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The hand-held fan and the Calming Hand for people with chronic breathlessness: a feasibility trial.

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Abstract

Introduction: The battery operated hand-held fan ("fan") and the Calming Hand (CH), a cognitive strategy, are interventions used in clinical practice to relieve chronic breathlessness.

Objective: To test the feasibility of a phase III randomised controlled trial (RCT) evaluating the impact of the fan and/or CH compared with exercise advice alone for the relief of chronic breathlessness due to respiratory conditions.

Methods: Single site, feasibility "2x2" factorial, non-blinded, mixed-methods RCT. Participants randomly allocated to four groups: fan + exercise advice *vs* CH + exercise advice *vs* fan + CH + exercise advice *vs* exercise advice alone. Measures included: recruitment, acceptability; data quality and study outcomes (baseline, day 28); modified incremental shuttle walk test (mISWT), recovery time from exertion-induced breathlessness, Life-space, General Self-Efficacy Scale and breathlessness numerical rating scales. Willing participants and carers were interviewed at study end.

Results: Recruitment/acceptability/data completion: 53 people were screened, 40 randomised *and* completed; (mean age 72 years (SD 9.8), 70% male). There were few missing data (2 mISWT). Recovery time [seconds] from exertion-induced breathlessness showed most improvement for the fan; mean reduction from baseline -33.5 *vs* CH mean increase from baseline 5.7. This represents a recovery speed at day 28 -20.4% faster for the fan *vs* 4.1% slower for the CH.

Qualitative data indicated participants valued the faster recovery and identified the fan as a useful "medical" device, but found the CH unhelpful.

Conclusion: A phase III RCT is feasible. Mixed-method data synthesis supports recovery time as a novel, meaningful outcome measure.

Introduction

People with progressive cardiorespiratory conditions frequently experience disabling chronic breathlessness that seriously affects daily life despite optimum treatment of their underlying disease (1). It is associated with poor health outcomes; reduced quality of life,(2) restricted activities,(3) emergency healthcare and hospital admissions.(4) Despite the widespread effects of breathlessness chronic breathlessness is often invisible to the clinician and therefore overlooked, leaving patients, carers and family members to manage the symptom burden with little professional help.(5)

Management is modelled on a multi-disciplinary, complex intervention that incorporates a range of pharmacological and non-pharmacological interventions.(6) Non-pharmacological interventions promote self-efficacy, with some patients becoming expert in self-management.(7) A clinical framework of “Breathing”, “Thinking” and “Functioning”, can be used to target interventions which address vicious circles (ineffective ventilation, anxiety, reduced physical activity) that perpetuate the effects of breathlessness.(8)

Worse breathlessness is most commonly induced by physical exertion.(9) Frequent episodes restrict normal daily activities, particularly if the patient and/or family carer perceives breathlessness as an unpleasant or harmful experience to be avoided. A deconditioning spiral is thus perpetuated as lack of activity weakens peripheral muscles until breathlessness is eventually precipitated from the slightest physical effort.

Therefore, interventions which target exertion-induced breathlessness may improve the patient’s experience of everyday activities and prevent exercise avoidance. Strong evidence supports the role of exercise and activity to reduce the impact of breathlessness,(10) yet the patients misperception of the symptom as inherently dangerous may act as a disincentive to continue activities and reduce adherence to a rehabilitation programme.(11, 12) However, the strength of evidence varies for non-pharmacological interventions, and is sparse for some, an issue highlighted by previous Cochrane review (update in preparation).(13)

Two interventions used in clinical practice are the battery operated hand-held fan (“fan”) and the Calming Hand (CH) (a cognitive strategy [Online supplementary diagram]). (14) Growing evidence suggests that cool airflow delivered from the fan can decrease

breathlessness.(15) Stimulation of facial, nasal or upper airway flow receptors may modulate the central perception of breathlessness and decrease neural respiratory drive.(16-18) Little or no effectiveness evidence exists for the CH and little is known about possible mechanisms for benefit, but is thought to target cognitive-emotional pathways to modulate the central perception of breathlessness. Both interventions are inexpensive, readily available, easy to use and portable providing the patient and carer with an intervention suited for self-management strategies for exertion-induced breathlessness.

We investigated the feasibility of conducting a phase III RCT to test the effectiveness of fan, CH or both compared with self-management and exercise advice alone for the relief of exertion-induced breathlessness in people with chronic breathlessness due to respiratory disease.

