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Title Page**Article type:** *Original Research***Article title:** Acceptability and validity of a home exercise diary used in home-based pulmonary rehabilitation: a secondary analysis of a randomised controlled trial.**Short title:** Home Exercise Diary**Authors:**

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AL, AEH, CFM, AM and PO contributed to the conception and design of the study; all authors contributed to data acquisition; AL, AEH, CFM contributed to data analysis and drafting the manuscript; all authors revised the manuscript critically for important content and approved the final version of the manuscript.

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Main Article

Article type: *Original Research*

Article title: Acceptability and validity of a home exercise diary used in home-based pulmonary rehabilitation: a secondary analysis of a randomised controlled trial.

Short title: Home Exercise Diary

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Abstract (word count: 249 words)

Introduction: Evaluating adherence to home-based pulmonary rehabilitation (PR) could be challenging due to lack of direct supervision and the complex nature of the rehabilitation

model. To measure adherence to home-based PR in the HomeBase trial, participants were encouraged to work towards a goal of at least 30 minutes of whole-body exercise on most days of the week and report their participation using a home exercise diary.

Objective: This project aimed to evaluate the acceptability and validity of the home exercise diary.

Methods: Diary return and completion rates assessed acceptability of the home exercise diary. Home participants underwent physical activity (PA) monitoring using the Sensewear armband during the final week of an eight-week PR. The correlation between self-documented and objective daily exercise minutes was calculated. Objective exercise minutes were defined as bouts of ≥ 10 minutes spent in $\geq$ moderate PA. Differences in self-documented weekly exercise minutes between sufficiently active ($\geq 7,000$ daily steps) and inactive participants were computed.

Results: Diaries were returned by 92% of programme completers. Of those who returned diaries, 72% have completed exercise documentation. Fifteen programme completers underwent PA monitoring (mean age 69 (9) (SD) years, FEV₁ 55 (19) %predicted). A moderate correlation was observed between self-documented and objective mean daily exercise minutes ($r=0.59$, $p=0.02$). Active participants ($n=6$, 10,253 (1,521) daily steps) documented more exercise (111 minutes) during week eight compared to inactive participants ($n=9$, 2,705 (1,772) daily steps, $p=0.002$).

Conclusion:

The self-documented home exercise diary is an acceptable and valid method to reflect exercise participation during home-based PR.

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Key words: Pulmonary Disease, Chronic Obstructive - Home Care Services - Motivational
Interviewing - Daily Diary - Quality of Health Care

Manuscript (word count: 2909 words)

Introduction

With respect to evaluating health-related behaviours, adherence refers to the extent to which a person's behaviour corresponds with agreed recommendations from a health care provider.¹ When implementing a model of care into clinical practice, measuring adherence to that model is essential in evaluating its feasibility and efficacy.² Additionally, adherence is one of the main elements essential to assess treatment fidelity and the integrity of intended programme delivery.³ Therefore, special attention is given to evaluate adherence across a wide range of healthcare interventions.⁴

In chronic obstructive pulmonary disease (COPD), pulmonary rehabilitation (PR) is a cornerstone for care when managing breathlessness and enhancing exercise tolerance and health-related quality of life.⁵ However, participants' levels of uptake, attendance and completion at typical outpatient PR programmes are suboptimal.⁶ High quality evidence supports home-based PR as an alternative model of PR delivery as compared to centre-based PR, with comparable clinical outcomes for patients with COPD.⁷⁻⁹ In a recent report, completion rates of home-based PR was measured to be 91% compared to 49% for centre-based PR programme.⁸ Additionally, those who completed home-based PR demonstrated a significantly longer time to their first hospital admission in the 12 months following the programme, and as a result those undertaking home-based PR tended to have fewer hospitalisations compared to centre-based PR.⁸ A comprehensive study to further investigate adherence to home-based PR could inform clinical implementations of the new model.

Home-based exercise models are largely unsupervised by health care professionals.¹⁰

Without the direct supervision, evaluating patients' engagement in exercise programmes or adherence to treatment plans at home could be difficult.^{11,12} Furthermore, exercise training models are complex in nature and often combine different approaches (e.g. behavioural

change strategies combined with an exercise plan).¹³ The home exercise diary used during the HomeBase trial included participants' documentation of exercise goals, confidence for goal attainment and documentation of exercise participation.⁸ In an attempt to appraise the implantation of home-based PR in clinical practice, the current analysis aimed to evaluate the validity and acceptability of self-documented exercise participation using the home exercise diary during home-based PR.

