UTS IMPACCT Trials Coordination Centre

# Series Manual

# Handheld Fans for Breathlessness– Series 55

**Background**

Clinical trials suggest that hand-held fans can improve breathlessness-related outcomes, but evidence varies between measures and patient populations. There is limited guidance for patients and clinicians on how to use hand-held fans optimally, especially in relation to other strategies for breathlessness management. It therefore seems likely that practice varies between services and clinicians, with unknown implications for effectiveness.

The Rapid series seeks to understand clinician practices regarding hand-held fans and their perceived benefits and adverse effects in everyday clinical settings.

## Patient tracking

A log or spreadsheet should be developed in order to track the patient medical record number and the study ID number allocated to each patient when commenced on an intervention. This spreadsheet will be the only link between the data collected and the identity of the patient and remains the property of the participating site. This information should not be shared with the IMPACCT Trials Coordination Centre (ITCC). The spreadsheet should also contain the date and time of the data entry at each time point.

| Participant ID number | Patient name | Patient medical record number | Date of initial data entry | Time of data entry |
|---|---|---|---|---|
| | | | | |

**Allocating a Participant ID (PID) number**

The PID for each set of data collected is a composite number built up using a series of three codes.

**i) Site identifier**

This is the number allocated to each participating site as a 2- or 3-digit number.

**ii) Medication number**

The medication number for the Fans for Breathlessness series is **55.**

**iii) Participant number**

This is a three-digit number starting with the first participant from 001, followed by 002, 003, and so on.

Therefore, the full patient ID number will be; ***Site identifier/medication number/patient number***

e.g., For site 01, it would look like 01/55/ 001, 01/55/002, 01/55/003… and so on.

**Time points**

There are 2 main time points, and 1 optional time point where data is required.

1. Commencement of the intervention (baseline) – ($T_0$)
2. If fan is used in initial consultation under clinical supervision – ($T_1$). This time point is optional.
3. Next consultation within 3 months post baseline – ($T_2$)

**Other data collection points are:**

1. Cessation of study
    - Not assessable within 3 months: If the participant is not assessed within 3 months, then at the T2 assessment, please note the date, tick the box, and end survey.
    - If the participant has not used a fan since the previous assessment: Please tick the reason, and end survey.

Each intervention of interest will have different time points for clinical benefit and adverse events according to its profile. Time points are determined by each Series subcommittee and are based on clinical experience and published product information.

**Adverse event assessment**

Adverse events (or harms) are assessed using a standard scale from the National Cancer Institute Criteria for Adverse Events (NCI CTCAE). The NCI uses a scale between 1 and 5 ranging from mild to serious (resulting in death) symptoms or sequelae. The NCI criteria are provided as a reference document which is supplied separately and should be referred to for any events recorded is association with the patient's clinical course.

Each intervention has a number of pre-populated expected adverse events (harms). These are listed at each time point, and the NCI grade is described and provided for easy reference. A grade should be provided for each listed adverse event.

**Data entry**

The REDCap data entry link can be acquired by emailing **rapid@uts.edu.au** and requesting the link to the series that is applicable to you.