Methods

Study Design

The Calming Hand and Fan Feasibility (CHAFF) was a mixed method study: phase II, single site, "2x2" factorial, un-blinded randomised controlled trial and qualitative semi-structured interviews of participants and their carer's. Potentially eligible participants were approached and screened by the patient's usual clinician at an out-patient appointment at Castle Hill Hospital, Hull**.** Eligible patients were consenting adult respiratory outpatients with Medical Research Council (MRC) breathlessness scale grade ≥3 (19) due to an optimally treated respiratory disease. Patients were excluded if they had used the fan or CH within the previous two weeks, had trigeminal nerve damage or were too unwell to complete study procedures. Carers (if present) of the patient participants were also invited to consent to providing data about carer experience. Participants were allocated to exercise advice alone or with the addition of the fan, CH or both, according to a block randomisation schedule generated by a web-based random number sequence generator using a 1:1:1:1 ratio. This was managed by the Hull Clinical Trials Unit, who had access to sequentially numbered, opaque, sealed envelopes. The allocation was concealed from the study investigators although once randomised, blinding was not possible. Measures were taken at baseline and again at day 28. Fidelity of patient adherence was assessed by fan and/or CH use at day 28. Participants and their carer's were invited to take part in a semi-structured interview at day 28.

Interventions

Participants were randomised after completion of all baseline measures. The intervention was delivered after randomisation during one visit to the Respiratory Clinical Trials Unit at Castle Hill Hospital, Hull. The intervention was provided by an academic physiotherapist researcher. All four groups received one-hour face-to-face individual training in standardised breathlessness self-management and exercise advice. All participants were given an information leaflet for use at home. This was adapted with permission from the Cambridge Breathlessness Intervention Service leaflets (20), available online and contained guidance on breathing control, recovery positions from breathlessness, activity pacing and exercise advice.

Participants allocated to the CH and/or fan were instructed how to use the intervention(s) and encouraged to use whenever they felt breathless during the 28 day study period. A plastic, 3 flexible blades, high flow fan was used. Their information sheets included instruction on how to use the CH and/or fan depending on allocation. Intervention components delivered were documented in the clinical record of each participant.

Study Assessments and outcomes

All study measures were assessed at baseline (day 0) and at 4 weeks (day 28) The same researcher who was not blinded to group assignment collected all of the outcome data and conducted the qualitative interviews at study end.

At baseline clinical demographic data were collected about age, sex, diagnosis, oxygen therapy, mobility aids, carer status and the Charlson Co-morbidity Index.

The feasibility outcomes were;

- Recruitment rate, screening/consent ratio, randomisation and attrition
- Data quality including patterns and proportions of missing data
- Baseline variance of the candidate outcome measures to estimate sample size for a phase III trial:

Exercise and activity

Modified Incremental Shuttle Walk Test [mISWT] distance, a standardised incremental field walking test that provokes a symptom limited maximal exercise performance.(21, 22) The

mISWT followed standard procedures.(21) Life-space questionnaire, a measure of spatial mobility according to the level of movement a patient is able to make away from home with or without assistance and/or equipment.(23-25)

Self-efficacy

General Self-Efficacy Scale [GSES] (patient and carer), a 10 item 0-4 point scale (0 = not at all true, and 4 = exactly true) measure of a person's beliefs about their capability to handle new or difficult tasks.(26, 27)

Breathlessness assessment

An 11 point numerical rating scale [NRS] 0-10 (0 = none, and 10 = worst possible) measure of breathlessness,(28) intensity on average and at its worst over the previous 24 hours, the unpleasantness of and distress due to breathlessness, and intensity at each time-point (every minute) during recovery time from maximal exertion-induced breathlessness from mISWT. Recovery time was defined as the time taken for the participant to return to their baseline NRS breathlessness intensity value from the point of maximal breathlessness after the ISWT.

Carer assessment

Zarit carer burden short-form, a 6 item 0-4 point scale (0 = never and, 4 = nearly always) measure of carer burden.(29, 30)

Interviews

Willing participants and carers were interviewed after study end (day 28). Participants were purposively sampled to include all participants from all four study arms and to gain maximum variation (age, sex, diagnosis, presence of carer). A topic guide was developed from the literature and research team experience to explore, i) the participant and carer experience of using the fan and CH (or not) and the impact on the self-management of breathlessness, daily activities and exercise, and ii) the feasibility and acceptability of study participation including design and outcome measures. Interviews were conducted at the participant's home individually and/or as a carer dyad. All interviews were audio-recorded and transcribed verbatim.

The quantitative data are reported according to CONSORT guidelines (31) and the intervention according to the TIDIER checklist.(32)

Ethics

Human Research Ethics approvals, including for the method of consent, and institutional permissions were obtained prior to recruitment (Leeds West Ethics committee, 12/YH/0410, 12/09/2012). The study protocol was registered; ISRCTN40230190.

Sample size

It was considered that 40 participants was sufficient to address the feasibility questions and inform the sample size for a phase III RCT.(33)

Statistical analysis

All randomly assigned participants were included in the Intention-to-Treat analysis. As a feasibility study the following descriptive analyses were conducted using SPSS (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp):

- Descriptive analysis of recruitment
- Descriptive analysis on the completion of endpoints
- Calculation of the variance of change associated with the study outcome measurements.