Materials and Methods

This report is a secondary analysis of data collected from the HomeBase trial.⁸ The HomeBase was a large randomised controlled study that evaluated the effects of home-based PR in COPD on clinical outcomes and its equivalence to the traditional, centre-based PR. The findings of the HomeBase were previously reported and the trial was prospectively registered at ([NCT01423227, clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT01423227)). Included participants were 40 years of age or older with a confirmed diagnosis of COPD and a smoking history of at least 10 packet years.

All participants randomised to the home group underwent home-based PR for eight weeks.

Home-based PR commenced following baseline assessment and comprised a structured exercise training programme, an initial home visit, weekly telephone calls and a home exercise diary provision. The overall goal was to participate in at least 30 minutes of whole-body exercise on most days of the week. Through the home visit, a physiotherapist assisted participants in setting an achievable and personalised starting goal for endurance and resistance training, reviewed inhaler techniques and supervised the first exercise session.

Participants were encouraged to document their goals and participation using the diary during the eight weeks of the programme. To help facilitate accuracy of self-documentation, participants were given a pedometer to use during exercise which was adjusted to their age, gender and measured stride-length (Omron Pedometer Hj-112). The pedometer measured walking distance and steps in count data visualised through the pedometer screen. Exercise goals and log documentations were reviewed weekly during the telephone calls from a physiotherapist. The telephone calls used a motivational interviewing approach to assist in

identifying participants' motivation to exercise, set achievable exercise goals for the week and identify strategies to overcome perceived barriers to exercise. The home exercise diary prompted weekly exercise goals documentation including planned exercise frequency, duration (and/or distance), barriers and facilitators to exercise, and place and time of planned exercise. Levels of confidence in achieving exercise goals were rated by participants each week using a 5-point Likert scale (1 = not at all confident, 5 = totally confident). Following the weekly exercise goal sheet, a weekly exercise log, where participants were instructed to document their daily exercise participation including type, duration and distance of endurance exercise and steps taken, was available. Additionally, the diary prompted participants to record their levels of dyspnoea using the Borg scale and leg fatigue using the rating of perceived exertion (RPE) scale.¹⁴ Illustrative boxes providing examples of how to document strengthening exercise types, repetitions and sets were included in the diary. Figure 1 displays a screen shot of week one exercise goal and log.

Objectively measured physical activity

Starting week eight of home-based PR, consecutive participants were asked to wear the SenseWear armband (SWA) 24 hours a day, exclusive of body hygiene time, for seven days. The SWA (SenseWear, BodyMedia, Pittsburgh USA) is a light weight activity monitoring device that is widely used in the COPD population and has shown to accurately document standardised physical activities at a range of intensities relevant to people with COPD.¹⁵ Energy expenditure in patients with COPD was measured by the SWA in a standardised, one-hour activity and validated against indirect calorimetry as the criterion measure, with a moderate correlation of $r=0.76$ (95% [Confidence Interval] CI 0.54-0.91).¹⁵ Extracted datasets of physical activity were included in the analysis if they contained a minimum of four valid days excluding the first and last day of monitoring.¹⁶ A valid day included at least 10 hours of data and at least one weekend day in each dataset. Physical activity variables extracted from the SWA comprised daily steps and daily minutes spent in physical activity of at least moderate intensity physical activity (MPA) defined as ≥ 3

metabolic equivalents of task (METs) undertaken in bouts between the hours of 0700 and 1900; a bout was defined as a minimum of 10 continuous minutes of time spent in MPA.¹⁶

Ethics approval was obtained from The Alfred, Austin Health and La Trobe University

Human Research Ethics committees. All participants provided informed consent prior to activity monitoring.

Statistical analysis

Analyses were performed using SPSS (version 22, IBM, Chicago, IL, US). Acceptability is defined as the participant's ability to use a certain measurement tool.¹⁷ To assess acceptability of the home exercise diary, the rate of diary return and diary completion rates were recorded. Rates of 71% or higher represents high acceptability while rates of 70-50% were considered moderate.¹⁸ Consistent with the attendance criteria of PR, an acceptable completion rate was pre-defined as reporting 70% of the exercise diary variables.⁶ This included documenting 70% of weekly exercise goals and weekly exercise log. Additionally, the completion rates of exercise goals, the Likert confidence scale and dyspnoea and PRE scores after exercise were obtained.

