post-hospitalisation for an AECOPD, is acceptable and feasible.

**Methods** A mixed method feasibility study was conducted including a parallel, two-group randomised controlled trial (RCT) (control group: usual HaH care; intervention group: usual care plus home-based exercise training) with convergent qualitative components (interviews: patients, family carers, researchers; focus groups: healthcare professionals [HCPs]).

**Results** 16/132 patients screened were recruited to the RCT with 8 allocated to each group and one withdrawn prior to receiving HaH care (56% were male, mean [SD] age: 74 [9] years, median [IQR] FEV₁: 29 [21, 40] percent predicted, 87% with an eMRC dyspnoea score of 4, 5a or 5b). Four vs eight and four vs seven attended four week and three-month follow-up assessments in the control and intervention groups respectively. There was no evidence of contamination in the control group. 25% of patients allocated to the intervention group were unable to receive the intervention due to Covid-19. The questionnaire-based outcomes were more complete and appeared more acceptable to patients than physical measures, with very poor uptake for physical activity monitoring via accelerometry. Qualitative findings (interviews: five patients, two family carers, four researchers; focus groups: PR and HaH service HCPs) demonstrated that trial and intervention processes were acceptable, clinically beneficial and safe, but did not explain the disparity between questionnaire-based vs physical outcome measure completion rates.

**Conclusion** The findings suggest an efficacy trial which investigates home-based exercise training integrated within a HaH service following hospitalisation for an AECOPD would be safe and acceptable to patients, family carers, HCPs and researchers alike, and is qualitatively felt to be of clinical benefit. However, additional piloting is required to optimise intervention fidelity and study processes given the low recruitment rates, high drop out of the control group and poor uptake of some physical assessments.

**REFERENCES**


2. Updated NICE guidance on chronic fatigue syndrome. BMI 2020.
COPD exacerbations: prevention, treatment, recovery

### Abstract S25 Table 1
Preliminary CPET data for patients with persistent symptoms following non-hospitalised SARS-CoV2 infection, demonstrating reduced levels of aerobic fitness compared to % predicted, as assessed by oxygen uptake at peak exercise, oxygen uptake at anaerobic threshold (AT) and O2 pulse.

<table>
<thead>
<tr>
<th>Patient number</th>
<th>Peak oxygen uptake % predicted</th>
<th>Peak AT % of peak oxygen uptake</th>
<th>O2 pulse % predicted</th>
<th>VEVO2 slope</th>
<th>Breathing reserve (litres/minute)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>110</td>
<td>69</td>
<td>101</td>
<td>26.9</td>
<td>59</td>
</tr>
<tr>
<td>2</td>
<td>70</td>
<td>31</td>
<td>76</td>
<td>22.6</td>
<td>138</td>
</tr>
<tr>
<td>3</td>
<td>91</td>
<td>45</td>
<td>80</td>
<td>31.4</td>
<td>36</td>
</tr>
<tr>
<td>4</td>
<td>108</td>
<td>63</td>
<td>93</td>
<td>28.1</td>
<td>84</td>
</tr>
<tr>
<td>5</td>
<td>81</td>
<td>46</td>
<td>78</td>
<td>27.7</td>
<td>31</td>
</tr>
<tr>
<td>6</td>
<td>81</td>
<td>44</td>
<td>82</td>
<td>26.4</td>
<td>71</td>
</tr>
<tr>
<td>7</td>
<td>111</td>
<td>47</td>
<td>106</td>
<td>25.4</td>
<td>69</td>
</tr>
<tr>
<td>8</td>
<td>61</td>
<td>33</td>
<td>70</td>
<td>27.5</td>
<td>96</td>
</tr>
<tr>
<td>9</td>
<td>64</td>
<td>43</td>
<td>78</td>
<td>29.6</td>
<td>40</td>
</tr>
</tbody>
</table>