Findings were not adjusted for baseline values. Missing data were not imputed.

Qualitative analysis.

Qualitative interviews were imported into NVivo Version 7. Thematic analysis was used following a process of immersion in data, line-by-line coding, grouping of codes into initial themes, and then generation of major themes.(34) Four interview transcripts were independently coded by two researchers, Flavia Swan (FS) and Miriam Johnson (MJ). FS and MJ, then formulated a working coding framework. This was used by FS to systematically code, develop and organise the dataset into relevant categories with appropriate examples to illustrate the relevance to the research questions.

Mixed-methods data synthesis

A convergent design used concurrent quantitative and qualitative data collection followed by separate analyses of the data types, prior to integration and triangulation of the dataset at the interpretative stage of the study.(35)

Results

Participant characteristics

Recruitment took place for 20 months during December 2012 and December 2014 (researcher leave between September 2013 and December 2013). 40 participants were randomised (mean age 72 years [SD 9.8], range 53-91; 28 [70%] male). Study flow can be seen in Figure 1. Baseline characteristics are summarised in Table 1. Of note breathlessness measures, particularly distress and worst intensity over the past 24 hours, were better in the groups allocated to CH. Most participants had idiopathic pulmonary fibrosis (IPF), 22 (55%) followed by chronic obstructive pulmonary disease (COPD) 12 (30%). All participants had co-morbid disease with three-quarters having a Charlson Co-morbidity index of ≤2. Baseline characteristics were generally balanced across the four arms, apart from participants with IPF, who were allocated to exercise advice 7 (70%), and exercise advice & CH 9 (90%). Interestingly, carers in the fan & CH group had less burden and better GSES.
All participants received all components of the intervention.

INSERT Table 1

Feasibility outcomes

The recruitment rate averaged 2.0/month. Of 53 participants screened, 13 (24%) were excluded; 2 (4%) were ineligible (1 cognitive impairment, 1 recent use of fan) and 11 (20%) declined to participate. Reasons for not participating were 1 (9%) carer duties, 1 (9%) hospitalisation, 4 (36.5%) other co-morbidity problems, 4 (36.5%) felt the study was too much and 1 (9%) no transport.

Data completion

40 participants were randomised and 40 completed the trial. All study measures were completed by all participants apart from 2 (5%) participants who did not take part in a mISWT on day 28. However, baseline mISWT data from 13 participants (33%) were excluded due to a protocol deviation (baseline mISWT and recovery time collected after delivery of intervention in error). 14 carers were recruited and 13 (92%) completed the study. Data were missing from one carer who was unable to attend the day 28 appointment.

INSERT Figure 1

Outcomes

Table 2 summarises the main outcomes for the 4 study arms at day 28 and the comparison of the mean change (day 28 minus baseline) and percentage between the groups for the potential phase III outcome measures. Recovery time after the mISWT and the mISWT distance were the only outcomes that signalled usefulness for a phase III trial. Recovery time (seconds) was fastest in the fan groups. Distress due to breathlessness improved by more in the CH groups. The mISWT distance (metres) increased in both groups allocated to the fan; mean changes from baseline were 55.33 (44%) fan & exercise advice and 31.86 (17%) fan & CH & exercise advice. In contrast, the CH & exercise advice group showed only slight improvement; 18.57 (15%) and the walking distance decreased in the exercise advice group (-19.53, -11%).

Improvements in carer outcomes were of note in the fan & CH & exercise advice arm only; mean change from baseline Zarit burden 1.75; (5%) and GSES 0.25; (7.1%).

Overall, all 20 (100%) participants allocated to a fan arm were still using it on day 28, and 15 (75%) said they used it every day. In contrast, although 18 (90%) of those allocated to a CH arm were still using it at day 28, only 8 (40%) said they used it every day. Of interest, those allocated to CH were more likely to use it every day if this was their sole intervention (CH only – 6 (60%) daily use *vs* CH and fan – 2 (20%) daily use)

INSERT Table 2

Semi-structured interviews

A purposive sample of 11 participants and five carers took part in semi-structured interviews. All interviews apart from one patient/carer dyad were conducted individually at home. The four study arms were represented with at least two participants and one carer from each arm; seven participants and three carers had had experience of the fan, and six participants and two carers had had experience of the CH. Overall, participants found the fan acceptable partly because of ease of use, and partly because they perceived benefit. The CH was largely dismissed in terms of acceptability.

Four key themes were generated from the data;

1. *The fan helps recovery from breathlessness*

Participants consistently suggested that one of the main benefits of using the fan was helping recovery from episodes of breathlessness. This influenced how participants used the device as it was considered an extra tool that could easily be tailored to their daily breathlessness needs at any time or in any location.