Construct validity is the degree to which a tool measures what it was designed to measure.¹⁹

In order to explore construct validity of the diary, the level of agreement between self-documented daily exercise minutes and objective daily MPA minutes during week eight of PR were compared. To determine the relationship between the two variables, Pearson's correlation coefficient and a Bland-Altman plot including limits of agreement (LoA) were calculated.²⁰

Criterion validity is the degree to which a tool can recognise previously set standards.¹⁹ In order to assess criterion validity of the diary, differences in self-documented exercise variables between sufficiently active and inactive participants were compared. Sufficiently active participants were defined as participants who accumulated a mean of at least 7,000 daily steps measured by the SWA during week eight of PR according to the step-based

recommendations for older adults.²¹ Self-documented exercise variables included the total number of exercise sessions and minutes during week eight and total number of documented goals during the eight weeks PR. Independent sample t-tests were used to detect differences in normally distributed variables and Mann-Whitney U tests were used in case of heterogeneity.

Results

Acceptability study

During the HomeBase trial, 80 participants were allocated to home-based PR, of whom 73 completed the programme. Sixty-seven (92%) of those who completed the programme returned the home exercise diary and were included in the analysis of acceptability (Table 1). In the returned diaries, 30 (45%) participants completed documentation of weekly exercise goals (median [interquartile range (IQR)], 5 [3-7] number of documented goals) and 26 participants (39%) documented exercise goal confidence scale (5 [2-7]). Forty-eight (72%) participants completed daily endurance exercise entries (42 [31-48]). Additionally, 45 (67%) participants completed daily strengthening exercise entries (39 [19-50]). Thirty-three (50%) participants completed documenting daily dyspnoea Borg and PRE scores after exercise participation (30 [12-40] entries).

Construct validity study

Construct validity was assessed based on the data collected from 15 participants (Table 1). Figure 2 illustrates a moderately positive correlation between self-documented mean daily exercise minutes and objective mean daily MPA time ($r = 0.59$, $p = 0.02$). The Bland-Altman plot of agreement levels between self-documented mean daily exercise minutes and objective mean daily MPA minutes showed that the mean differences were -15.5 minutes/day ($p=0.08$) favouring the objective minutes and the data were largely within the limits with one outlier (LoA from 47.8 to -78.8; Figure 3).

Criterion validity study

Six participants accumulated at least 7,000 daily steps and were classified as sufficiently active (mean (SD) 10,253 (1,521) daily steps) while nine participants were considered inactive (2,705 (1,772)). During week eight of home-based PR, active participants documented participating in one additional exercise session per week compared to inactive participants (active 6.1 (1.5) versus inactive 5.3 (1.8) sessions, $p = 0.18$) and undertaking an additional 111 minutes of exercise during week eight compared to inactive participants (active 201 (49) versus inactive 90 (61) minutes, $p < 0.01$). No significant differences were detected between active and inactive participants in the total number of documented exercise goals (active 6 (2.5) versus inactive 4 (2.4) goals, $p = 0.24$).

Discussion

This cross-sectional analysis reports the acceptability and validity of the home exercise diary used during pulmonary rehabilitation in the HomeBase trial. The home exercise diary had moderate to high acceptability and validity when compared to the well-validated SWA device in patients with COPD undertaking home-based PR. Completion rates were high when self-documenting daily exercise participation. Although self-documented exercise minutes using the home exercise diary showed a moderate correlation with objective exercise minutes, complete agreement between both variables was not documented. Our results show that the home exercise diary may accurately reflect adherence levels to exercise participation during largely unsupervised home-based PR in clinical practice settings.

A recent literature review evaluated methods of measuring adherence in home-based rehabilitation across a wide range of conditions.¹⁸ The review evaluated the quality of adherence measures in terms of validity, reliability, responsiveness to change and acceptability and concluded that self-documented adherence diaries had moderate to high validity and acceptability rates. However this has not been evaluated in the sedentary COPD cohort.²² Additionally, studies included in this review assessed acceptability based on diary return rates, with insufficient information provided regarding completion rates of diaries.

Consistently, we found that the home exercise diary was acceptable with a high return rate

of 92% and acceptable exercise log completion rates. However, completion rates for exercise goals documentation were low. All participants undertaking the home-based PR programme were encouraged to work towards an exercise goal of 30 minutes of whole-body exercise most days of the week. This goal was established during the initial home visit and emphasised through the weekly telephone calls from the physiotherapist.⁸ It is possible that our participants found it sufficient to be verbally reminded of the exercise goals and thus abstained from documenting goals in their home exercise diary. In addition, it could be possible that some elements of the diary were perceived more important to the participant or the therapist than others. Further investigations regarding the best method of recording exercise goals during home-based exercise models may be of value. Understanding the perspectives of home-based PR therapists and participants regarding the home exercise diary would add value to future structure of the home exercise diary.

