



iRehab TRIAL

Remote multicomponent rehabilitation compared to standard care for survivors of critical illness after hospital discharge: a randomised controlled assessor-blind clinical and cost-effectiveness trial with internal pilot

CRF COMPLETION GUIDELINES

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General Instructions for CRF Completion

DATES

- All dates should be recorded in the format DD-MMM-YYYY format e.g. 01-OCT-2022

TIMES

- Enter all times in the 24-hour format e.g. 14:15

UNITS

- When entering numerical values, ensure the correct unit is used.
- Where available, enter numerical values to two decimal places. If decimal values are required but not known, enter 0 e.g. 92.00 kg.

GENERAL

- Tick 'Yes' or 'No' where applicable. Do not leave any Yes/No questions blank.
- All CRFs must be completed, signed and dated by an appropriately trained member of staff who is listed on the Site Signature and Delegation Log with the relevant trial responsibilities.

General Instructions for Remote Data Entry

- To navigate to a particular participant, type the participant trial number in the 'Search by TNO' field and press enter.
- Scheduled Events include the screening form, contact details form, registrations consent form and the comorbidities form
- Unscheduled Events include the discontinued treatment form, readmission form, protocol deviation and file note form, AE form, SAE form, withdrawal form and notification of death form.
- At the end of some forms on the RDE system there is a 'Form Completion' section which must be completed before saving the form. Here, the individual who completed the form should select their name from the drop-down list, enter the date signed and complete 'Form Status' to categorise the information within the form. Once data is entered into the form, one of three statuses must be selected:
 - If the form has been completed, all of the fields have been entered and there is no outstanding data, mark the form as 'Clean'.
 - If the form has been completed but some data is unattainable, mark the fields as unobtainable (using the three dots to the right of the data field)
 - If trial office identify any information in a CRF that they would like to query, the form will be marked with 'Data Query'.

FORM COMPLETION	
Form completed by	<input type="text"/>
Date signed	<input type="text"/>
Form status	<input type="text"/>

Save Cancel

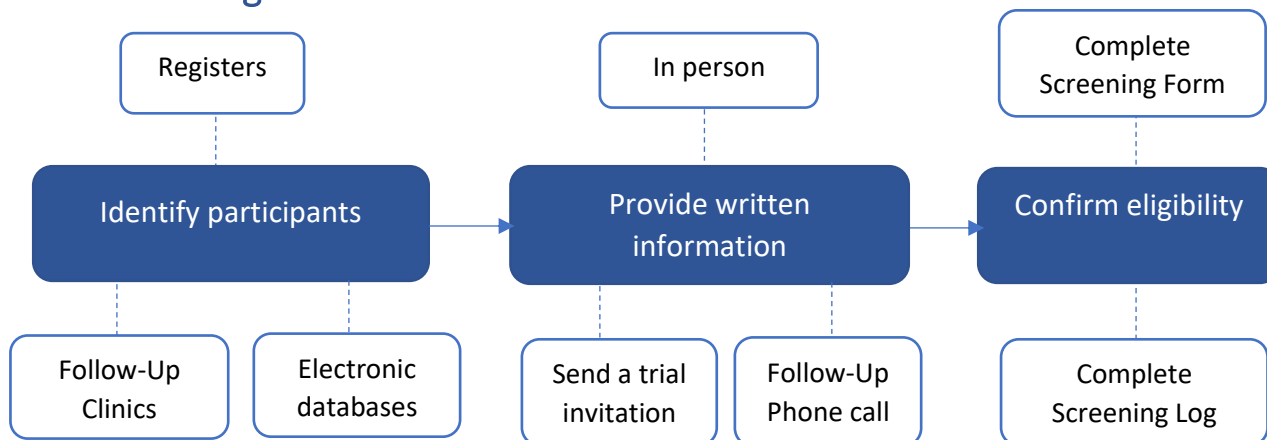
General Instructions for Paper CRF Completion

When completing a paper CRF:

- Record participant trial number, participant initials and randomising site
- Use a **black ball point** pen
- Complete the *Initial Serious Adverse Events, Follow Up Serious Adverse Events and Serious Adverse Events Continuation Form* by paper only.

