Research Protocol

**(GREATER THAN LOW RISK (GTLR) / NON-CLINICAL TRIAL)**

Protocol Title: PILOT STUDY INVESTIGATING THE EFFECTS OF AN EXERCISE VIDEO ON PHYSICAL ACTIVITY AND PATIENT SELF-EFFICACY WITH UNSUPERVISED HOME EXERCISE IN THE MAINTENANCE PHASE AFTER COMPLETION OF PULMONARY REHABILITATION

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| **Protocol Number** | X09-0289 |
| **Coordinating Principal Investigator** | Dr Tiffany Dwyer |
| **Signature:** | **Date:** 23/09/2024 |
|  |  |
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* Ms Megan Wong, Physiotherapy Honours Student, University of Sydney

Megan Wong is conducting the study to partially fulfil the requirements of Bachelor of Applied Sciences (Physiotherapy) (Honours) under the supervision of Tiffany Dwyer, Sonia Cheng and Marita Dale.  |
| **Sponsor**  | SLHD |

**Ethics Statement:**

The study will be conducted in accordance with the *National Statement on Ethical Conduct in Human Research* (2023) ([Link to National Statement)](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023) , the *CPMP/ICH Note for Guidance on Good Clinical Practice* ([Link to CPMP/ICH](https://www.tga.gov.au/publication/note-guidance-good-clinical-practice-july-2000) ) and consistent with the principles that have their origin in the Declaration of Helsinki. Compliance with these standards provides assurance that the rights, safety and well-being of study participants are respected.

**Protocol Version Control box**

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| **Protocol** **Version Number** | **Date**  | **Summary of Changes** |
| 1 | 04/09/2024 | NA |
| 2 | 23/09/2024 | Protocol number added; Sponsor changed to SLHD; Clarification on potential study risks; Clarification about interview recruitment, consent process, where conducted and how audio file data stored; Additional information on where data will be stored and analysed |
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# **1. BACKGROUND AND INTRODUCTION**

Pulmonary rehabilitation is a comprehensive intervention including exercise training, education, and behaviour change, designed to improve the physical and psychological condition of people with chronic lung conditions and promote long-term adherence to health-enhancing behaviours1. The benefits of pulmonary rehabilitation on improving exercise capacity, health-related quality of life, and dyspnoea in people living with chronic lung conditions are well-established, including people with COPD2, bronchiectasis3, and interstitial lung disease4.

Following completion of the pulmonary rehabilitation programme, these benefits begin to decline unless people with chronic lung conditions continue to exercise. Adherence to supervised maintenance programmes is reported to be as low as 50% at 12 months following pulmonary rehabilitation 5,6 and has been attributed to barriers such as exacerbations, anxiety, lack of social support, and difficulty accessing community exercise programmes7.

Unsupervised maintenance exercise may be more accessible and less costly than supervised maintenance exercise to promote continued exercise in the home and community. Phone calls, diaries, pedometers, and more recently technology such as mobile phone with self-monitoring and telerehabilitation, have been investigated been investigated as strategies to improve adherence to unsupervised maintenance exercise programmes8. In a recent international randomised controlled trial, unsupervised training at home using a treadmill was as effective as telerehabilitation for reducing hospital admissions and maintaining improvements in exercise capacity over two years in people with COPD9.

However, these type of maintenance programmes may not be suitable for people who have limited access to exercise equipment or who have low confidence and competence in using technology. Online exercise videos using minimal equipment may be a promising strategy for improving adherence to self-efficacy for exercise during the maintenance phase of pulmonary rehabilitation, but have not yet been tested in people with chronic lung conditions.

# **2. PARTNERING WITH CONSUMERS**

The online exercise video used in this study was developed in response to the needs and preferences of people living with chronic lung conditions attending during the COVID-19 pandemic, where the transition of many health services to telehealth necessitated the development of exercise programmes and resources that could be delivered remotely.

To continue to partner with consumers in this study, patient questions will be encouraged during study visits and participants will be invited to take part in user experience surveys and interviews to elicit and document their individual needs, preferences, and goals during the maintenance phase of pulmonary rehabilitation.

### **2.1 CULTURAL AND LINGUISTICALLY DIVERSE AND ABORIGINAL AND TORRES STRAIT ISLANDER PARTICIPANTS**

All participants meet all the inclusion criteria and none of the exclusion criteria will be invited to take part in this study, including participants from Cultural and Linguistically Diverse (CALD) and Aboriginal and Torres Strait Islander (ATSI) backgrounds. Resources and services provided by the SLHD, including the services of interpreters and Aboriginal Liaison Officers, will be sought where needed. This study does not aim to exclusively recruit participants from CALD and ATSI backgrounds.

