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Long term conditions

What is the Minimal Clinically Important Difference in the One-Minute Sit-to-Stand Test During Remote Interventions?

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Background

Pulmonary rehabilitation (PR) is the most effective therapeutic strategy to improve health status in people with chronic obstructive pulmonary disease (COPD). With poor uptake and adherence to PR, a home-based rehabilitation programme could improve exercise capacity in these patients. A suitable outcome measure for home settings is required to assess such a programme's effectiveness.

Purpose

The one-minute sit-to-stand test (1-min STS) can easily be performed within home settings, and has been validated for other clinical scenarios. This service evaluation aimed to calculate the minimal clinically important difference (MCID) for the 1-min STS following a remote exercise-based intervention.

Methods

Anonymised data were analysed retrospectively from a comprehensive remote exercise-based intervention for patients with COPD. The 1-min STS, COPD Assessment Test and MRC dyspnoea scale were completed before and after the programme. Change in health status was recorded using the Global Rating of Change Questionnaire (GRCQ). Anchor-based methods were used to evaluate the MCID of the 1-min STS.

Results

Data were available from 106 patients. The median (IQR) improvement in 1-min STS after the programme was three (1-5) repetitions. Changes in 1-min STS repetitions were non-significantly and only weakly correlated with changes in MRC dyspnoea scale, COPD Assessment Test and GRCQ (r=-0.15, -0.12 and 0.09, respectively). The estimated MCID for the 1-min STS was three repetitions.

Conclusions

An improvement of at least three repetitions in the 1-min STS was considered meaningful in this service evaluation. Anchors that display stronger correlations would be required to increase the robustness of the MCID estimates.

INTRODUCTION

Pulmonary rehabilitation (PR) is the most effective therapeutic strategy to improve dyspnoea, health status and exercise tolerance in people with chronic obstructive pulmonary disease (COPD).[1] Despite the beneficial effects of PR, adherence and uptake remain poor.[2] During the COVID-19 pandemic, some UK NHS Trusts trialled alternative home-based self-management exercise programmes to improve uptake to exercise. We are now in a transition period whereby physiotherapists are considering the advantages of remote self-management programmes, whilst not wanting to lose the benefits of traditional PR. Thus, there is the need for research into remote interventions and outcome measures to assess their effectiveness.

The six-minute walk test (6MWT) is used to prescribe individualised PR exercises and evaluate changes in exercise capacity. It has high validity and reliability and is sensitive to changes post-PR.[3] However, the 6MWT requires space to walk and the direct supervision of trained staff. Alternative tests such as the one-minute sit-to-stand (1-min STS) test have also been considered, to allow physiotherapists to monitor the progress of patients undertaking self-management programmes.

The 1-min STS assesses patients' functional capacity.[4] Studies have found strong correlations between the 1-min STS and the 6MWT. Thus, the 1-min STS could be a feasible

outcome for home-based settings. This service evaluation aimed to evaluate the minimally clinically important difference (MCID) of this instrument for a home exercise-based self-management programme. The secondary aim was to evaluate whether the outcome measures selected for the programme were responsive to changes following the programme.

METHODS

STUDY DESIGN

This was an evaluation of the remote exercise intervention service provided at Guy's and St Thomas' NHS Foundation Trust, permissions for this service evaluation were granted from the St Thomas' audit department. As this study used retrospective data that were routinely collected from an existing service, did not involve randomization of patients and findings were not generalized, this study was not classified as 'research'. An anonymised spreadsheet of data (with no patient identifiers) was provided to the primary author for data analysis.

HOME-BASED SELF-MANAGEMENT EXERCISE PROGRAMME

Patients with a confirmed diagnosis of COPD were invited to join the programme between November 2019 to January 2021. Participants had to be medically stable with no contraindications to exercise. Individuals unable to walk ten metres even with a walking aid, those who had recurrent falls in the last six months, had developed an abdominal aortic aneurysm exceeding 5.50cm or had a recent myocardial infarction were excluded from the programme.

The programme was a six-week non-supervised exercise programme conducted at the patient's home with one weekly telephone call for follow-up and exercise progression. Exercise training was individualised and consisted of seven aerobic and strengthening exercises. A maximum of three telephone calls were conducted over each week.

The 1-min STS test was performed by patients before and after the exercise programme. It was carried out during a telephone consultation with the physiotherapist according to a standardised protocol.[5] Oxygen saturations were noted before the test at rest, monitored during the test and for one minute afterwards.

MINIMAL CLINICALLY IMPORTANT DIFFERENCE

To determine the MCID for the 1-min STS, anchor-based methods were used. Changes in the 1-min STS were compared against changes in the external anchors – MRC scale and CAT. For the GRCQ, the median (IQR) change in 1-min STS score with remote interventions was calculated in those reporting feeling "a little better". Those reported feeling "much better" were not included to avoid the overestimation of the MCID.