SCHEDULED EVENTS (Mandatory)

1. Screening Form



A patient pre-screening log has been provided to assist in screening and documenting patients who have received > 48 hours of mechanical invasive ventilation and are ≥ 18 years of age. All patients who are pre-screened and reach criteria are to be added to the screening form (e-CRF) to continue assessing eligibility and screening the patient.

The *Screening form* (e-CRF), also known as onboarding acts as a checklist to confirm eligibility and should be completed prior to consent.

- The *Screening Form* should be completed on the iRehab database system
- Participant trial numbers will be automatically generated on the database system

1a. Screening Details

- If not automatic, select the appropriate recruitment type from the drop-down menu
- The following formats should be used for all dates: 06-Jun-1956

SCREENING DETAILS	
Recruitment type?:	Computer
Date of screening:	12-Sep-2022

- Please select one option from the drop-down list for ethnicity. If the applicable category is absent, select 'Other' and briefly specify using free text entry.
- Confirm eligibility by selecting 'Yes' or 'No' from the drop-down menu
- Participant trial numbers will be automatically generated on the database system
- Select the reason from the drop-down menu for ineligibility. If the applicable category is absent, select 'Other' and briefly specify using free text entry.

1b. Participant Eligibility checklist

Inclusion criteria

1. Aged ≥ 18 years
2. Received invasive mechanical ventilation for 48 hours or longer
3. Are within 12 weeks following discharge home from hospital at time of consent
4. Understands spoken English or has family member/friend/other present to translate trial materials
5. Able to participate in the intervention and with trial procedures (e.g. using equipment such as telephone)

Exclusion criteria

1. Declined consent or unable to provide consent.
 2. Previous randomisation into the present trial.
 3. Participating in another rehabilitation or self-management support trial
 4. Contra-indication to exercise
 5. Severe mental health problems that preclude participation in a group intervention
 6. Discharged to a rehabilitation unit, or care home with/without nursing care
 7. Prisoners
- In order for the patient to be eligible 1) all answers in the inclusion criteria must be yes and 2) all answers in the exclusion criteria must be no.
 - Confirm if the patient was approached by selecting 'Yes' or 'No' from the drop-down menu. If no is selected, provide the reason for non-approach in the free text option. If yes is selected, you will be asked to provide a series of dates:

Date written information given/sent to patient:	<input type="text"/>	example: 21-DEC-1980
Date trial discussed with patient once patient has had time to consider the trial:	<input type="text"/>	example: 21-DEC-1980
Initials of staff member who discussed the trial with the patient:	<input type="text"/>	
Date invited to join trial:	<input type="text"/>	example: 21-DEC-1980

- Date written information given/sent to patient: refers to the date PIL given/sent
 - Date trial discussed with patient once patient has had time to consider the trial: this refers to when you have contacted the patient after initial approach to discuss the trial
 - Date invited to join trial: this refers to a formal invitation to join the trial after consideration
- Confirm if the patient wants to take part in iRehab by selecting 'Yes' or 'No' from the drop-down menu. If no is selected, provide the reason for the participant not wanting to take part
 - Continue through drop down menus

2. Contact Details Form

2a. Contact Details

- Write the participants first/given name and surname/family name in the relevant field
- The following formats should be used for all dates: 06-Jun-1956
- The patient's NHS and hospital number should be entered in the relevant field
- Select appropriate response from the drop-down menu to provide details regarding the patient access method (e.g. email, telephone). **NOTE: COMPLETE ASSOCIATED ACCESS CONTACT DETAILS AS APPROPRIATE. The database automatically validates responses based on your selection**

2b. Address Details

- Confirm the participants address so they can receive study materials, enter address details into the relevant fields

2c. GP Details

- Confirm the participants GP details, enter address details and contact details into the relevant fields

2d. Next of Kin Details

- Confirm the participants next of kin details, enter address details and contact details into the relevant fields

3. Registration Consent Form

The registration consent form is a confirmation CRF to ensure consent has been taken. To be completed after participant consent, using the online case report form *consent form and comorbidities form*.