# **3. STUDY AIMS/RESEARCH QUESTION/HYPOTHESIS**

The primary research question is:

* In the maintenance phase following completion of pulmonary rehabilitation, does an online exercise video increase physical activity and self-efficacy for exercise with unsupervised home exercise in people with chronic lung conditions?

The secondary research questions are:

* In the maintenance phase following completion of pulmonary rehabilitation, does an online exercise video maintain exercise capacity and quality of life in people with chronic lung conditions?
* in people with chronic lung conditions, what are their perspectives of using an online exercise video to pulmonary rehabilitation promote unsupervised home exercise in the maintenance phase following completion of pulmonary rehabilitation? Do perspectives vary with patient levels of self-efficacy for exercise and type of delivery of pulmonary rehabilitation?

# **4. STUDY DESIGN**

**DESIGN / STUDY TYPE**

This is a longitudinal observational pilot study.

**EXPECTED PARTICIPANT NUMBERS**

Approximately 26-28 participants are required to demonstrate a statistically significant improvement in step count of 1100 steps/day from completion of pulmonary rehabilitation to 6 months post completion of pulmonary rehabilitation, which is upper end of the minimally important difference for step count in people with COPD10. Approximately 26-28 participants are required to demonstrate a statistically significant improvement in step count of 1100 steps/day from completion of pulmonary rehabilitation to 6 months post completion of pulmonary rehabilitation, which is upper end of the minimally important difference for step count in people with COPD 10. Thirty-three participants will be recruited based on a 15% loss to follow up.

**TIME PERIOD OF THE STUDY**

|  |  |  |
| --- | --- | --- |
| **Task** | **Start Date** | **End Date**  |
| **Ethics Submission** | August 2024 | September 2024 |
| **Ethics Review and Approval** | September 2024 | October 2024 |
| **Site Authorisation** | October 2024 | November 2024 |
| **Advertising** | NA | NA |
| **Recruitment** | December 2024 | July 2025 |
| **Conduct study activities/data collection** | December 2024 | July 2025 |
| **Analysis of Data** | September 2024 | November 2025 |
| **Preparations of Reports** | September 2024 | November 2025 |
| **Publication Draft**  | September 2024 | November 2025 |
| **Submission of Publications and Final Reports** | September 2024 | July 2026 |

**ENDPOINTS**

**Primary endpoints:**

* Physical activity measured using a wearable device
* Self-Efficacy for Exercise Scale

**Secondary endpoints:**

* 6-minute walk test distance
* 5 sit-to-stand test
* 1-minute sit-to-stand test
* St George’s Respiratory Questionnaire
* COPD Assessment Test
* User experience survey of the online exercise video
* Qualitative interviews with participants

**SITES**

|  |  |
| --- | --- |
| ***Site Name/s and Location*** | Royal Prince Alfred Hospital |
| ***Site Contact/Investigator*** | Dr Tiffany DwyerProf Lissa SpencerMr Jack ReevesDr Sonia ChengDr Marita DaleMs Megan Wong |
| ***Public Health Organisation (PHO)*** |  **Yes** |
| ***Study Procedures*** | * Submission of the project for ethical and scientific review
* Communication with the HREC regarding project status, updates, and milestones
* Organisation and review of study documents and materials
* Review of participant eligibility
* Enrolment of study participants
* Administration of questionnaires and follow up with participants
* Coordination of participant scheduling, testing and other study procedures
* Collection, entry, and analysis of data
* Conduct interviews
* Provision of support to the research team in data collection and review processes
* Creation of organisational systems for data storage that allow research team members to access specific information subsets quickly
* Oversight of daily research practices and activities
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|  |  |
| --- | --- |
| ***Site Name/s and Location*** | Balmain Hospital |
| ***Site Contact/Investigator*** | Dr Tiffany DwyerMr Joshua BishopDr Sonia ChengDr Marita DaleMs Megan Wong |
| ***Public Health Organisation (PHO)*** |  **Yes** |
| ***Study Procedures*** | * Organisation of study documents and materials
* Review of participant eligibility
* Enrolment of study participants
* Administration of questionnaires and follow up with participants
* Coordination of participant scheduling, testing and other study procedures
* Collection, entry, and analysis of data
* Conduct interviews
 |

# **5. STUDY PARTICIPANTS**

**INCLUSION CRITERIA**

1. Adults with a chronic lung condition who are in their final two weeks of a pulmonary rehabilitation program
2. Clinically stable and appropriate for discharge from a pulmonary rehabilitation program at time of initial data collection (i.e., including no change in respiratory medications or worsening of respiratory symptoms in last 2 weeks)
3. Signed informed consent.

