^{a,*,1}

^a Institute of Public Health, University of Southern Denmark, J.B. Winsløws Vej 9B, 5000 Odense C, Denmark

^b VIA University College, Denmark

^c Aarhus University Hospital & Department of Psychology, Aarhus University, Denmark

^d Odense Patient Data Explorative Network (OPEN), Institute of Clinical Research, University of Southern Denmark, Denmark

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Abstract

Introduction: The problems associated with clinical trial participation have been highlighted in the literature, but few studies have examined why patients decline to participate.

Aims: To describe non-participants' and participants' characteristics and examine reasons for non-participation in a pragmatic trial of energy healing for rehabilitation for colorectal cancer.

Methods: Three to seven days after postal recruitment, all eligible participants ($n = 783$) were contacted by telephone. Reasons given for non-participation were recorded in 5 categories. Data were analyzed using χ^2 .

Results: More men than women declined to participate (men = 55.7%; women = 44.3%; $p = 0.022$). Non-participants were on average older than participants (non-participants: mean age 68.4; SD (9); participants: mean age 64; SD (8.8); $p < 0.001$), and had only received surgery (non-participants = 54.1%; participants = 40.1%; $p < 0.001$). The most frequent reasons for non-participation were (1) No need for rehabilitation ($n = 81$; 28.6%), (2) participation too burdensome ($n = 67$; 23.7%), and (3) no interest in energy healing ($n = 57$; 20.1%). If the time span between study recruitment and surgery was 0–9 months, participation was frequently considered too burdensome ($p = 0.020$), especially by women ($n = 45$; 67.2%; $p = 0.001$) and those aged ≥ 68 ($n = 54$; 80.6%; $p = 0.013$); rehabilitation was frequently considered not needed 10–17 months after surgery ($p = 0.035$).

Conclusion: Non-participation in a trial of energy healing as rehabilitation for colorectal cancer revealed an interplay between non-participants' demographic characteristics, health experiences, everyday life priorities and the offered rehabilitation intervention. To optimize recruitment to studies of cancer rehabilitation, consideration of disease trajectories and potential participants' rehabilitation needs is suggested.

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Keywords: Pragmatic trial; Trial non-participation; Trial participation; Cancer rehabilitation; Complementary and alternative medicine; Energy healing

Background

In 2012, colorectal cancer was estimated to be the second most common form of cancer diagnosed in Europe and the second most common form of death from cancer [1]. Diagnosis and

treatment of colorectal cancer has significant impact on people's lives. People with colorectal cancer experience poor quality of life following surgery and treatment [2], and continue to experience side-effects after treatment [3–5]. Colorectal cancer-related symptoms include fatigue, digestive problems, memory lapses, sexual problems, lack of concentration, and sleep interruptions [5]. These and other symptoms may make daily activities difficult [6,7].

Complementary alternative medicine (CAM) is widely used by cancer patients [8–11], including in colorectal cancer [12], and is commonly combined with biomedical treatment [13–16].

* Corresponding author. Tel.: +45 6550 4316.

E-mail address: nimissen@health.sdu.dk (N. Nissen).

¹ The authors wish it to be known that these authors should be regarded as joint first/last authors.

Amongst cancer patients, energy healing is one of the ten most chosen therapies for CAM cancer care in Europe [16] and used by up to 10% of cancer patients in Denmark [14].

In 2011–2012, a pragmatic trial on energy healing as rehabilitation for colorectal cancer was conducted in Denmark in order to test guidelines for effectiveness studies measuring personalized goals of treatments [17–20]. Considerable efforts were made to enlist participants for the trial, based on strategies to increase trial participation examined in the literature [e.g. 21–23], such as the inclusion of a pre-paid envelope and follow-up contact by telephone. Despite these efforts, only 31.5% of eligible participants responded. The aim of this article is to contrast non-participants' and participants' characteristics and examine non-participants' reasons for declining to take part in the trial. Although the problems associated with trial participation have been highlighted in the literature [e.g. 24–26], few studies have examined why patients refuse to participate in clinical trials [24]. This article provides insights into motivations and reasons that underpin non-participation in a pragmatic trial of energy healing as cancer rehabilitation.

