

Participant ID	
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Initials of person entering data	
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Staff email	
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CONFIDENTIAL CASE REPORT FORM

Handheld fans for breathlessness

Series 55

IMPACCT Trials Coordination Centre (ITCC)

UTS IMPACCT Rapid Program

The case report form (CRF) is to be completed in compliance with
ITCC Standard Operating Procedures (SOP)

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Baseline (T₀)**Date of Assessment**

DD/MM/YYYY

Demographics**Gender** (*please tick*) Male Female Non-binary Prefer not to say**Age (yrs)****Weight (kg)****Height (cm)****Tick** ✓**Likely primary driver/mechanism of breathlessness***Please tick one*

Advanced cancer

Neurodegenerative disease

Cardiac disease

Non-malignant respiratory disease

Other; Please specify: _____

Charlson Comorbidity Index - Does the patient have any of the following?*Please tick all that apply*

Tick ✓		Tick ✓	
	Myocardial Infarction (history, not ECG changes only)		Hemiplegia
	Congestive Cardiac Failure		Moderate or Severe Renal Disease
	Peripheral Vascular Disease (includes aortic aneurysm ≥ 6 cm)		Diabetes with End Organ Damage
	Cerebrovascular Disease (CVA with mild or no residual or TIA)		Any Tumour without metastasis (exclude if >5 yr from diagnosis)
	Dementia		Leukaemia (acute or chronic)
	Chronic Pulmonary Disease		Lymphoma
	Connective Tissue Disease		Moderate or Severe Liver Disease
	Peptic Ulcer Disease		Metastatic Solid Tumour
	Mild Liver Disease (without portal hypertension, includes chronic hepatitis)		AIDS (not just HIV positive)
	Diabetes (without organ damage) (excludes diet-controlled alone)		

Tick ✓**Australian Modified Karnofsky Performance Scale (AKPS)**

100 - Normal; no complaints; no evidence of disease

90 - Able to carry on normal activity; minor sign of symptoms of disease

80 - Normal activity with effort; some signs or symptoms of disease

70 - Cares for self; unable to carry on normal activity or to do active work

	60 - Requires occasional assistance but is able to care for most needs
	50 - Requires considerable assistance and frequent medical care
	40 - In bed more than 50% of the time
	30 - Almost completely bedfast
	20 - Totally bedfast and requiring extensive nursing care by professionals and/or family
	10 - Comatose or barely rousable
	0 - Dead
	Not able to determine

Tick ✓	Palliative Care Phase
	1. Stable Phase: The person's symptoms are adequately controlled by established management. Further interventions to maintain symptom control and quality of life have been planned.
	2. Unstable Phase: The person experiences the development of a new problem or a rapid increase in the severity of existing problems either of which requires an urgent change in management or emergency treatment.
	3. Deteriorating Phase: The person experiences a gradual worsening of existing symptoms or the development of new but expected problems. These require the application of specific plans of care and regular review but not urgent or emergency treatment.
	4. Terminal Care Phase: Death is likely in a matter of days and no acute intervention is planned or required.

Tick ✓ (Optional)	Breathlessness duration (ICD 11.5)
	<i>Acute (up to 3 weeks)</i>
	<i>Sub-acute (3 – 8 weeks)</i>
	<i>Chronic (more than 8 weeks)</i>
	<i>Comment:</i>

Symptom Severity Scores *Please grade each symptom; indicate that each has been assessed by ticking the square box above each.*

Breathlessness

1 2 3 4 Ungradable No Symptom

modified Medical Research Council (mMRC) breathlessness scale

- 0. Breathlessness only with strenuous exercise
- 1. Breathlessness when hurrying or walking up a slight hill
- 2. Walks slower than people of the same age because of breathlessness or has to stop for breath when walking at own pace
- 3. Stops for breath after walking 100m or after a few minutes
- 4. Too breathless to leave house or breathless when dressing or undressing

Anxiety

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

- 1: Mild symptoms; intervention not indicated
- 2: Moderate symptoms; limiting instrumental ADL
- 3: Severe symptoms; limiting self-care ADL; hospitalization not indicated
- 4: Life-threatening; hospitalization indicated

5: Death

Fatigue

1 2 3 Ungradable No Symptom

NCI Criteria

1. Fatigue relieved by rest
2. Fatigue not relieved by rest; limiting instrumental ADL
3. Fatigue not relieved by rest, limiting self-care ADL

Other symptom (*only if applicable – can be related or unrelated to the intervention*)

Please specify other symptom here _____

1 2 3 4 5 Ungradable

1. Mild
2. Moderate
3. Severe
4. Life-threatening
5. Death

Additional other symptom (*only if applicable – can be related or unrelated to the intervention*)

Please specify additional other symptom here _____

1 2 3 4 5 Ungradable

1. Mild
2. Moderate
3. Severe
4. Life-threatening
5. Death

Tick ✓	Which symptom is the <u>most</u> bothersome to the patient? (<i>Tick one only</i>)
	Breathlessness
	Anxiety
	Fatigue
	Other
	Additional other
	Not applicable

Tick ✓	What other pharmacological treatments (if any) does this person use for breathlessness? <i>Tick all that apply</i>
	Short-acting inhaler
	Benzodiazepine
	Oxygen therapy
	Low-dose opioid
	None
	Other; please specify:

Tick ✓	What other non-pharmacological strategies (if any) does this person use for breathlessness? <i>Tick all that apply</i>
	Breathing techniques

	Relaxation
	Positioning
	None
	Other; please specify:

What is the patient's respiratory rate (breaths/min)	
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Fan education

Which disciplines and specialties were involved in training the patient in using the fan? (tick all that apply)
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Tick ✓	Discipline
	Medical
	Nursing
	Physiotherapy
	Occupational therapy
	Other; please specify:

Has a hand-held fan been provided to the patient?
<input type="radio"/> Yes <input type="radio"/> No, they will self-source

Was training given to the patient to help them use the fan?
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Tick ✓	Type of training (tick all that apply)
	None
	Verbal
	Written
	Video
	Other:

T₁ – Fan used in initial consultation under clinical supervision

Please complete if you used the fan during or immediately after your baseline consultation.
If not, please tick 'not applicable' and continue to T₂

Tick ✓	T₁: Assessed/Not assessed reason
	Assessed today (continue to complete T ₁) OR
	Not applicable

How was the fan trialed during consultation?