**EXCLUSION CRITERIA**

1. Unable to perform unsupervised and independent moderate intensity exercise (e.g., severe cognitive impairment, high falls risk, other comorbidities that would make remote exercise unsafe)
2. No internet access in their home (either via phone or computer), so unable to watch the online exercise video.

**STUDY LIMITATIONS**

This study will only recruit participants for whom it is safe and appropriate to perform unsupervised moderate intensity exercise in the home setting. Subsequently, the findings of this study will not be generalisable to all people with chronic lung conditions who are eligible to participate in a maintenance pulmonary rehabilitation program.

# **6. STUDY PROCEDURES**

## **METHODOLOGY**

**Final two weeks of pulmonary rehabilitation**

Participants are screened and recruited to the study during their final two weeks of pulmonary rehabilitation. The following demographic information will be collected from participants’ medical records: age; sex; height and weight; comorbidities; number of exacerbations in the previous 12 months; and lung function. This information is routinely collected on commencement of a pulmonary rehabilitation program.

Their physical activity levels over seven days during the pulmonary rehabilitation program will be measured using a wearable device. Participants will fill out a daily diary of their wake and sleep times over the seven days.

**Completion of pulmonary rehabilitation assessment**

Participants will return the wearable device and diary to the research team on attendance of their completion of pulmonary rehabilitation assessment.

At the completion of pulmonary rehabilitation assessment, the following questionnaires and exercise tests will be conducted: Self-Efficacy for Exercise Scale, 6-minute walk test, 5 sit-to-stand test, 1-minute sit-to-stand test, St George’s Respiratory Questionnaire, and COPD Assessment Test. All measures are routinely assessed at the commencement and completion of pulmonary rehabilitation.

Participants will be provided with another wearable device to measure their physical activity levels over seven days. Participants will fill out a daily diary of their wake and sleep times over the seven days. Participants will return the device and diary to the research team by post with a stamped and addressed envelope.

**Maintenance phase of pulmonary rehabilitation**

In the first week of the maintenance phase of pulmonary rehabilitation, participants will attend a telehealth appointment with a member of the research team. During this telehealth appointment, participants will watch an online exercise video and will be encouraged to exercise at home using the video with the supervision of a member of the research team. Any issues with accessing or using the video in the home environment will be troubleshooted. A member of the research team will explain how to access the online exercise video over the next six months and will encourage participants to use the online exercise video for independent exercise during the maintenance phase of pulmonary rehabilitation.

Participants will be sent weekly automated email reminders via REDCap to maintain their engagement with exercise during the maintenance phase of pulmonary rehabilitation. The emails will contain:

* A link to the online exercise video.
* A link to a REDCap survey, in which participants will report if they have completed any exercise sessions during the week, how many exercise sessions, for how many sessions they used the online exercise video, and any reasons for not engaging with exercise (e.g., unwell, travelling, not able to access the online exercise video).
* The contact details of the research team if participants have any questions or concerns.

One week prior to their in-person 6-month follow-up appointment, participants will be provided with another wearable device to measure their physical activity levels over seven days. Participants will fill out a daily diary of their wake and sleep times over the seven days. Participants will also complete the following questionnaires via a REDCap survey link: Self-Efficacy for Exercise Scale, St George’s Respiratory Questionnaire, COPD Assessment Test, and user experience survey to report the usability of the online exercise video.

**6 months post completion of pulmonary rehabilitation**

Participants will return the wearable device and diary to the research team on attendance of their 6-month post completion of pulmonary rehabilitation assessment.

At the 6-month post completion of pulmonary rehabilitation assessment, the following exercise tests will be conducted: 6-minute walk test, 5 sit-to-stand test, and 1-minute sit-to-stand test. Participants’ height and weight will also be measured.