- Select 'Yes' or 'No' from the drop-down menu to confirm the participant has signed the consent form.
- Provide the version number of the consent form used into the relevant fields
- The following formats should be used for all dates: 06-Jun-1956
- Select 'Yes' or 'No' from the drop-down menu to confirm the method of consent and if the participant has consented to an interview. Non-participation in the interview elements does not affect participation in the main trial

3a. Section B: Participant Details

- Please select one option from the drop-down list for gender

- Please record by selecting 'Yes' or 'No' from the drop-down menu if a translator was required. If 'Yes', using the free text entry box enter the language
- The hospital the patient was discharged from, and their consultants name should be entered into the relevant fields
- Provide the dates/times surrounding the patients stay in intensive care unit and hospital. Please use the following formats for time: 13:45 (24-hour clock)
- Please select one option from the drop-down list for the primary ICU admission diagnosis. If the applicable category is absent, select 'Other' and briefly specify using free text entry
- The intensive care national audit and research centre number should be entered into the relevant fields
- If the participant is co-enrolled in other trials that have agreed co-enrolment with iRehab, please select 'Yes' and provide the name(s) of the trials using free text entry.
- If the patient is co-enrolled in more than one clinical trial, enter each trial name separately followed by a full stop.
- Select 'Yes' or 'No' from the drop-down menu to provide details regarding patient self-referral. **NOTE: At this time, no patients will be self-referred, please select no for this option.**
- The patient's acute physiology and chronic health evaluation score should be entered into the relevant fields

4. Comorbidities Form

- Please indicate any comorbidities that are currently present (yes)/absent (no)

CO-MORBIDITIES DETAILS	
Co-morbidities: Arthritis (rheumatoid and osteoarthritis):	NO this comorbidity is absent
Co-morbidities: Osteoporosis:	YES this comorbidity is present NO this comorbidity is absent

NOTE: ALL THREE FORMS (REGISTRATION CONSENT FORM, CONTACT DETAILS AND COMORBIDITIES FORM MUST BE 100% COMPLETE OTHERWISE THE PARTICIPANT WILL NOT PROGRESS THROUGH THE TRIAL.

UNSCHEDULED EVENTS (Ad-hoc)

5. Readmission Form

This form must be completed for an unscheduled hospital readmission. Readmission are defined by your local classification of a readmission

5a. Unscheduled Hospital Readmission

- The following formats should be used for all dates: 06-Jun-1956
- Select where the participant was readmitted from using the drop-down menu. If the applicable location is not specified, select 'Other' and briefly specify using free text entry.
- Please indicate the number of days spent in the type of location

6. Protocol Deviation Form

This form should be used to record any protocol deviation/ non-compliance, any protocol violations or potentially a serious breach

Date of event

- Specify the date the event took place using the format DD-MMM-YYYY

Details of the event

- Specify details of the event using free text entry. Provide as much detail as possible including, where applicable, why an event took place, corrective actions and any preventative measures which have been put in place to prevent similar events in future

7. File Note Form

On the database this form is the same as the protocol deviation form

Date of event

- Specify the date the event took place using the format DD-MMM-YYYY

Details of the event

- Provide details of the event used to clarify an. error, omission or discrepancy or to document a problem or corrective action

8. Adverse Events

An Adverse Event (AE) is defined as any untoward medical occurrence in a participant participating in a clinical trial and which does not necessarily have a causal relationship with the treatment/intervention.

Events exempt from recording as AE, but must be reported as per timepoint below

Breathlessness

Light headedness/dizziness

Muscle stiffness/soreness

Tiredness/fatigue

Oxygen desaturation (that resolves with appropriate management e.g. rest, breathing exercises, inhaled medications)

Timepoint:

During the assessment timepoint record on the participants outcome assessment notes

During the intervention record on the participants notes

- Report all AEs, except those listed above in the appropriate *Adverse Event e-CRF*.
- The recording of AEs and the seriousness assessment should be conducted by the person identifying the AE.
- Please ensure you give comprehensive details of the AE in the free text box.