Tick ✓	Level of exertion (<i>tick one</i>)
	While sitting or lying down, with no exertion
	With minimal exertion (e.g. eating or talking)
	When sitting to stand
	When walking a few steps
Tick ✓	(If related to exertion) Timing of fan use (<i>tick all that apply</i>)
	Before exertion
	During exertion
	After exertion

Based on your assessment at this time, rate any change on the following.

Variables	Impression of change
Recovery time	Improved / no change / worse
Breathlessness severity	Improved / no change / worse
Breathlessness distress / bother / unpleasantness	Improved / no change / worse
Other; please specify:	Improved / no change / worse

Based on the T₁ assessment, is the decision to continue fan therapy in the community?

- Yes - please complete T₂ at next consultation
 No – please describe below, then end CRF

Tick ✓	If no, please specify reason
	Ineffective
	Adverse effects; please specify:

	Other; please specify:

T₂ – next consultation within 3 month window	
Date of T₂ Assessment	DD/MM/YYYY
Not assessable within 3 months*	Tick here

****End survey here***

Has the patient used the fan since the previous CRF?	
<input type="radio"/> Yes – please move to the next question <input type="radio"/> No – please complete this table and then end CRF	
Tick ✓	Reason the fan wasn't used
	Wasn't given a fan at baseline and hasn't sourced one since
	Hasn't been breathless enough to need any intervention
	Was breathless but controlled through other means
	Other; please specify:

Tick ✓	Fan type (tick as many as apply)
	Hand-held
	Pedestal
	Other

Tick ✓	Australian Modified Karnofsky Performance Scale (AKPS)
	100 - Normal; no complaints; no evidence of disease
	90 - Able to carry on normal activity; minor sign of symptoms of disease
	80 - Normal activity with effort; some signs or symptoms of disease
	70 - Cares for self; unable to carry on normal activity or to do active work
	60 - Requires occasional assistance but is able to care for most needs
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	40 - In bed more than 50% of the time
	30 - Almost completely bedfast
	20 - Totally bedfast and requiring extensive nursing care by professionals and/or family
	10 - Comatose or barely rousable
	0 - Dead
	Not able to determine

Symptom Severity Scores

Please grade both symptoms; indicate that each harm has been assessed by ticking the square box above each.

Breathlessness

1 2 3 4 ungradable no symptom

modified Medical Research Council (mMRC) breathlessness scale

0. Breathlessness only with strenuous exercise
1. Breathlessness when hurrying or walking up a slight hill
2. Walks slower than people of the same age because of breathlessness or has to stop for breath when walking at own pace
3. Stops for breath after walking 100 yards or after a few minutes
4. Too breathless to leave house or breathless when dressing or undressing

Anxiety

1 2 3 4 5 ungradable no symptom

NCI Criteria

- 1: Mild symptoms; intervention not indicated
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- 4: Life-threatening; hospitalization indicated
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Fatigue

1 2 3 Ungradable No Symptom

NCI Criteria

1. Fatigue relieved by rest
2. Fatigue not relieved by rest; limiting instrumental ADL
3. Fatigue not relieved by rest, limiting self-care ADL

Other symptom *(only if applicable – can be related or unrelated to the intervention)*

Please specify other symptom here _____

1 2 3 4 5 Ungradable

1. Mild
2. Moderate
3. Severe
4. Life-threatening
5. Death

Additional other symptom *(only if applicable – can be related or unrelated to the intervention)*

Please specify additional other symptom here _____

1 2 3 4 5 Ungradable

1. Mild
2. Moderate
3. Severe
4. Life-threatening
5. Death

Tick ✓	Which symptom is the most bothersome to the patient? <i>(Tick one only)</i>
	Breathlessness

	Anxiety
	Fatigue
	Other
	Additional other
	Not applicable

What is the patient's respiratory rate (breaths/min)	
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Based on your assessment at this time, rate any change on the following.	
Variables	Impression of change
Recovery time	Improved / no change / worse
Breathlessness severity	Improved / no change / worse
Breathlessness distress / bother / unpleasantness	Improved / no change / worse
Activities of daily living (including community engagement)*	Improved / no change / worse
Other; please specify	Improved / no change / worse

Change in pharmacological breathlessness management since previous timepoint (if any)	
Pharmacological Strategies	
Use of inhaler	Reduced / no change / increased / not applicable
Use of benzodiazepines	Reduced / no change / increased / not applicable
Use of oxygen	Reduced / no change / increased / not applicable
Use of opioids	Reduced / no change / increased / not applicable
Other (please specify):	Reduced / no change / increased / not applicable

Were there any problems with the fan?		
<input type="radio"/> Yes – please complete this table <input type="radio"/> No – end CRF		
Tick ✓	Problems	Ceased use as a result?
	Unpleasant sensation – coldness	Yes / No
	Unpleasant sensation - airflow	Yes / No
	Felt self-conscious using the fan in public	Yes / No
	Fan caught in hair or beard	Yes / No
	Technical issues with fan	Yes / No
	Unable to use independently (e.g. too unwell)	Yes / No
	Other; please specify:	Yes / No