The construct validity of the home exercise diaries was assessed using Pearson's correlation coefficient rather than linear regression methods. The main argument behind our analytic approach was that we were more interested in the diaries' ability to reflect exercise participation and adherence to exercise goals during home-based PR and, as such, analyses were not targeted to explore the diaries' ability to predict daily physical activity levels and energy expenditure.²³ The validity analysis showed that self-documented daily exercise minutes were moderately correlated with objectively measured daily MPA minutes. These findings were similar to validity analyses of an exercise diary used in women in the first 12 weeks of pregnancy when validated against pedometer counts per day ($r=0.49$, $p<.02$)²⁴ and an exercise diary used for newly diagnosed cancer patients when validated against pedometer steps ($\rho=0.42$, $p<.001$) and against physical activity questionnaire METs of previous four weeks ($\rho=0.67$, $p<0.001$).²⁵ Our further analyses found that the mean difference between daily exercise minutes recorded using the two measurement tools was approximately 16 daily minutes. While this shows that a home exercise diary is not a valid activity monitoring tool, the correlation between documented exercise minutes and objective

exercise minutes suggests that the home exercise diary is able to reflect exercise participation levels during home-based PR.

Using criterion validity analyses, we found that the diaries could detect differences in exercise log documentation between sufficiently active and inactive participants. This indicates that sufficiently active participants adhered to the set exercise goal of participating in 150 minutes or more per week and accumulated a mean of 202 exercise minutes, whereas inactive participants only documented participating in 90 minutes exercise during week eight of home-based PR. This demonstrates the diaries' ability to identify sufficiently active participants based on their self-documented exercise minutes.

The moderate to high validity rate of the home exercise diary may have resulted from several factors. The home exercise diary was introduced during the initial home visit by the physiotherapist and participants were provided with a verbal explanation and visual illustrations that guided them to document their exercise goals and log correctly. Following the visit, participants were encouraged to complete their exercise diaries through the weekly telephone calls.²⁶ During each telephone call, participants were guided to review their exercise participation in the previous week and set an exercise goal for the upcoming week.

Another factor that may have contributed to self-documentation was the provision of the pedometer which collected data about exercise participation, including distance and duration walked and steps taken during exercise. Thus, these well-integrated components of the home-based PR model may have contributed to the high exercise diary completion rates and enhanced validity of the diary.⁸ As a result, the home exercise diary should be utilised within a fully structured model of home-based PR. It should be noted that our experience with the diary was within the context of a research trial, and carryover to usual clinical care has not yet been evaluated. The results reported here reflect use of the diary only within the 8-week pulmonary rehabilitation program. Further research is required to establish the usefulness of longer-term exercise diary use, after the period of pulmonary rehabilitation has finished.

Previous literature has shown that self-reported measurements of physical activity are often over-estimated when compared to valid objective measures.²⁷ In contrast to this, our analyses showed objectively measured MPA minutes to be greater than self-documented exercise minutes. These findings could be explained with two possible speculations.

Primarily, participants were only asked to self-document their exercise session duration not daily physical activity time. Thus, this would not have included activities of moderate intensity nature that were not perceived as exercise by the participants (e.g. walking to the shops or climbing the stairs). Secondly, although objective physical activity variables only included time spent in bouts of 10 minutes or more of MPA, these data may have been contaminated by time spent in activities of daily living that were not structured exercise. It is important to emphasise that the home exercise diary is being validated as a component of a home-based PR intervention and not as a self-documented physical activity measurement tool. It is possible that in the future the use of wearable consumer devices (eg step counters and activity monitors) may simplify the recording of physical activity and adherence to home exercise programs, although validity and acceptability to pulmonary rehabilitation participants will need to be established.

Strengths and limitations

This is the first study to assess the acceptability and validity of an exercise diary used during PR in people with COPD.¹⁸ The report provides in-depth acceptability analyses including completion rates for different sections of the home exercise diary as well as return rates and overall diary completion statistics. The home exercise diary was validated against objective physical activity data provided by the SWA; a well-validated activity tool in the sedentary COPD population.²³ A limitation of this report is the small sample size included in the validity study (n=15) using the SWA, due to funding constraints. The small sample size might have reduce the sensitivity of the reported construct validity analysis.²⁸ It cannot be ruled out that participants who showed high compliance with wearing the SWA were more likely to complete their diary. Consecutive participants were asked to wear the monitor where three

refused and 17 collected insufficient data for the validity analysis. Further larger studies to evaluate the validity of exercise diaries against well-validated devices are encouraged.