All participants will be invited to complete a semi-structured open interview regarding their experiences with and perspectives of the online exercise video during the maintenance phase of pulmonary rehabilitation. Interviews will be conducted via Zoom or Microsoft Teams (as per participants’ preference) by staff who were not involved in the delivery of the pulmonary rehabilitation program and or in the telehealth session.

|  |  |  |  |
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| **Outcome measures taken** | **Enrolment Visit*****Final two weeks of pulmonary rehabilitation*** | **Visit 1*****Completion of pulmonary rehabilitation assessment*** | **Final Study Visit*****6 months post completion of pulmonary rehabilitation*** |
| **Inclusion/exclusion criteria** | ✓ |  |  |
| **Participant consent** | ✓ |  |  |
| **Physical activity measured using wearable device** | ✓ | ✓ | ✓ |
| **Physical activity wear diary** | ✓ | ✓ | ✓ |
| **Self-Efficacy for Exercise Scale**  |  | ✓ | ✓ |
| **6-minute walk test**  |  | ✓ | ✓ |
| **5 sit-to-stand test**  |  | ✓ | ✓ |
| **1-minute sit-to-stand test**  |  | ✓ | ✓ |
| **St George’s Respiratory Questionnaire** |  | ✓ | ✓ |
| **COPD Assessment Test** |  | ✓ | ✓ |
| **User experience survey of the online exercise video** |  |  | ✓ |
| **Interview** |  |  | ✓ |

**STUDY PROCEDURE RISKS AND BURDENS**

**Study procedure risks**

There is a slight possibility of an adverse reaction during the exercise testing, but it is extremely unlikely that any unforeseen cardiac events (e.g., myocardial infarct, arrhythmias, unstable blood pressure) would occur. The 6-minute walk test, 5 sit-to-stand stand, and 1-minute sit-to-stand test are regularly performed by people with chronic lung conditions. Heart rate and oxygen saturation will be monitored continuously during the 6-minute walk test, and all tests will be terminated if requested by the participant or if it is found to be unsafe.

There is a low risk of skin irritation or discomfort from wearing the wearable device continuously for seven days to measure physical activity levels. The activPAL will be worn on the anterior thigh and secured using a waterproof adhesive dressing. Participants will be advised on how to minimise skin irritation (i.e., remove any body hair prior to attaching the device; appropriate skin care to prevent water, sweat or soap being held against the skin under the device). If any skin irritation or discomfort occurs, participants will be provided with multiple adhesive dressings and will be advised to wear the device on alternate legs each day.

**Study procedure burdens**

Time taken to complete endpoints:

* Physical activity: 7 days on three occasions
* Sleep and wake time diary: 1 minute on three occasions
* Exercise tests, including rests: 15 minutes on three occasions
* Questionnaires (Self-Efficacy for Exercise Scale, St George’s Respiratory Questionnaire, and COPD Assessment Test): 15 minutes on three occasions
* User experience survey: 10 minutes on one occasion
* Interview: 30 minutes on one occasion

Time taken to engage with online exercise video:

* Telehealth appointment: 60 minutes on one occasion
* Exercise survey: 5 minutes on 24 occasions (weekly over six months)

**Costs**

There are costs associated with travel to the site for the final study visit at 6 months post completion of pulmonary rehabilitation. To access the online exercise video, participants will require internet access in their home via phone or computer. Participants will not be reimbursed for these costs.

There are no out-of-pocket costs to the participant for procedures performed as part of routine care.

**PARTICIPANT RECRUITMENT AND SCREENING**

**Who will be recruited and from where? (e.g., hospital patients, private room patients, private hospital patients, community members, etc)**Participants who are attending an outpatient pulmonary rehabilitation program at Royal Prince Alfred Hospital or Balmain Hospital who meet the following inclusion criteria will be recruited:

1. Adults with a chronic lung condition who are in their final two weeks of a pulmonary rehabilitation program
2. Clinically stable and appropriate for discharge from a pulmonary rehabilitation program at time of initial data collection (i.e., including no change in respiratory medications or worsening of respiratory symptoms in last 2 weeks)
3. Signed informed consent.

**How will participants be identified and recruited (if the study involves recruitment of patients, they should initially be approached by someone known to them from their treating team)?**

Eligible participants will be identified while they are participating in an outpatient pulmonary rehabilitation program and will be approached in person by their treating pulmonary rehabilitation therapist. As participants near completion of the program, it is part of routine care for the treating pulmonary rehabilitation therapist to discuss options for maintenance exercise with participants, including their suitability for remote exercise. During the recruitment process, potential participants will be informed about the optional interview after the six-month follow-up visit. If they wish to participate in the optional interview, they provide written, informed consent on the participant consent form when they first consent to participate in the study. The participant information sheet and consent form include information about the audio recording and transcription of the interview.