9. Initial Serious Adverse Event

A Serious Adverse Event is an AE that fulfils one or more of the following criteria:

- Results in death
- Is immediately life-threatening
- Requires hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability or incapacity
- Is a congenital abnormality or birth defect
- Is an important medical condition or Immediate intervention was required to prevent one of the above

Events Exempt from reporting:

- Hospitalisation, or death, for pre-existing conditions e.g. respiratory exacerbation and infection, or a complication related to the initial ICU admission
- Treatment, which was elective or pre-planned, for a pre-existing condition, not associated with any deterioration in condition
- General care, not associated with any deterioration in condition

SAEs should be reported **within 24 hours** of the research staff becoming aware of the event.

- Please send a scanned copy of the dedicated SAE Form to the WCTU trial team (irehab@warwick.ac.uk) and the WCTU QA Team (wctuqa@warwick.ac.uk).
- This form should be signed off by both the reporting clinician and the individual responsible for completing the *SAE Form*. Both individuals must be present on the site signatures and delegation log.

9a. Event Type

- Tick 'Yes' for each applicable category and 'No' for all remaining options. If 'Other reason' has been ticked, specify using free text entry.

9b. Event Details

- Specify relevant details of the event using free text entry.
- Specify relevant details of medical history, concomitant medication and associated dates of administration using free text entry.
- If necessary, a *SAE Continuation Form* should be completed to capture additional information. These forms should be signed and dated by the same reporting clinician and the same individual responsible for completing the *SAE Form*.

9c. Severity Assessment

- Only one option should be indicated for Severity Assessment.

9d. Causality

Only one option should be indicated for causality.

- The treating clinician MUST initial this section to confirm their opinion.
- If 'Definitely', 'Probably' or 'Possibly' are ticked, Section E should be completed.
- If 'Unlikely' or 'Unrelated' are completed, Section E should be skipped.

Relationship to trial intervention	Description
Unrelated	There is no evidence of any causal relationship
Unlikely to be related	There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the trial intervention e.g. within 48 hours). There is another reasonable explanation for the event (e.g. the participant's clinical condition, other concomitant treatment).
Possible relationship	There is some evidence to suggest a causal relationship (e.g. because the event occurs within a reasonable time after administration of the trial intervention). However,

	the influence of other factors may have contributed to the event (e.g. the participant's clinical condition, other concomitant treatments).
Probable relationship	There is evidence to suggest a causal relationship and the influence of other factors is unlikely.
Definitely related	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.

9e. Outcome of Event

Only one option should be ticked for outcome.

- If **1.** is ticked, a resolution date should be provided.
- If **2.** is ticked, details of the sequelae and a resolution date should be provided.
- If **3.** is ticked, *the SAE Follow-up Form* should be completed at a later date.
- If **4.** is ticked, a *Notification of Death Form* should be completed.
- If **5.** is ticked, a *Notification of Death Form and withdrawal form* should be completed

10. Serious Adverse Event Continuation Form

- This CRF should be signed off by the same reporting clinician and the same individual responsible for completing the corresponding initial or follow-up *SAE form*.
- This form should always be completed as a paper CRF.

10a. This Report Relates to the Adverse Event Deemed Serious On

- The date entered here must match the date provided on the initial report
- Tick to confirm whether the continuation form is linked to the Initial Report or a Follow-up Report
- The *SAE form* section number should be completed to show which section the information relates to
- Additional information should be completed using free text entry.

11. Serious Adverse Event Follow Up Form

This form should be completed when further information comes to light regarding the initial SAE, when the SAE is resolved or to provide an update following queries from Warwick CTU.

- This form should be signed off by both the reporting clinician and the individual responsible for completing the *SAE form*. Both individuals must be present on the site signatures and delegation log. These individuals may not necessarily be the same as those who signed off the *Initial Serious Adverse Event Form*.
- Please send a scanned copy of the dedicated SAE Form to the WCTU trial team (irehab@warwick.ac.uk) and the WCTU QA Team (wctuqa@warwick.ac.uk).

