Original Article

A Mixed-Methods, Randomized, Controlled Feasibility Trial to Inform the Design of a Phase III Trial to Test the Effect of the Handheld Fan on Physical Activity and Carer Anxiety in Patients With Refractory Breathlessness

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Abstract

Context. The handheld fan is an inexpensive and safe way to provide facial airflow, which may reduce the sensation of chronic refractory breathlessness, a frequently encountered symptom.

Objectives. To test the feasibility of developing an adequately powered, multicenter, multinational randomized controlled trial comparing the efficacy of a handheld fan and exercise advice with advice alone in increasing activity in people with chronic refractory breathlessness from a variety of medical conditions, measuring recruitment rates; data quality; and potential primary outcome measures.

Methods. This was a Phase II, multisite, international, parallel, nonblinded, mixed-methods randomized controlled trial. Participants were centrally randomized to fan or control. All received breathlessness self-management/exercise advice and were followed up weekly for four weeks. Participants/carers were invited to participate in a semistructured interview at the study's conclusion.

Results. Ninety-seven people were screened, 49 randomized (mean age 68 years; 49% men), and 43 completed the study. Site recruitment varied from 0.25 to 3.3/month and screening:randomization from 1.1:1 to 8.5:1. There were few missing data except for the Chronic Obstructive Pulmonary Disease Self-Efficacy Scale (two-thirds of data missing). No harms were observed. Three interview themes included 1) a fan is a helpful self-management strategy, 2) a fan aids recovery, and 3) a symptom control trial was welcome.

Conclusion. A definitive, multisite trial to study the use of the handheld fan as part of self-management of chronic refractory breathlessness is feasible. Participants found the fan useful. However, the value of information for changing practice or policy is unlikely to justify the expense of such a trial, given perceived benefits, the minimal costs, and an absence of harms demonstrated in this study. J Pain Symptom Manage 2016;■:■–■.

Key Words

Breathlessness, fan, nonpharmacological, RCT, palliative care, semistructured interviews

This study has been registered in Australian and New Zealand Clinical Trials Registry (ACTRN12614000525684).

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Introduction

Breathlessness is a devastating symptom prevalent in many progressive chronic illnesses. It affects most people with lung cancer,[1] chronic obstructive pulmonary disease (COPD),[2] and heart failure.[3] It is a frightening and disabling symptom for both patient and carer and is associated with poorer survival,[4] unscheduled hospital attendance,[5] and admission.[6,7] Despite advances in managing breathlessness,[8,9] many patients experience chronic refractory breathlessness, often worsening as death approaches.[10] The multifaceted nature of breathlessness means any incremental improvements in its management are likely to benefit patients' well-being and their physical function, while helping to minimize carers' distress.[11]

Such patients often experience breathlessness precipitated or exacerbated by exertion or anxiety. A smaller subgroup may experience episodic, unheralded breathlessness for which no precipitating cause can be identified.[12,13] Nonpharmacological and pharmacological interventions are the mainstay of breathlessness management.[14] Self-efficacy assists patients manage difficult symptoms more effectively, improving quality of life.[15] Pharmacological treatments for breathlessness, such as regular, low-dose, sustained-release morphine, provide some relief[16–18] but may have adverse effects and may not be suitable or acceptable for some people. Exercise may reduce the impact of breathlessness in some people through increasing self-efficacy and fitness.[19,20] Despite benefits associated with exercise, exercise-induced breathlessness often limits physical activity because it is unpleasant or because patients believe it may be harmful,[19] further reducing their capacity to cope with being breathless. Supporting continued physical activity is a key strategy for minimizing chronic refractory breathlessness.

There is emerging evidence that facial airflow can reduce the sensation of breathlessness.[21] In studies evaluating a U.K. Breathlessness Intervention Service,[22–24] patients and carers consistently cited the fan as an important intervention. A randomized controlled crossover study of "fan to face" versus "fan to leg" in patients with breathlessness at rest due to any etiology demonstrated relief.[25] Another Phase II, parallel group trial of "fan to face" versus acupressure wristband in people with advanced cancer/COPD demonstrated that 50% were still using the fan at two months compared with only 20% using the wristband.[26] A recent randomized controlled trial (RCT) of medical air versus oxygen showed equal benefit from both,[27] with the authors concluding that the effective agent may have been the simple passage of air.

This Phase II study explored the feasibility of conducting an adequately powered, multicenter, multinational RCT comparing the efficacy of a handheld fan and exercise advice with exercise advice alone in increasing activity levels in people with optimally treated etiologies of breathlessness from any cause to evaluate 1) Is recruitment possible in terms of number and rate? 2) What are the data quality and utility of the proposed outcome measures? 3) What is the best primary outcome measure for any subsequent Phase III study? and 4) Is there any signal of a dose response?

Methods

Study Design

The Fan, Activity, Breathlessness (FAB) study was a Phase II, multisite, international, parallel arm, nonblinded, feasibility RCT with a qualitative substudy. Participants were allocated to an intervention or control arm according to a block randomization schedule generated by a central registry using a 1:1:2 ratio: low flow rate (Fan A); high flow rate (Fan B); no fan. Each site had access to sequentially numbered, opaque, sealed envelopes with the allocation concealed from the investigating team. All groups received standardized advice regarding breathlessness self-management exercises. Participants were followed up weekly for four weeks.

Participants and their carers were invited to participate in a semistructured interview as they finished the study, purposively sampled to include all groups, and by etiology of breathlessness. A topic guide, developed from the literature and expertise of the research team, was used to 1) explore the experience of using the fan (or not) and its impact on activities, well-being, and self-efficacy and 2) understand the experience of study participation. Interviews were conducted at the participants' homes or clinical setting of choice.

Participants and Setting

Eligible participants provided written informed consent and were community-dwelling adults with refractory breathlessness caused by a variety of medical conditions and scoring 3 or higher on the modified Medical Research Council dyspnea scale.[28] Those who had used a handheld fan within the previous week, had a documented cognitive impairment, or were too unwell were excluded. All participants were informed that the trial intervention was the fan, and if allocated to the control arm, a fan would be provided at study completion. Participants were identified from cardiorespiratory, oncology, and palliative care outpatient clinics and day hospices at two U.K. services and two Australian sites.

Interventions

In addition to verbal advice, participants received an information leaflet, which contained some breathing