**Will existing databases be reviewed and by whom? (identify database(s) & custodian(s))**No databases will be reviewed as part of this study.

**Review of clinic files (who will review these files. Patient files and records should only be accessed by investigators who have authority to do so e.g. clinician on the patient’s treating team).**The treating pulmonary rehabilitation therapists will review patient files and records to extract relevant demographic information, including comorbidities and lung function. Other members of the research team may review this extracted information in order to provide participants with information about any changes in their health across the intervention period (i.e., from the start of the pulmonary rehabilitation program to completion of the pulmonary rehabilitation program to 6 months following completion of the pulmonary rehabilitation program).

**Advertisements with version number and date (please include where the advertisement will be placed for example, in a newspaper, poster in a clinic or hospital foyer, radio announcements, website etc.)**No advertisements will be used as part of this study. Eligible participants will be identified while they are participating in an outpatient pulmonary rehabilitation program and will be approached in person by their treating pulmonary rehabilitation therapist.

 **Add the statement: This study has been approved by the Human Research Ethics Committee (CRGH/RPAH Zone) of the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study should contact the Executive Officer on … and quote protocol number …**This statement has been added to the Participant Information Sheet.

 **For social media provide a** [**social medial plan**](https://www.slhd.nsw.gov.au/RPA/research%5Ccontent/pdf/Social_Media_Plan_Template-v4-final.zip)**.**

No social media will be used as part of this study.

**State whether the** **potential participants will be screened? YES / NO**Yes.

**If YES - What is the screening process? Who will screen potential participants?**Eligible participants will be screened by their treating pulmonary rehabilitation therapist, who, as part of routine care, will discuss with participants the options for exercise programs the maintenance phase of pulmonary rehabilitation. Participants who meet the inclusion criteria, are able to perform unsupervised and independent moderate intensity exercise and have internet access in their home will be offered to participate in this study.

**If YES, what screening data will be collected? (NB, if participant is not eligible, will data collected be destroyed or kept?) This should be mentioned in PIS/CF)**Data will be collected on whether participants agree to take part in the study, decline to take part in the study (and the reason), or are ineligible to take part in the study (and the reason). Since it is part of routine care for the treating pulmonary rehabilitation therapist to discuss all suitable options for maintenance exercise with participants, including their suitability for remote exercise, these screening data will be kept as part of routine care.

**Will participants be given at least 24 hours to consider participating? If not, please justify**Yes. Participants will be invited to take part in the study during the final two weeks of the pulmonary rehabilitation program and will be given more than 24 hours to consider participating.

**What is the impact of any relationship between researchers and potential participants on recruitment? How will perception of coercion to participate be avoided?**The research team includes participants’ treating pulmonary rehabilitation physiotherapists. To avoid the perception of coercion to participate, as part of routine care the treating pulmonary rehabilitation therapist will discuss all suitable options for maintenance exercise with participants, including the option to participate in this study and use an online exercise video.

Participants will be reassured that if they are interested in using the online exercise video but are *not* interested in taking part in the study, they will still have to opportunity to access and use the online exercise video during the maintenance phase of pulmonary rehabilitation. Participants will be reassured that they can withdraw from the study at any time without having to give a reason and that their decision will not affect their treatment or their relationship with the staff caring for them. Only the treating pulmonary rehabilitation therapist will be aware of participation or non-participation in the study.

**How will the recruitment strategy ensure that participants can make an informed decision about participation?**Eligible participants will be screened by their treating pulmonary rehabilitation therapist, who as part of routine care will discuss with participants all suitable options for maintenance exercise, including the option to participate in this study and use an online exercise video. Participants can therefore make an informed decision about the type of maintenance exercise that best suits their individual needs and preferences, including the decision to participate in this study.

**Any other potential recruitment methods?**

No other recruitment methods will be used.

**PARTICIPANT ENROLMENT**

Potential participants will be enrolled into the study after the informed consent process has been completed and the participant has been assessed to meet all the inclusion criteria and none of the exclusion criteria. Study participants will receive a study enrolment number and this will be documented in all study documents.

**INFORMATION AND CONSENT**

Eligible participants will be screened by their treating pulmonary rehabilitation therapist during the final two weeks of the pulmonary rehabilitation program. A member of the research team will invite eligible participants to take part in the study, provide the Participant Information Sheet, answer any questions, and obtain written informed consent on a paper form. Paper consent forms will be stored in locked filing cabinets for the duration of the data retention period located in the Department of Respiratory and Sleep Medicine at Royal Prince Alfred Hospital and Balmain Hospital, according to the recruitment site.