11a. This Report Relates to the Adverse Event Deemed Serious On

- The date entered here must match the date provided on the initial report

11b. Severity Assessment

Only one option should be indicated for Severity Assessment.

11c. Further Details of Event

- Relevant further details of the event should be entered using free text entry.
- If necessary, a *SAE Continuation Form* should be completed to capture additional information. These forms should be signed and dated by the same reporting clinician and the same individual responsible for completing the SAE form.

11d. Causality

Only one option should be indicated for causality.

- The treating clinician **MUST** initial this section to confirm their opinion.
- If 'Definitely', 'Probably' or 'Possibly' are ticked, Section E should be completed.
- If 'Unlikely' or 'Unrelated' are completed, Section E should be skipped.

Relationship to trial intervention	Description
Unrelated	There is no evidence of any causal relationship
Unlikely to be related	There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the trial intervention e.g. within 48 hours). There is another reasonable explanation for the event (e.g. the participant's clinical condition, other concomitant treatment).

Possible relationship	There is some evidence to suggest a causal relationship (e.g. because the event occurs within a reasonable time after administration of the trial intervention). However, the influence of other factors may have contributed to the event (e.g. the participant’s clinical condition, other concomitant treatments).
Probable relationship	There is evidence to suggest a causal relationship and the influence of other factors is unlikely.
Definitely related	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.

11e. Outcome of Event

Only one option should be ticked for outcome.

- If **1.** is ticked, a resolution date should be provided.
- If **2.** is ticked, details of the sequelae and a resolution date should be provided.
- If **3.** is ticked, *the SAE Follow-up Form* should be completed at a later date.
- If **4.** is ticked, a *Notification of Death Form* should be completed.
- If **5.** is ticked, a *Notification of Death Form and withdrawal form* should be completed

12. Discontinued Treatment Form

This form must be completed if a participant/ practitioner decides to discontinue the participant from the intervention only. The intervention team will most likely be completing this e-CRF, however there may be instances where it is appropriate for the trial site team to complete this e-CRF.

DISCONTINUED TREATMENT DETAILS	
Has the participant discontinued trial treatment?:	Yes <input type="button" value="v"/>
Date of discontinuation:	<input type="text"/> example: 21-DEC-1980
Level of discontinuation:	<input type="button" value="v"/>
Reason for discontinuation:	<ul style="list-style-type: none"> Discontinued from exercise classes Discontinued from one-to-ones Discontinued from iRehab cafe <li style="background-color: #cccccc;">Discontinued from all trial intervention

12a. Has the Participant Discontinued Trial Treatment

- Select 'Yes' or 'No' from the drop-down menu to provide details regarding whether the participant has discontinued from the intervention. **NOTE: Discontinuation from all trial intervention does not mean the participant is automatically withdrawn from the trial.**

12b. Discontinuation Treatment Details

- The following formats should be used for all dates: 06-Jun-1956
- From the drop-down menu indicate the participants level of discontinuation and reason for discontinuation. If the response is the withdrawal was a practitioner decision, provide further information into the relevant fields. If the applicable response is not specified, select 'Other' and briefly specify using free text entry.

13. Withdrawal Form

This form must be completed if a participant has their consent withdrawn from all future trial involvement.

13a. Date of Participant Withdrawal

- The following formats should be used for all dates: 06-Jun-1956.

13b. Withdrawal details

- Please select the level of withdrawal from the drop-down menu.
- Please select the main reason for participant withdrawal from the drop-down menu. If the applicable reason is not listed, select 'Other' and briefly specify using free text entry. **PLEASE NOTE: Death is not to be listed on the Withdrawal Form as a reason for withdrawal. There is a separate Notification of Death Form.**
- If the practitioner decision is the main reason for withdrawal and they have offered information as to why, record this information as free text entry. If not, leave this blank and mark as unattainable.

14. Notification of Death Form

- Specify the date of death using the format: 06-Jun-1956
- Select if the primary cause of death was known from using the drop-down menu. If known, specify the main reason using free text entry.
- All deaths should be reported within **24 hours** of a staff member becoming aware of the event via e-CRF.