### EFFECT OF SINGLE-INHALER EXTRAINE BECLOMETASONE/FORMOTEROL/GLYCOPHYRINUM PMDI (BDP/FF/GB) COMPARED WITH TWO-INHALER FLUTICASONE FURANO/VI/BERALONER DPI + TIOTROPNI DPI (FLF/VIL+TIO) TRIPLE THERAPY ON HEALTH-RELATED QUALITY OF LIFE (HRQOL) IN PATIENTS WITH COPD: THE TRISTAR STUDY

1. M Kots, 2G Georges, 3A Guasci, 4 C Vogelmeier. 1Chiesi Farmaceutici S.p.A., Parma, Italy; 2Chiesi USA, Cary (NC), USA; 2Klinik für Pneumologie, Marburg, Germany
10.1136/thorax-2021-BTSabstracts.32

### Rationale
To evaluate the effect of single-inhaler extrafine BDP/FF/GB pMDI vs two-inhaler (FLF/VIL+TIO) triple therapies on HRQoL in patients with COPD to support market access dossiers in Europe.

### Methods
In this phase III, multicenter, randomized study patients received BDP/FF/GB 100/6/12.5 μg extrafine pMDI 2 inhalations BID or FLF/VIL 100/25 μg 1 inhalation QD + TIO 18 μg/d 1 inhalation QD for 26 weeks. The primary efficacy variable was the change from baseline in the St. George Respiratory Questionnaire (SGRQ) total score at Wk 26 in the intent-to-treat (ITT) and per-protocol (PP) populations, with non-inferiority defined as an upper confidence limit of the adjusted mean difference between treatments < 4 units. Secondary endpoints included SGRQ response (defined as a decrease of ≥4 units in total score), change in pre-dose FEV1 at Wk 26, and rate of moderate-to-severe COPD exacerbations over 26 weeks.

### Results
A total of 1157 patients were randomized (1095 completed), of whom 53.5% were < 65 years of age, 75.5% males, 54.4% current smokers and 84.1% had 1 exacerbation in the past year. Baseline SGRQ total score was 52.8. In both groups the adjusted mean change from baseline in the SGRQ total score significantly decreased at Wk 26, with -6.77 for BDP/FF/GB and -7.82 for FLF/VIL+TIO in the ITT population. Non-inferiority was demonstrated in both ITT and PP populations, with an upper confidence interval of the adjusted mean change below 4. SGRQ response rates at Week 26 were similar (51.1% and 53.0%) and pre-dose FEV1 mean changes from baseline were 59 and 105 mL (p < 0.001). Adjusted rate ratio was 1.086 (p = 0.525) for moderate-to-severe exacerbations and 0.568 for severe exacerbations (p = 0.068). Serious TEAEs occurred in 39 (6.7%) and 56 (9.7%) in each group, respectively.

### Conclusion
Treatment with BDP/FF/GB extrafine pMDI for 26 weeks significantly improved HRQoL as measured by the SGRQ and was non-inferior compared to FLF/VIL+TIO. Lung function improved with both treatments but more so with FLF/VIL+TIO whereas a larger reduction in severe exacerbations occurred with extrafine BDP/FF/GB. Both treatments were safe and well tolerated.

Please refer to page A188 for declarations of interest related to this abstract.

### Background and Objectives
Triple therapy with inhaled corticosteroid, long-acting muscarinic antagonist and long-acting β2-agonist (ICS/LAMA/LABA) is recommended for patients with COPD who continue to experience exacerbations on dual therapy (LAMA/LABA or ICS/LABA). Adherence to multiple-inhaler triple therapy (MITT) has previously been shown to be inadequate. Single-inhaler triple therapy, such as fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI), may improve adherence due to decreased treatment complexity. This study investigates the real-world comparative adherence to FF/UMEC/VI vs any MITT combination in UK patients with COPD.

### Methods
This retrospective analysis of linked UK primary and secondary care data (Clinical Practice Research Datalink [CPRD] Aurum; Hospital Episode Statistics [HES]) indexed patients with COPD on the first prescription of FF/UMEC/VI