

Supplement: Comparative measurement properties of constant work rate cycling and the endurance shuttle walking test in COPD: the TORRACTO® clinical trial

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Exercise testing methods

Patients were not permitted to eat or consume any caffeinated drinks for at least 2 hours before the exercise tests. The seat height was set for each patient at their first visit and maintained for all subsequent visits.

Cycle ergometry

Cycle ergometry was conducted on an electronically braked cycle ergometer. Subjects breathed through a mouthpiece/mask attached to a transducer capable of sensing bidirectional flow. The valve set-up was adjusted to a fixed height for each subject, thus ensuring a relatively fixed position of the torso. Inspiratory and expiratory flows were measured by a flow meter, from which tidal volume was integrated. Expired gas was directed to an expired gas analysis system, and oxygen saturation by pulse oximetry and electrocardiographic monitoring were carried out continuously throughout testing.

Endurance time was determined using a stopwatch.

Work-rate for the constant work rate cycle ergometry (CWRCE) was determined in an incremental cycle ergometry test, in which patients started pedalling with a load of 0W for 1 minute before the work rate was increased and the stopwatch started. Work rate was increased every minute in increments of 10W. Patients were encouraged to continue pedalling at their self-selected frequency (50–90 revolutions per minute) for as long as possible. Patients received continuous standardised encouragement by a member of the

trial team to maintain the pedalling frequency. Maximal work capacity was defined as the highest work rate that is maintained for at least 30 seconds.

For subsequent CWRCE tests, patients cycled for 1 minute with 0W load; the work rate was then increased to 75% of the maximal work capacity and patients were encouraged to maintain their cycle frequency for as long as possible.

ESWT

The endurance shuttle walking test (ESWT) was performed in a subset of patients at sites with experience of the test and/or suitable infrastructure and personnel. The shuttle walk test was performed on a flat, straight walking track, in a quiet treatment area at least 12 metres in length and approximately 2 metres wide, and clear of hospital traffic and obstacles. Subjects walked, jogged or ran back and forth, in loops of 10 metres. Cones were placed half a metre from the end (hence they were 9 metres apart). The subject had to keep pace with the pre-recorded auditory signal such that he/she completes a turn as each audio signal sounds. Patients continued until they were too breathless or fatigued to continue, could not keep up with the auditory signals, or were unable to continue safely.

Speed for the ESWT was determined by an incremental shuttle walking test. In this test, patients walked/jogged/ran up and down a 10-metre course at a speed dictated by an audio signal. The speed increased once every minute, starting at 0.5 m/s up to 2.37 m/s. Every change in speed was indicated by a triple audio signal (triple bleep). Patients were encouraged in a standardised way to either keep the pace or catch up if lagging behind and were asked to continue until they were limited by symptoms, unable to maintain the pace or unable to continue safely. The distance completed was recorded and using this the speed of

walking on the ESWT that corresponded to 85% of VO₂ peak was calculated (see Supplementary Figure 1).¹

Test standardisation measures

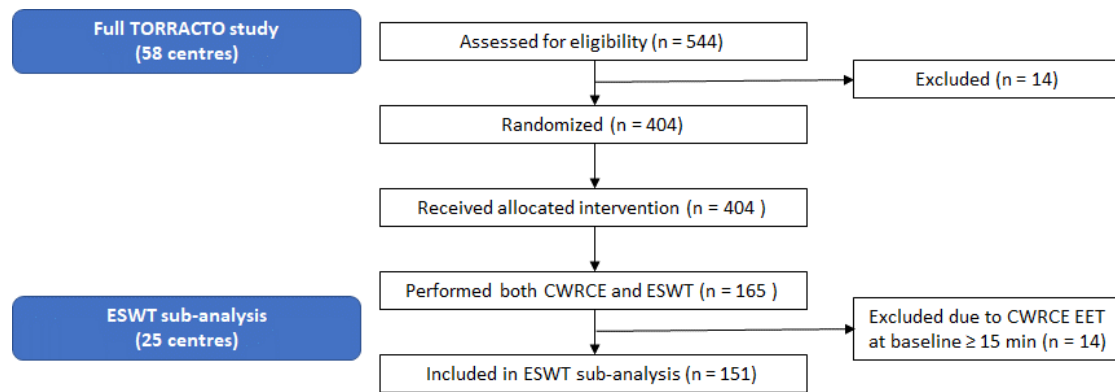
Trial centres were selected to ensure investigators and their staff were qualified to conduct the trial and that the facilities were adequate for trial conduct.