Table 1. Baseline characteristics of patients

Variables	Baseline
Age (years)	67 (59-74.3)
Sex (n)	
- Male	54 (50.9)
- Female	52 (49.1)
Height (m)	1.65 (1.57-1.76)
Weight (kg)	76.4 (58.8-94.0)
BMI (Kg/m^2)	25.9 (21.1-34.0)
Smoking status (n)	
- Never	6 (5.7)
- Ex-smoker	69 (65.1)
- Current smoker	31 (29.2)
FEV_1 (% predicted)	50.0 (39.3-68.8)

Data are median (IQR) or n(%) unless otherwise specified. BMI: Body mass index; FEV_1: Forced expiratory volume in one second.

STATISTICAL ANALYSIS

Continuous variables that were normally distributed were displayed as mean (SD), while non-normally distributed variables were displayed as median (first quartile, third quartile) unless otherwise specified. Categorical variables were displayed as numbers (percentages).

Analysis was performed using the IBM Statistical Package for Social Sciences (SPSS) Version 27 (IBM, New York, USA). Pairwise deletion was applied to missing data. In the estimation of the MCID for the 1-min STS, only data from participants who obtained paired 1-min STS measurements were included. Spearman's correlation and linear regression were used to compare the change in 1-min STS with other outcome measures. ROC curves were used to estimate the MCID of the 1-min STS test, the number of 1-min STS repetitions cut-off that best distinguished between patients who improved their health status by the established MCID in the CAT total score (-2 point change), MRC score (-1 point change), and change in GRCQ to feeling "a little better" (score of 2) was identified, with equal weighting in both sensitivity and specificity.[6,7]

Responsiveness to the programme was measured by comparing data for outcome measures collected before and after the programme. A Wilcoxon test was applied to assess for significant differences.

RESULTS

In total, data were successfully retrieved from 106 patients who agreed to take part in, and completed, the remote exercise programme. Data were collected between May 2020 and September 2021. Baseline characteristics are displayed in Table 1.