2. *The fan supports exercise and activity*

This helped promote self-efficacy and participants felt more confident about self-managing their exertional breathlessness such that they were able to continue or even try activity that they had not previously thought possible or had learned to avoid.

3. *The fan was used like a medical device*

The value of the intervention was reflected in the way participants likened their use of the fan to a medical device, such as a replacement for a Ventolin inhaler or an adjunct between nebulisers.

4. *The CH was considered common sense and already known*

In contrast the CH was perceived as common sense and of little help managing breathlessness. Participants stated that the CH was a strategy that they had already tried in the past and as such it was nothing new. They described infrequent use to the extent of disregard.

INSERT Table 3

Discussion

It is feasible to conduct a phase III RCT in terms of recruitment, data completion, and acceptability of study procedures and measures. However, the mixed-method data synthesis supports a future test of effectiveness of the fan, particularly during recovery from exertion-induced breathlessness, but gives a less clear signal for the CH. Recovery time showed a quantitative signal of activity with the fan and was identified by participants as a particular and important benefit of the fan. Although only a small change in terms of recovery time, this

was discernible as welcome by the patient; this benefit from the fan was seen as an important factor in breathlessness self-management,(36) and contributed to its acceptability to the participants. Participants described how the fan enabled them to do more physical activity, sufficient to restore lost activities of daily living such as shopping or hobbies such as fishing.

Quantitative data showed reduction in average daily distress due to breathlessness with the CH, but did not indicate benefit in either unpleasantness, intensity or worst distress in the past 24 hours. Worst distress is likely to be related to exertion, and it may be that the CH is less useful in recovery where a fan is simpler to use under these circumstances.

The recovery time data demonstrated a rapid return to baseline breathlessness score; all participants fully recovered from maximal exertional breathlessness in less than three minutes on average, and no longer than five, even after a walking test to maximal breathlessness. These figures are consistent with results from people with intra-thoracic cancer (median 4 (IQR 2-5) minutes),(37) and indicate that patients with a diagnosis of COPD, IPF or asthma experience a similar rapid recovery from exertional breathlessness. This is clinically relevant important information to reassure patients that exertion-induced breathlessness usually recovers quickly countering beliefs that breathlessness is harmful.

Implications for clinical practice

The fan is a valuable component of breathlessness management that is pragmatic and easy to-administer. (15, 36, 38-40) Fear of breathlessness is a significant obstacle to exertion and exercise in people with chronic breathlessness and is a recognised factor in non-attendance of and drop-out from rehabilitation programmes.(12, 41) If the fan shortens recovery time and improves patient confidence, this may help reduce the vicious circle of deconditioning through exercise avoidance. It may also be useful to help adherence to pulmonary rehabilitation and long-term maintenance of outcomes.

The other important potential for the fan is for use in breathlessness crisis; often exacerbated by anxiety and helplessness. “Fan to face” is already recommended as part of a breathlessness crisis plan.(42) A third of patients with acute-on-chronic breathlessness attending the emergency departments (ED) are discharged without need for hospital admission.(4) As many of such attendances occur out of office hours when usual clinicians are unavailable,(4)

and panic can be a greater risk,(7) the fan as a self-management strategy usable by patients *and* family carers may be of value to increase perceived control over breathlessness, particularly if used as a medical device. Indeed the qualitative findings suggest a useful role for the fan with "out of the blue" breathlessness (P18), a breathlessness category known to cause severe distress and initiate help-seeking.(7)

Such self –efficacy is an important concept (43), and links to how effectively patients manage difficult symptoms with their quality of life.(44) Self-efficacy in coping with a breathlessness crisis is an important factor in avoiding ED presentation.(7) The patient's experience of performance success or failure will likely validate or undermine their capabilities to cope with a given activity or situation. Significant improvements in the Chronic Respiratory Questionnaire's breathlessness self-mastery domain were seen with a complex intervention for breathlessness management that included the fan.(45) Feasibility data has also indicated that the fan helps patients regain control and improve self-confidence to manage breathlessness by integrating into their daily activities and offering them a device that can be tailored to particular situations.(39)

Implications for future research

Although further value of information of a phase III trial of the fan as an isolated component for the benefit of breathlessness in everyday life is unlikely,(39), confirming its specific benefit on recovery time would be useful. If confirmed, this places the fan firmly as a tool to help improve daily physical activity, attendance and adherence to rehabilitation programmes, and as an adjunct to breathlessness crisis management.

The lack of signal with CH may be because the trial was not designed to discard the null hypothesis. However, given the strong comments from the qualitative study and the lack of other literature to support effectiveness, or to delineate possible mechanisms of action, these data do not support further study where recovery from exertion-induced breathlessness is the primary outcome. It may benefit distress due to breathlessness in general and further work should be directed here rather than as a recovery measure.