### **WAIVER OF CONSENT (if applicable)**

Not applicable.

**PATIENT WITHDRAWAL**

When a participant is withdrawn from the study, no further study-related data will be collected from the participant (i.e., physical activity measured using a wearable device, exercise tests, and questionnaires). Participants do not require any further follow-up and will not attend the final study visit, which is not part of routine care (i.e., 6 months post completion of pulmonary rehabilitation).

Any collected data will be removed from the study records and will not be included in the study results if requested by the participant, unless the research team has already analysed and published the results. Removal of participant data from the study records includes deletion of electronic data from REDCap and shredding and disposal of any paper forms in secured bins, located in the Department of Respiratory and Sleep Medicine at Royal Prince Alfred Hospital. Patients will have been made aware of their rights and given options for withdrawal in the Participant Information Sheets and consent form.

If participants choose to withdraw from the study during the final two weeks of pulmonary rehabilitation, measures that are routinely collected at the completion of pulmonary rehabilitation assessment will still be collected by the treating pulmonary rehabilitation therapist.

# **7. OUTCOMES**

**Primary outcomes:**

* Physical activity measured using a wearable device (activPAL, PAL Technologies Ltd, Glasgow, Scotland, UK)
* Self-efficacy measured measured using Self-Efficacy for Exercise Scale

**Secondary outcomes:**

* Functional exercise capacity measured using 6-minute walk test distance
* Functional lower limb strength measured using 5 sit-to-stand test
* Functional lower limb strength measured using 1-minute sit-to-stand test
* Health-related quality of life measured using St George’s Respiratory Questionnaire
* Respiratory symptoms measured using COPD Assessment Test
* Experiences with and perspectives of the online exercise video measures using a user experience survey and qualitative interviews

# **8. DATA COLLECTION**

**FORMS AND PROCEDURES FOR COLLECTING DATA**
Participants’ medical records will be reviewed to obtain the following demographic information: age; sex; height and weight; comorbidities; number of exacerbations in the previous 12 months; and lung function. This information is routinely collected on commencement of a pulmonary rehabilitation program and will be obtained from the medical record by the treating pulmonary rehabilitation therapist.

Physical activity data from the wearable device will be downloaded, extracted to a password protected computer, and processed and analysed using activPAL software.

At the completion of pulmonary rehabilitation assessment, the following questionnaires and exercise tests will be performed: Self-Efficacy for Exercise Scale, 6-minute walk test, 5 sit-to-stand test, 1-minute sit-to-stand test, St George’s Respiratory Questionnaire, and COPD Assessment Test. All measures are routinely assessed at the commencement and completion of pulmonary rehabilitation using paper forms, which will be stored in locked filing cabinets and will not leave the site. Entry of these data into REDCap will be performed manually by a member of the research team.

At 6 months post completion of pulmonary rehabilitation, the following questionnaires will be completed electronically via a REDCap survey link and subsequently will be entered electronically into REDCap: Self-Efficacy for Exercise Scale, St George’s Respiratory Questionnaire, COPD Assessment Test, and user experience survey to report the usability of the online exercise video. Participants’ height, weight and exercise tests results (i.e., 6-minute walk test, 5 sit-to-stand test, and 1-minute sit-to-stand test) will be recorded using paper forms. Entry of these data into REDCap will be performed manually by a member of the research team. Semi-structured interviews will be audiotaped and qualitative data from the interviews extracted from de-identified interview transcripts.

Participants will be given the opportunity to review the transcript prior to analysis and publication. Ambiguous or conflicting data will be resolved through review and discussion of the data by two members of the research team.

# **9. ANALYSIS PLAN**

**SAMPLE SIZE CALCULATION**

The sample size for this study was estimated using a before-after study (paired t-tests) calculator (<https://sample-size.net/sample-size-study-paired-t-test/>). Approximately 26-28 participants are required to demonstrate a statistically significant improvement in step count of 1100 steps/day from completion of pulmonary rehabilitation to 6 months post completion of pulmonary rehabilitation, which is upper end of the minimally important difference for step count in people with COPD10. Approximately 26-28 participants are required to demonstrate a statistically significant improvement in step count of 1100 steps/day from completion of pulmonary rehabilitation to 6 months post completion of pulmonary rehabilitation, which is upper end of the minimally important difference for step count in people with COPD 10. Thirty-three participants will be recruited based on a 15% loss to follow up.