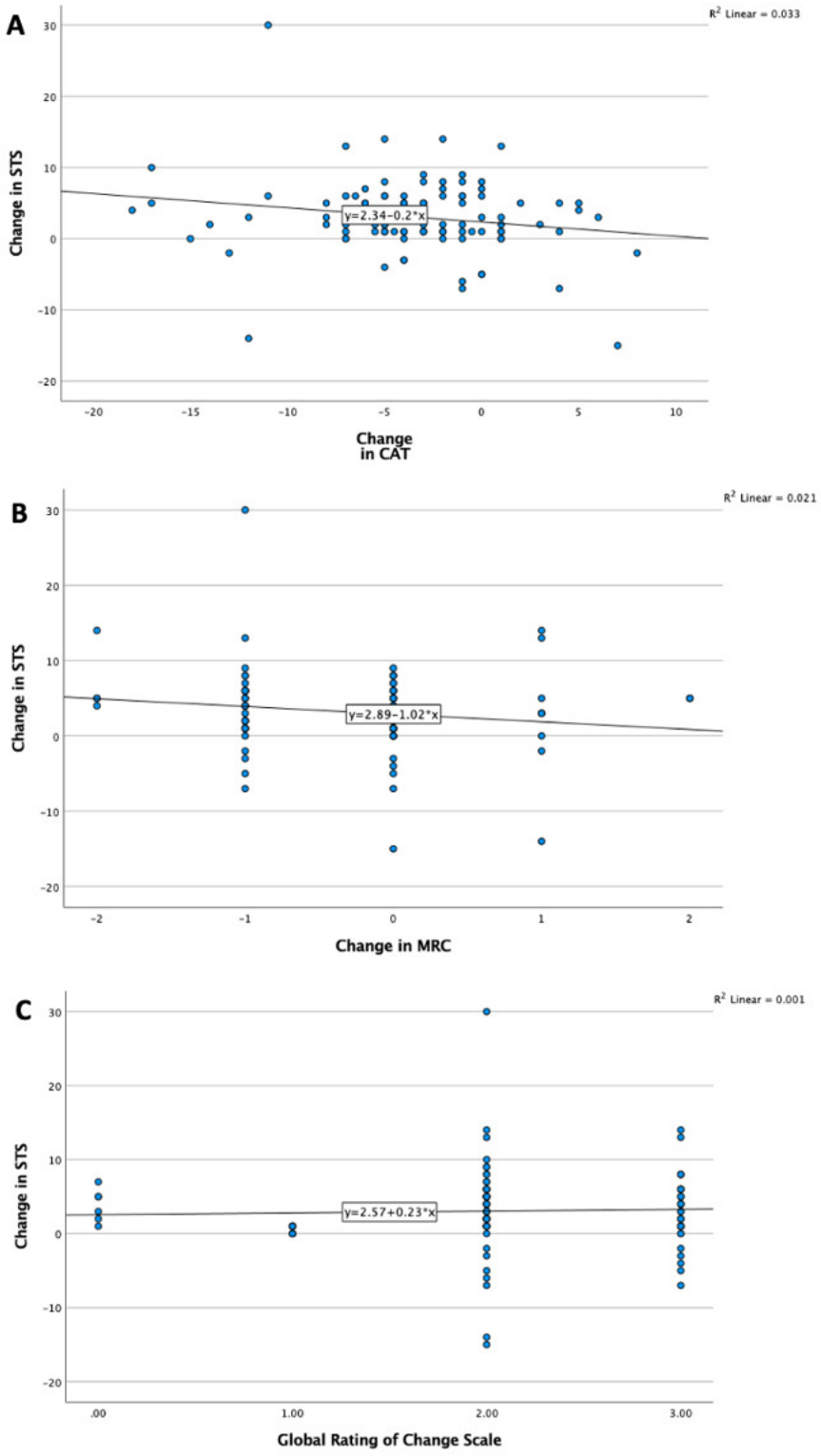

Figure 1. Correlation between the change in 1-min STS test and (A) change in CAT, (B) change in MRC and (C) GRCQ

CAT: COPD assessment test; MRC: Medical Research Council dyspnoea scale; STS: sit-to- stand. Anchor question is the Global Rating of Change Questionnaire (GRCQ), 0 – "no change", 1 – "much the same", 2 – "a little better", 3 – "much better". None of the participants reported feeling "worse", therefore it was not displayed in Figure 1(C)

DETERMINATION OF THE MCID

Figure 1 demonstrates the correlation between the 1-min STS and other patient-reported outcomes, no significant correlations were found between the outcomes.

By using a change of -1 in the MRC dyspnoea scale as a cut-off to determine the minimum clinically important improvement, 38 of 96 (39.6%) patients had a total change score exceeding the anchor MCID of -1. Linear regression analysis estimated the MCID of the 1-min STS as 3.9 rep-

Figure 2. Individual patients' change scores in 1-min STS test after the remote exercise programme

1-min STS: one-minute sit-to-stand

etitions when anchored against the MRC dyspnoea scale. A similar MCID estimate was found using ROC; an improvement of 3.5 repetitions in the 1-min STS best distinguished patients who improved by the MCID or more in the MRC scale, with the best sensitivity of 60.5%, specificity of 62.1%, and an area under curve (AUC) of 0.60.

A total change of -2 in the CAT was used as a cut-off to determine the MCID of the 1-min STS. 71 of 106 (67.0%) patients had a total change in CAT score equal to or greater than -2. For those who improved their CAT score, linear regression analysis estimated the MCID of the 1-min STS as 2.7 repetitions. A similar MCID of 2.5 repetitions was also found using the ROC plot, with the best sensitivity of 54.9% and specificity of 54.3%, and an AUC of 0.58.

For the GRCQ, a score of two (defined by "feeling a little better") was used as a cut-off to determine the MCID. 56 of 106 (52.8%) patients reported feeling "a little better". Linear regression analysis derived an MCID estimate of 3.3 repetitions. Whilst the ROC plot demonstrated the change in 1-min STS repetitions that best distinguished patients feeling "a little better" was 1.5, with the best sensitivity of 73.2%, specificity of 68.7% and an AUC of 0.64.

Since none of the external anchors had a significant correlation with the change in 1-min STS repetitions after a remote exercise programme, the median value is considered as the MCID of the 1-min STS, which is three repetitions. 55 of 106 (51.9%) patients achieved an improvement of three repetitions or more in the 1-min STS after a remote exercise programme (Figure 2).

RESPONSIVENESS TO THE REMOTE EXERCISE-BASED INTERVENTION

There was a significant increase in 1-min STS repetitions between baseline and the end of the programme (Table 2). Changes in MRC and CAT were also statistically significant, although the change in MRC score is unlikely to be clinically meaningful due to the slight change of less than one point.

More than half of the patients (52.8%) reported feeling "a little better" after the remote exercise programme. Median changes in 1-min STS repetitions, CAT scores and MRC scores were statistically significant in those that reported feeling "a little better", with p-values less than 0.01 (Table 3).