Limitations

The same person delivered the interventions and collected the outcome data, which could have added to the reporting bias resulting from the lack of blinding. In addition, as participants did not perform a training mISWT, any change in mISWT distance at day 28 may represent learning.(22) However, i) these sources of bias will be consistent across all four study arms and, ii) the aim of this feasibility study was to inform the design of a phase III RCT, rather than evaluate effectiveness. The exclusion of 13 baseline mISWTs and breathlessness recovery measurements reduce the data anticipated for analysis. Therefore although the aim was to perform a sample size calculation this was deemed inappropriate as the estimate would have relied on too few data or would have involved combining data from two of the study arms; fan & exercise advice and fan & CH & exercise advice. Consequently further feasibility data is recommended to inform a more precise estimate for a future test of the fan.

The lack of IPF patients in either fan groups might be important if there is differential response to the fan or CH by diagnosis. However, the authors are unaware of any published observations with this regard.

Our choice of a single face-to-face training session was made pragmatically aiming to minimise participant burden as our recruitment pathway was likely to lead to a significant proportion of people with IPF. However, although their prognosis is similar to cancer, there are no data to confirm the effectiveness of a single session as there is for cancer.(46) This should be reviewed in the design on a subsequent trial.

Finally, qualitative study is not designed to provide generalizable data. The semi-structured interview is inevitably influenced by the social interaction between the researcher and participant. Patients and carers may say what they think the researcher wanted to hear about the interventions in an attempt to please, although they did not seem to be constrained in reporting their adverse views about the CH. However, their views on cognitive interventions, rather than ones that can be more easily understood in a medical model (it was apparent that they viewed the fan in the same way as a medical device) may reflect regional and demographic culture and not be found in other areas.

Conclusion

A future phase III RCT to test the fan is feasible. Further feasibility data is recommended to accurately inform the sample size calculation. Mixed method data synthesis supports recovery time as a novel, meaningful outcome measure. The data do not support the use of the CH as a recovery measure.

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Table 1 Demographic Characteristics of study groups at baseline

Demographic data	Exercise advice (n=10)	Fan & exercise advice (n=10)	CH & exercise advice (n=10)	Fan & CH & exercise advice (n=10)	Total (n=40)
Age:	70 (11.2), 53-86	70 (7.2), 61-84	79 (12.1), 59-91	71 (5.9), 56-71	72 (9.8), 53-91
Gender: Male	6, (60%)	8, (80%)	7, (70%)	7, (70%)	28, (70%)
Primary Diagnosis					
COPD Pulmonary Fibrosis Others	1, (10%) 7, (70%) 2, (20%)	5, (50%) 3, (30%) 2, (20%)	1, (10%) 9, (90%) 0, (0%)	5, (50%) 3, (30%) 2, (20%)	12, (30%) 22, (55%) 6, (15%)
Charlson Co-Morbidity Index score					
1 point: 2 points: 3 points: 4 points:	5, (50%) 3, (30%) 1, (10%) 1, (10%)	5, (50%) 3, (30%) 2, (20%) 0, (0%)	6, (60%) 2, (20%) 1, (10%) 1, (10%)	4, (40%) 2, (20%) 4, (40%) 0, (0%)	20, (50%) 10, (25%) 8, (20%) 2, (5%)
NRS Intensity Average last 24hrs	5.0 (2.11) 2-8	5.5 (1.43) 4-8	4.7 (1.77) 2-8	4.8 (1.13) 3-7	5.0 (1.62) 2-8
NRS Distress Average last 24hrs	4.8 (3.26) 0-9	5.6 (2.55) 0-9	3.7 (3.37) 0-9	3.3 (2.63) 0-8	4.3 (3.0) 0-9
NRS Unpleasantness Average last 24hrs	6.1 (2.68) 1-9	6.3 (2.16) 3-10	5.7 (2.26) 3-9	5.9 (2.18) 3-9	6.0 (2.25) 1-10
NRS Intensity At worst last 24hrs	7.3 (1.7) 3-9	7.8 (1.32) 5-9	5.9 (2.28) 3-9	6.9 (1.66) 4-9	6.9 (1.85) 3-9
NRS Distress At worst last 24hrs	6.1 (4.04) 0-10	7.0 (2.94) 0-10	4.1 (3.41) 0-9	4.3 (3.13) 0-9	5.3 (3.49) 0-10
Life-space questionnaire score	54.45 (24.74) 20-100	60.85 (22.69) 20-96	47.05 (13.9) 29-69	55.5 (19.37) 12-78	54.46 (20.4) 12-100
General Self-efficacy Scale (GSES)	30.30 (5.44) 19-38	28.8 (6.53) 21-38	31.7 (6.31) 19-40	33.3 (4.90) 24-40	31.03 (5.85) 19-40
Recovery time mISWT (seconds)	179.0 (69.14) 98-303 MD = 3	164.0 (70.18) 90-291 MD = 4	140.29 (36.75) 91-201 MD = 3	163.57 (47.44) 85-232 MD=3	161.63 (55.57) 85-303 MD=13
mISWT distance (metres)	192.86 (138.05) 70-430 MD =3	126.67 (81.65) 30-210 MD =4	121.43 (90.26) 40-300 MD =3	187.14 (85.97) 80-290 MD =3	158.15 (102.02) 30-430 MD=13
Zarit carer burden	8.5 (4.95) 5-12 (n=2)	8 (3.56) 3-11 (n=4)	7.25 (4.19) 1-10 (n=4)	3.5 (3.0) 0-6 (n=4)	6.57 (3.89) 0-12 (n=14)
Carer GSES	33 (2.83) 31-35 (n=2)	33.5 (3.11) 30-37 (n=4)	32.5 (2.89) 30-35 (n=4)	35.0 (3.56) 31-38 (n=4)	33.57 (2.95) 30-38 (n=14)