**ANALYSIS PLAN**

This study will use both descriptive statistics and statistical methods.

Demographic information will be reported as mean and standard deviation for continuous variables, and as counts and percentages for categorical variables. Changes in physical activity, self-efficacy for exercise, functional exercise capacity, functional lower limb strength, health-related quality of life, and symptoms over time (i.e., from during pulmonary rehabilitation to completion of pulmonary rehabilitation to 6 months post completion of pulmonary rehabilitation) will be analysed using paired t-tests. Qualitative data from the user experience survey and from the semi-structured interviews will be analysed descriptively and using the Theoretical Framework of Acceptability, respectively.

# **10. PUBLICATION & INTELLECTUAL PROPERTY**

The research team agrees that publications or presentations of any of the results from this study will consider the cooperative nature of the conduct of the study. Team members in the protocol who have all agreed to assist with undertaking this project, statistical analysis and writing of any manuscript will be recognised with co-authorship in the publication of results. Authorship will be determined in line with the NHMRC Authorship Guide, and any authorship issues will be resolved by consensus amongst the research team. All existing and future intellectual property rights, including all future copyright, contained in the study materials will automatically be assigned to the research team.

Participants will be directly informed of the study findings via email correspondence. This information has been included on the consent form, where participants indicate if they would like to receive a copy of the study results when they become available and provide their email address.

# **11. ETHICS**

**INVESTIGATOR AUTHORISATION PROCEDURE**

The conduct of this study will commence once the initial approval process has been completed through Ethics and Governance authorisation for each site (Royal Prince Alfred Hospital and Balmain Hospital). Updated documents will be implemented once they have been reviewed and approved by an Ethics Committee and Governance Officer for each site (Royal Prince Alfred Hospital and Balmain Hospital).

### **PROTOCOL AMENDMENTS**

If, during the course of the study, it is found that changes need to be made to the protocol or other study documents, then approval will be sought from the HREC. HREC approval will be obtained before the amendment is implemented.

# **12. SPONSORSHIP AND FUNDING**

This study is not funded. There are no plans to seek funding for this study for the duration of the research and archival period.

Dr Tiffany Dwyer and Dr Sonia Cheng have received financial support from The University of Sydney for research activities. This financial support will be used to cover the costs of the stamped envelopes so that participants can return the wearable device and diary to the research team on one occasion. Dr Tiffany Dwyer, Dr Sonia Cheng and Dr Marita Dale, in their supervision of Ms Megan Wong who will be undertaking research activities as part of this study to satisfy the requirements of a Bachelor of Applied Sciences (Physiotherapy) (Honours) degree, will provide in-kind support with respect to administration of questionnaires and follow up with participants; coordination of participant scheduling, testing and other study procedures; and collection, entry, and analysis of data. Dr Sonia Cheng will provide in-kind support for the wearable devices and associated consumables to measure physical activity in this study.

Prof Lissa Spencer, Mr Jack Reeves and Mr Joshua Bishop will provide in-kind support with respect to time for enrolment of study participants; coordination of participant scheduling, testing and other study procedures; and entry and analysis of data.

# **13. CONFLICTS OF INTEREST AND MANAGEMENT PLAN**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Research or Non-research member name** | **Type of Interest (please specify and provide details including monetary value ($$)** | **Management of the Potential Conflicts of Interest** | **If applicable;** **Have the relevant details been disclosed in the Participant Information Statement?** | **Comments** |
| Dr Tiffany Dwyer | Current employment with Royal Prince Alfred Hospital, SLHD | Requirement for the public disclosure of the interests (e.g., when presenting or publishing the research) | Yes, the member’s affiliations are stated on the PIS. |  |
| Prof Lissa Spencer | Current employment with Royal Prince Alfred Hospital, SLHD | Requirement for the public disclosure of the interests (e.g., when presenting or publishing the research) | Yes, the member’s affiliations are stated on the PIS. |  |
| Mr Jack Reeves | Current employment with Royal Prince Alfred Hospital, SLHD | Requirement for the public disclosure of the interests (e.g., when presenting or publishing the research) | Yes, the member’s affiliations are stated on the PIS. |  |
| Joshua Bishop | Current employment with Balmain Hospital, SLHD | Requirement for the public disclosure of the interests (e.g., when presenting or publishing the research) | Yes, the member’s affiliations are stated on the PIS. |  |
| Dr Sonia Cheng | Voluntary involvement to meet employment requirements at The University of Sydney | Requirement for the public disclosure of the interests (e.g., when presenting or publishing the research) | Yes, the member’s affiliations are stated on the PIS. |  |
| Dr Marita Dale | Voluntary involvement to meet employment requirements at The University of Sydney | Requirement for the public disclosure of the interests (e.g., when presenting or publishing the research) | Yes, the member’s affiliations are stated on the PIS. |  |
| Ms Megan Wong | Voluntary involvement to satisfy the requirements of a Bachelor of Applied Sciences (Physiotherapy) (Honours) degree at The University of Sydney | Requirement for the public disclosure of the interests (e.g., when presenting or publishing the research) | Yes, the member’s affiliations are stated on the PIS. |  |