Exploring in-depth views of home-based PR participants and therapists regarding their experience with the home exercise diary would inform future attempts to evaluate adherence tools to home-based interventions.

Conclusion

This study found that a participant-completed home exercise diary was moderately to highly acceptable and valid in reflecting exercise participation and adherence levels in people with COPD during home-based PR. These properties could be highly associated with the weekly encouragement of diary completion during the physiotherapists' phone calls along with other components of home-based PR such as the home visit and the provision of pedometers to track daily exercise participation. Thus, a home exercise diary may be an acceptable and valid tool for measuring adherence when implementing home-based PR into clinical practice.

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Table 1: Demographic characteristics of home participants included in the acceptability study (n=67) and the validity study (n=15)

	Acceptability Study (n=67)	Validity Study (n = 15)
Age (years)	71 (9)	69 (9)
Male/female (n)	39/28	12/3
BMI (kg/m ²)	29 (6)	28 (5)
FEV ₁ (litres)	1.4 (0.5)	1.37 (0.5)
FEV ₁ % predicted	54 (18)	55 (19)
FVC (litres)	2.8 (0.7)	2.8 (0.7)
FVC % predicted	80 (17)	84 (17)
FEV ₁ /FVC	48 (17)	49 (13)
Current/previous smoker (n)	7/60	2/13
Pack years	47 (37)	42 (20)
GOLD stage I-II-III-IV (n)	5-30-30-2	2-6-6-1

Data are mean (SD) unless stated otherwise.

BMI - body mass index; FEV₁ - forced expiratory volume in 1 second; FVC - forced vital capacity; GOLD - Global Initiative for Chronic Obstructive Lung Disease.

Figure 1 legend. A screen shot of the week 1 exercise goals sheet and exercise log from the home exercise diary used in the HomeBase trial

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Figure 2 legend. The relationship between objectively measured mean daily exercise minutes of moderate intensity physical activity spent in bouts and self-documented mean daily exercise time

Figure 2 abbreviations: MPA – moderate intensity physical activity

Figure 3 legend. Bland and Altman plot demonstrating the agreement between objectively measured mean daily minutes of moderate intensity physical activity spent in bouts and self-documented mean daily exercise minutes

Figure 3 abbreviations: MPA – moderate intensity physical activity; LoA - limits of agreement

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Week 1 – My Exercise Goals							
My exercise goal for this week is: _____							
Aerobic exercise: _____							
Strength exercises: _____							
How often will I exercise: _____							
When I will do my exercise: _____							
Where I will do my exercise: _____							
What might get in the way of my plan: _____							
What I can do about it: _____							
How confident am I that I can achieve my exercise goal (please circle one):							
Not at all confident	A little confident	Somewhat confident	Very sure	Totally confident			
Week 1 – My Exercise Diary							
Day Date	Monday / /	Tuesday / /	Wednesday / /	Thursday / /	Friday / /	Saturday / /	Sunday / /
Moderate flare up?	Yes • No •	Yes • No •	Yes • No •	Yes • No •	Yes • No •	Yes • No •	Yes • No •
Severe flare up?	Yes • No •	Yes • No •	Yes • No •	Yes • No •	Yes • No •	Yes • No •	Yes • No •
If you answer 'yes', please follow the instructions on page 5.							
My endurance exercises							
Type: _____							
Duration: (goal) _____							
Steps/distance: (goal) _____							
Breathing score: (goal) _____							
Leg score: (goal) _____							
My strengthening exercises							
1. _____							
2. _____							
3. _____							
4. _____							
5. _____							
Comments							

Figure 1. A screen shot of the week 1 exercise goals sheet and exercise log from the home exercise diary used in the HomeBase trial

90x88mm (300 x 300 DPI)

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Figure 2. The relationship between objectively measured mean daily exercise minutes of moderate intensity physical activity spent in bouts and self-documented mean daily exercise time!! + Abbreviations: MPA – moderate intensity physical activity

70x49mm (300 x 300 DPI)

Author

Figure 3. Bland and Altman plot demonstrating the agreement between objectively measured mean daily minutes of moderate intensity physical activity spent in bouts and self-documented mean daily exercise minutes!! + Abbreviations: MPA – moderate intensity physical activity; LoA - limits of agreement

80x53mm (300 x 300 DPI)

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