Mean (SD) Range, MD = missing data; (n=) number of participants mISWT = modified incremental shuttle walk test; NRS = numerical rating scale; COPD = chronic obstructive pulmonary disease; fan = hand-held fan; CH= calming hand

Table 2 Patient and carer outcome measures day 28 mean change from baseline, absolute and percentage

	Exercise advice (n=10)		Fan & Exercise advice (n=10)		CH & Exercise advice (n=10)		Fan & CH & Exercise advice (n=10)	
Patient Outcome measures	Day 28	Mean Change; absolute, %	Day 28	Mean Change; absolute, %	Day 28	Mean Change; absolute, %	Day 28	Mean Change; absolute,%
NRS Intensity *Average last 24hrs*	5.2 (1.99) 1-8 MD = 0	0.2; 4%	6.1 (2.23), 3-10 MD = 0	0.6; 10.9%	4.8 (2.04), 2-9 MD = 0	0.1; 2.1%	4.9 (2.56), 1-8 MD = 0	-0.1; -2%
NRS Distress *Average last 24hrs*	5.2 (2.3), 2-8 MD = 0	0.4; 8.3%	5.3 (3.65), 0-10 MD = 0	-0.3; -5.3%	3.1 (2.02), 0-7 MD = 0	-0.6; -16.2%	3.8 (3.15), 0-10 MD = 0	-0.5; -11.6%
NRS Unpleasantness *Average last 24hrs*	5.9 (1.91), 3-9 MD = 0	-0.2; -3.2%	5.8 (2.53), 1-10 MD = 0	-0.5; -7.9%	6.2 (2.20), 3-10 MD = 0	0.5; 8.7%	4.7 (2.75), 0-10 MD = 0	-1.2; -20.3%
NRS Intensity *At worst last 24 hours*	6.7 (1.34), 5-9 MD = 0	-0.6; -8%	7.5 (2.59), 2-10 MD = 0	-0.3; -3.8%	6.8 (2.25), 3-10 MD = 0	0.9; 15.2%	5.8 (2.53), 2-10 MD = 0	-1.1; -15.9%
NRS Distress *At worst last 24 hours*	6.1 (2.47), 2-9 MD = 0	0.0; No change	6.5 (3.44), 0-10 MD = 0	-0.5; -7.1%	4.1 (2.99), 0-9 MD = 0	0.0; No change	4.9 (3.41), 0-10 MD = 0	-0.6; -11.3
Life-space questionnaire	54.0 (24.21), 25-100 MD = 0	-0.45; -0.8%	64.05 (19.23), 32-84 MD = 0	3.2; 5.2%	55.2 (14.67), 35-76 MD = 0	8.15; 17.3%	61.05 (27.06), 20-100 MD = 0	5.55; 10%
General Self-efficacy Scale (GSES)	32.0 (5.96), 20-40 MD = 0	1.7; 5.6%	31.9 (4.36), 28-40 MD = 0	3.1; 10.8%	31.8 (4.96), 23-40 MD = 0	0.1; 0.3%	32.4 (4.40), 22-40 MD = 0	-0.9; -2.9%
Recovery time (seconds)	152.56 (41.45), 111-224 MD = 1	-26.44; -14.7%	130.5 (64.60), 74-305 MD = 0	-33.5; -20.4%	146.0 (38.88), 89-200 MD = 1	5.71; 4.1%	123.30 (24.93), 85-160 MD = 0	-40.27; -24.9%
mISWT distance (metres)	173.33 (124.9), 60-470 MD = 1	-19.53; -10.8%	182.0 (103.69), 50-340 MD = 0	55.33; 43.7%	140.0 (84.41), 30-310 MD = 1	18.57; 15.3%	219.0 (93.39), 120-410 MD =0	31.86; 20.1%