# **14. CONFIDENTIALITY AND STORAGE AND ARCHIVING OF STUDY**

**CONFIDENTIALITY**

Participants’ data will be treated confidentially and will be stored on REDCap supported by the Sydney Local Health District. Access to REDCap is restricted and only members of the research team will have access to these data. It is anticipated that all members of the research team will be involved in data collection, data interpretation and analysis, and dissemination of study results in publications and presentations. The study results will be submitted as part of a research thesis in November 2025 by Ms Megan Wong to satisfy the requirements of a Bachelor of Applied Sciences (Physiotherapy) (Honours) degree.

Identifiable data, including participant name, medical record number, date of birth, and address, will be stored in locked filing cabinets at Royal Prince Alfred Hospital or Balmain Hospital and will not leave the site. The scanned consent forms containing identifiable data will be stored on REDCap. All other data collected as part of this study will be re-identifiable based on the participants’ study enrolment number. Re-identifiable study data will be stored separately to the scanned consent forms on REDCap (i.e., REDCap will auto generate a de-identified record within a separate research data project in the REDCap system using a “Record ID” as a participant identifier), which will reduce the risk of re-identification and ensure participant privacy.

**STORAGE AND ARCHIVING**

The scanned consent forms will be stored on REDCap during the study and for the required seven years after study completion. Data from wearable device diaries, questionnaires, exercise test results, qualitative surveys, and the audio recordings and transcripts from qualitative interviews will be stored on REDCap during the study and for the required seven years after study completion. Physical activity data from the wearable device will be stored as computer files on a password-protected computer, since the software used for processing and analysis of the physical activity data requires the raw data files to be located on a local hard drive. Once the raw data files have been processed and analysed, physical activity data will be entered and stored on REDCap during the study and for the required seven years after study completion. The backup process is maintained by SLHD IM&TD. Backups of data stored through REDCap are performed daily to a separate server. A sixty-day history of backups is retained at any one time.

Paper consent forms and returned paper sleep diaries will be stored in locked filing cabinets for the duration of the data retention period, located in the Department of Respiratory and Sleep Medicine at Royal Prince Alfred Hospital and Balmain Hospital, according to the recruitment site. Data collected as part of routine care during pulmonary rehabilitation and at the completion of pulmonary rehabilitation assessment recorded using paper forms will be stored in locked filing cabinets at Royal Prince Alfred Hospital or Balmain Hospital and will not leave the site.

De-identified data will be analysed on password-protected computers of The University of Sydney study investigators. Following the seven-year data retention period, all paper and electronic study records and files will be deleted.

Since the database for this study is yet not finalised, a copy of the Master Code Sheet and Data Collection Form will be submitted with REGIS application to display to the Committee what variables the research team intends to collect.

# **RESEARCH DATA MANAGEMENT PLAN (RDMP)**

The RDMP has been completed at this link (<https://redcap.sswahs.nsw.gov.au/surveys/?s=CXD8WLEAWC>). A PDF copy of the RDMP will be submitted with the application in REGIS.

# **FUTURE USE OF DATA**

It is anticipated that data will be used for future use and there are plans to share non-identifiable data with local and international collaborators for the purposes of research, specifically the ‘Physical activity, posture and sleep in clinical populations (ClinPASS)’ repository at The University of Sydney. The data can only be shared provided the requestor has approval from an Australian Human Research Ethics committee within the past four years and will reference the original study in the dissemination of any findings.

EXTENDED or UNSPECIFIED in Q2.2.2.2 in the HREA has been selected and future use of data requested in the PIS and consent form. The statement ‘Any stored data that is used for related or future research, will first be reviewed and approved by an appropriately constituted Ethics Committee’ has been included.

# **15. REFERENCES**

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