DISCUSSION

METHODS USED TO DERIVE THE MCID

Using anchors that are widely used in the COPD population to measure patients' HRQoL, the MCID estimates for the 1-min STS test ranged from 1.5 to 3.9 repetitions. After careful consideration, the authors estimated the MCID to be three repetitions. This corresponds with the multicentre validation study of the 1-min STS test in COPD.[5]

Methods for determining the MCID of clinical instruments remain controversial. Challenges of employing anchor-based methods include a meaningful relationship between the outcome of interest and the external anchors. There is also a lack of agreement on the threshold strength of the correlation between the outcome of interest and anchors. Some researchers have suggested the requirement of a minimum correlation coefficient of 0.50 between outcome measures to be eligible for analysis to calculate the MCID,[8] while others have suggested 0.30.[9]

CORRELATION OF THE 1-MIN STS TEST WITH EXTERNAL ANCHORS

Only minimal and insignificant correlations were found between changes in the 1-min STS and the external anchors in this service evaluation. The weak correlations could have resulted from the external anchors being strongly based on the patient's health status at the time of undertaking the questionnaire rather than the amount of change from baseline, which is a common criticism for patient-reported outcomes.[8,9] Little or no correlation was found between the GRCQ and patients' health status at baseline (r=0.00 to 0.18).[10] Hence, the GRCQ is not a valid measure of change over time, which could explain the poor correlations between the GRCQ and the 1-min STS since this service evaluation analysed the change in 1-min STS repetitions over six weeks and quantified the amount of change from baseline. Therefore, to ensure the credibility of the MCID derived using anchor-based methods, it is essential to select an anchor that measures the same or similar constructs as the targeted outcome to ensure a substantial correlation.

Table 2. Baseline, follow-up and change scores for the 1-min STS test and patient-reported outcomes

	Baseline (a)	End of remote exercise programme (b)	Change (b-a)	p-value
1-min STS	17.5 (13-21)	20 (16-24)	3 (1-5.3)	<0.001
MRC	4 (3-4)	3 (2-4)	0 (-1 -0.0)	<0.001
CAT	21 (16.8-27.0)	18 (12-23)	-3 (-6 – -1)	<0.001

Data are median (IQR). CAT: COPD assessment test; MRC: Medical Research Council dyspnoea scale; 1-min STS: one-minute sit-to-stand.

Table 3. Changes in the different outcome measures according to the different categories of the GRCQ

GRCQ	Change in 1-min STS	Change in CAT	Change in MRC
The same	4.0 (1.75 to 5.5)**	0.0 (-2.0 to 2.0)	0.5 (-0.25 to 2.0)
Much the same	0.0 (0.0 to 1.0)*	-4.0 (-7.0 to 0.0)*	0.0 (-0.5 to 0.0)
A little better	4.0 (1.0 to 6.0)***	-3.0 (-5 to -1)***	-0.3 (-1.0 to 0.0)**
Much better	4.0 (1.0 to 6.0)***	-4.0 (-7.25 to -1.75)***	0.0 (-1.0 to 0.0)***

Data are median (IQR). CAT: COPD assessment test; GRCQ: Global rating of change questionnaire; MRC: Medical Research Council dyspnoea scale; 1-min STS: one-minute sit-to-stand;. * denotes statistical significance p<0.05; **p<0.01:***p<0.001. None of the participants reported feeling "worse", therefore it was not displayed in table 3.

RESPONSIVENESS TO REMOTE EXERCISE-BASED INTERVENTION

Findings from this service evaluation demonstrated that the 1-min STS is responsive to change after a remote exercise programme for patients with COPD. This corresponds with a recent study investigating the effects of a ten-week non-supervised remote PR programme in patients with COPD; a mean difference of 3.8 repetitions was found in the 1-min STS before and after the programme,[11] which was slightly higher than the mean change of 3.1 repetitions in this service evaluation. The longer duration could have impacted on the effectiveness of the programme. Our service evaluation proposes an MCID of three repetitions for the 1-min STS.

STRENGTHS AND LIMITATIONS

The strengths of this service evaluation included the different anchor-based methods used to derive the MCID for the 1-min STS after remote exercise-based interventions. Despite the multiple methods used, the range of valid MCID estimates generated was relatively narrow; therefore, it was practical to determine one value for the MCID. On the contrary, only weak correlations were found between the 1-min STS and the chosen external anchors, impacting the reliability of the MCID estimates. Therefore, different external anchors could be used in future studies to derive MCID estimates with higher credibility.

CONCLUSION

This service evaluation study suggested an improvement of at least three repetitions to be the MCID of the 1-min STS after a remote exercise-based intervention. However, this is only a tentative value based on poor correlations with external anchors. Results also showed the 1-min STS to be responsive to changes resulting from remote interventions, making it a potential alternative to the 6MWT.

Key points

- The 1-min STS test was responsive to change after a remote exercise-based programme, making it a potential alternative to the 6MWT.
- Although the proposed MCID was three repetitions, further studies are required to increase the credibility of this MCID.
- A remote home-based self-management programme was found to be beneficial in improving exercise capacity and HRQoL.

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