Table 2 Patient and carer outcome measures day 28 mean change from baseline, absolute and percentage

	Exercise advice (n=2)		Fan & Exercise advice (n=4)		CH & Exercise advice (n=3)		Fan & CH & Exercise advice (n=4)	
Carer Outcome measures	Day 28	Mean Change; absolute, %	Day 28	Mean Change; absolute, %	Day 28	Mean Change; absolute, %	Day 28	Mean Change; absolute,%
Zarit Carer burden	10.0 (1.41), 9-11 MD =0	1.5; 17.6%	8.75 (6.5), 0-15 MD = 0	0.75; 9.3%	5.00 (6.08),1-12 MD = 1	-2.25; -31%	3.75 (2.63), 0-6 MD = 0	0.25; 7.1%
Carer GSES	32.5 (3.54), 30-35 MD = 0	-0.5; 1.5%	31 (4.69), 25-36 MD = 0	-2.5; -7.5%	32.67 (4.62), 30-38 MD = 1	0.17; 0.5%	36.75 (2.06), 35-39 MD = 0	1.75; 5%

Mean (SD): range, MD = missing data, (n=) number of participants); mISWT = modified incremental shuttle walk test; NRS = numerical rating scale

Table 3 Illustrative quotes

Fan helps with recovery • *P18: "I don't know why I started cos I wasn't exerting me-self as such I don't know why I started sorta gasping and I thought right fan and after a few seconds back to normal"* • *P19: "I'll just sit…put the fan six to eight inches away from me face on an angle so if I want it to go up me nose as well I can...I find coupla minutes it does take the breathlessness down."* • *P24: "the recovery is quicker…it's fifty percent I believe the air is being pushed in and fifty percent I'm confident as to what's happening so I calm down quicker*."
Fan supports activity and exercise • *P9: "I can walk round when I take the fan…which I find very nice as I have never done it…this is a really big change…I can walk round [the shop]I can look at everything and I can read everything and it's wonderful"* • *P11: "I've been going a bit further just recently since I've had me fan thing"* • *P19: Got me fan in me pocket and I've got me inhaler in me pocket so that I know if I ever go anywhere I've got more, more bases covered now I've got me fan as well"* • *P24 "So you're hoping to go fishing again? A: "with me son next, next week, and it'll be the first time in three years… and that'll be [points to fan] going with me in me fishing bag"*
Fan is used like a medical device • *P10: "I carry it around with me and I'll use it you know because I feel a bit out of puff because it's between nebulisers, I can't take too many nebulisers so that acts as a prop in between."* • *P12: " I've been using the fan instead of Ventolin"* • *P17: "a little instrument or a tool you know…it's a functional thing, it is a bit of equipment, not an idea yeah? You feel, once it's switched on ….it is a physical thing , you can feel the effect of it"* • *P24: "Now I have the alternative, i.e. the fan, whereas I used to grab me inhaler and have two puffs, wait and hope something gets better; instead of that I get the fan…I'm not using my inhaler half as much as I did."*
Calming Hand is common sense and things already known • *P10: "What do you get with the Calming Hand?" A: "Nothing." Q: Nothing? A: "No the Calming Hand are things I do myself any how if I feel very breathless… so that's nothing really new."* • *P15: "The Calming Hand…how did you find that?" A: "Well, common sense, its common sense."* • *P17: "The Calming Hand, I didn't think it was really of much value…I think I could find a lot of better ways of calming me-self down."* • *P24: "I stopped doing the Calming Hand thing 'cos to me I don't need to do that to know there's a list to go through."*