Methods

Recruitment of patient participants

Based on an extraction from the Danish National Patient Registry a total of 783 persons were considered eligible to participate in the trial. Eligibility criteria included: (1) primary diagnosis of colorectal cancer, defined as C18–C20, according to the International Classification of Diseases (ICD10); (2) treated with surgery or surgery combined with chemotherapy and/or radiotherapy in the Southern or Central Region of Denmark between 1 March 2010, and 1 August 2011, and without evidence of current cancer; and (3) aged ≤ 80 at study inclusion. Patients were excluded if they: (1) were unable to comply with the data collection protocol, (2) had poor understanding of the Danish language, or (3) were receiving palliative care or had a recurrence of cancer prior to inclusion.

Using a centralized, computerized procedure, Minim (Minimization Program for Allocating Patients to Treatments in Clinical Trials), eligible participants were randomly stratified according to gender into a self-selection arm or a randomization arm prior to initial contact. This randomization design, based on energy healing versus no treatment, was chosen because of the primary hypothesis that patients who self-select the energy healing intervention will experience greater effects for primary outcomes than patients who are randomized to the intervention. This design also makes it possible to examine whether there might be a relationship between trial participation or non-participation and allocation to randomization or self-selection arms.

Eligible participants were mailed a folder containing: written information about the study; a leaflet containing information about the healers in the study; an informed consent form; a pre-paid envelope; and the first part of a questionnaire package. The accompanying letter differed, depending whether recipients were allocated to the self-selection arm or the randomization

arm. Recipients in the self-selection arm were informed that they could choose between treatments with energy healing and allocation to the control group. Recipients in the randomization arm were informed that they would be allocated either to receive energy healing or to be in the control group. Participants not receiving the energy healing intervention during the trial were offered one free treatment with an energy healer after trial completion; this was taken up by one participant only (for details of recruitment and randomization, see Fig. 1).

Three to seven days after the mailed invitation, two research assistants made telephone calls to all eligible participants ($n=783$) in order to answer any possible questions concerning the study, exclude potential participants who did not fulfill the inclusion criteria (such as known recurrence of cancer), and to ask for possible reasons if participation was declined. Questions such as 'do you have a particular reason for not wanting to participate?' and 'why do you not want to participate in this trial' guided the elicitation of reasons for non-participation, if no reasons had been forthcoming during the earlier part of the conversation. The elicited primary reason (one reason per person only), was immediately recorded in a non-participation log, according to six topics: (1) does not wish to participate in a trial of CAM or energy healing, (2) does not have the vitality, strength or energy to participate in such an extensive trial, (3) does not wish to use time on any trial participation, (4) does not like to be in randomization arm of trial, (5) rehabilitation not relevant, as the respondent is well and does not want to focus on illness any longer, and (6) cannot complete questionnaires, find transport, and similar. These six topics derived from engagement with literature about trial participation [for example, 21–24,26] and the interest to establish whether the therapy of energy healing impacted on non-participation.

If an eligible participant had not returned the questionnaire within 2–4 weeks a reminder call was made, following the same above procedure; hereafter no-response was considered non-participation. A total of 247 individuals participated in the study (response rate 31.5%; men $n=115$, 46.6%; women $n=132$, 53.4%).

Intervention procedure

The intervention consisted of four sessions of energy healing spread over a 2-months period; the distribution of sessions was decided by each participant-healer² pair. Patient participants chose one of the participating healers, and the energy healing sessions took place at the healers' clinic. The energy healing delivered was not restricted to a specific form of energy healing, provided that it was based on the general idea of the healer transmitting some kind of "energy" to the participant. Conversation "as usual" was accepted, but no other form of therapy than energy healing was allowed.

² Healers were identified and recruited through a national association of healers ('Healer-Ringen'). Additional inclusion criteria were: (1) treatment facilities used solely for the practice of healing, and (2) clinic location within the regions of Central and Southern Denmark. A total of 31 healers were included.

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