Great care was taken to ensure that all exercise tests were performed according to the highest current published standards on cardiopulmonary exercise testing.

Detailed training on the conduct of the exercise tests was provided to site staff at pre-study Investigator Meetings, including a workshop in which all participants observed the conduct of the exercise tests. A clinical research associate (CRA) at each site checked that all site personnel conducting the exercise tests had sufficient qualifications, and that they demonstrated competency in conducting the tests on a healthy volunteer. In addition, a global exercise trainer was contracted by the sponsor to work with selected exercise specialists in each country to ensure consistency in the conduct of the cycle ergometry tests and measurements. Sites were not able to enrol patients until signed copies of all proficiency tests were received from the regional trainer. During the study, the CRAs were responsible for checking the exercise data and identifying any concerns. To supplement the information on exercise testing in the protocol, a Manual of Procedures was developed. Sites were also required to perform a monthly biological quality control test using a healthy volunteer to ensure stability of the equipment and gas analysis systems.

Reference

1. Singh S. Endurance Shuttle Walk Test Conversion Table, <https://www.leicestershospitals.nhs.uk/aboutus/departments-services/pulmonary-rehabilitation/for-health-professionals/endurance-shuttle-walk/> (accessed October 14 2019).

Supplementary Figure S1: Patient selection

Supplementary Figure S2

Endurance Shuttle Walk Test Conversion Table¹

ESWT level corresponding to 85% VO₂ peak based on ISWT walking distance. The distance walked and the speed (from ISWT) are used to approximate the ESWT level needed to achieve 85% VO₂ peak.

<i>Distance Walked (m)</i>	<i>Speed km/h</i>	<i>ESWT level</i>	<i>Distance Walked (m)</i>	<i>Speed km/h</i>	<i>ESWT level</i>	<i>Distance Walked (m)</i>	<i>Speed km/h</i>	<i>ESWT level</i>
10	1.78	1	230	3.6	7	450	5.14	13
20	1.78	1	240	3.6	7	460	5.54	14
30	1.78	1	250	3.79	8	470	5.54	14
40	1.78	1	260	3.79	8	480	5.54	14
50	1.78	1	270	4.11	9	490	5.54	14
60	1.78	1	280	4.11	9	500	5.54	14
70	2.09	2	290	4.11	9	510	5.54	14
80	2.09	2	300	4.36	10	520	5.54	14
90	2.44	3	310	4.36	10	530	5.76	15
100	2.44	3	320	4.36	10	540	5.76	15
110	2.44	3	330	4.65	11	550	5.76	15
120	2.72	4	340	4.65	11	560	5.76	15
130	2.72	4	350	4.65	11	570	6	16
140	3	5	360	4.65	11	580	6	16
150	3	5	370	4.65	11	590	6	16
160	3	5	380	4.97	12	600	6	16
170	3.27	6	390	4.97	12	610	6	16
180	3.27	6	400	4.97	12	620	6	16
190	3.27	6	410	4.97	12	630	6	16
200	3.6	7	420	4.97	12	640	6	16
210	3.6	7	430	5.14	13	650	6	16
220	3.6	7	440	5.14	13	660	6	16

Reproduced from <https://www.leicestershospitals.nhs.uk/aboutus/departments-services/pulmonary-rehabilitation/for-health-professionals/endurance-shuttle-walk/>

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Supplementary table S1: Participating centres

No. centres participating in the ESWT sub-study	25
No. centres with 1–4 participating patients	11
No. centres with 5–10 participating patients	11
No. centres with >10 participating patients	3