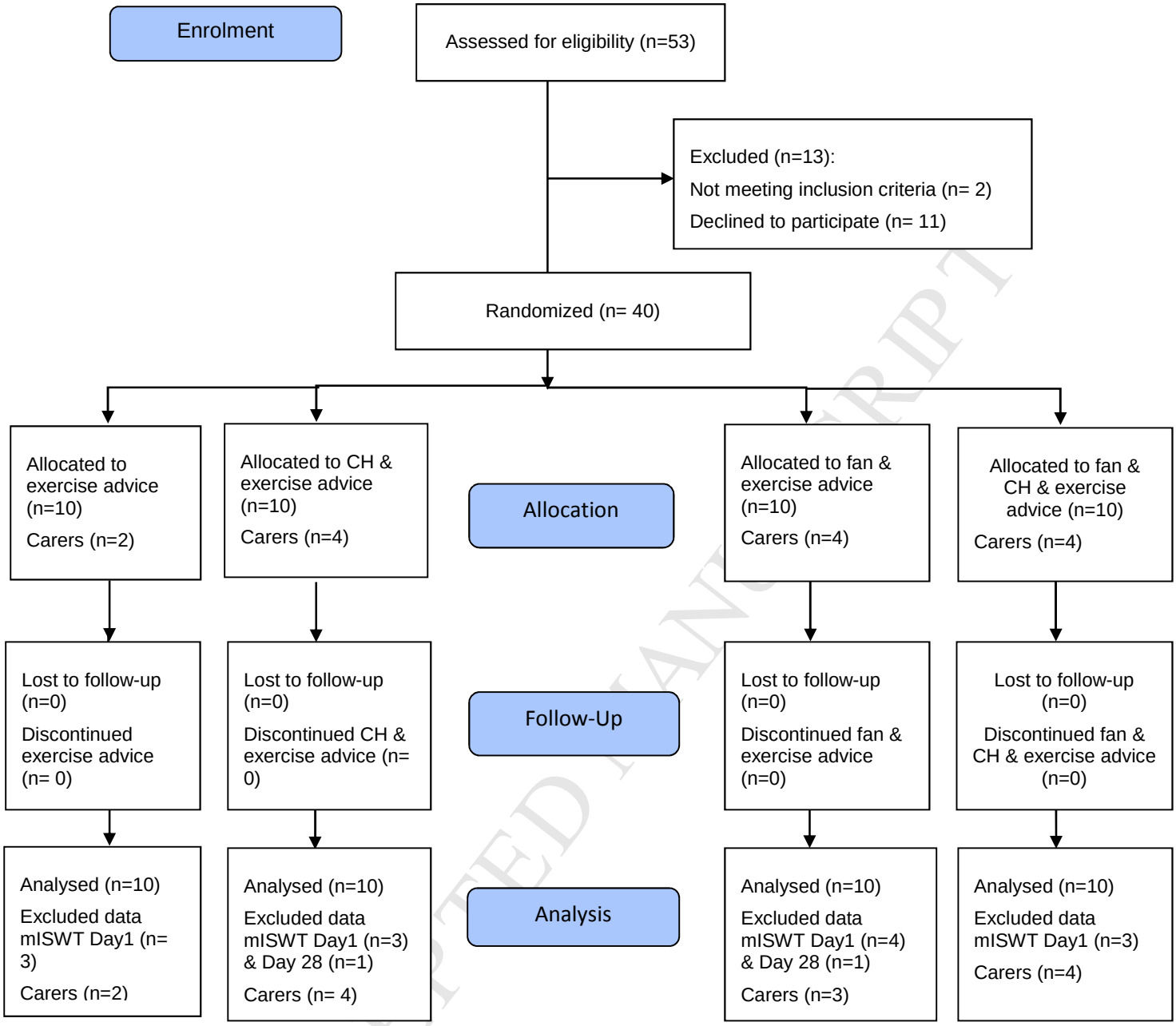
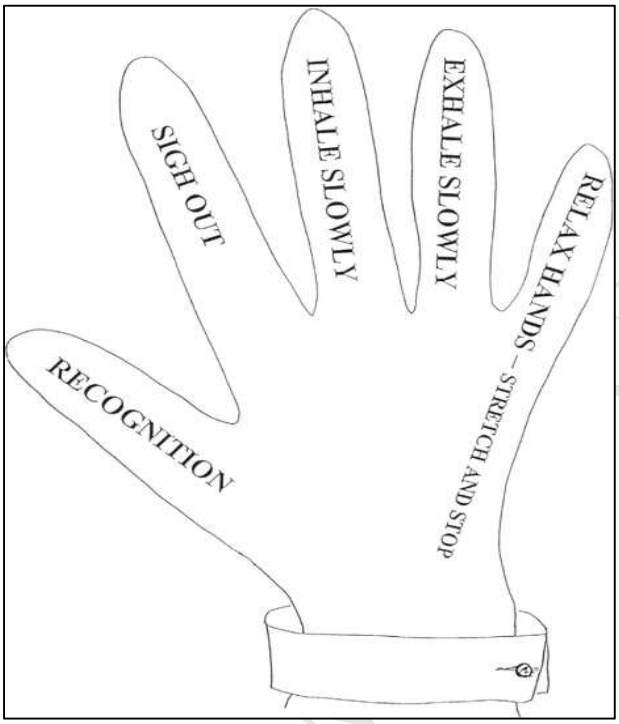


Figure 1 CONSORT Flow-diagram (31)

Online supplementary diagram

Calming Hand



Using the Calming Hand

1. Acceptance – Squeeze thumb and recognise that you are starting a breathless or panic attack.
2. Sigh out. Flop and Drop – relax shoulders
3. Breathe in and out slowly, gently and focus on the breath out.
4. Stretch hands fully and then let them go

You may need to repeat this several times before your breathing and anxiety start to