Evaluating the Impact and Benefits of Fluticasone Furoate/Vilanterol in Individuals with Asthma or COPD: A Mixed-Methods Analysis of Patient Experiences

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ABSTRACT

Introduction: This study evaluated patients' experiences with fluticasone furoate/vilanterol (FF/VI) combination therapy in UK patients with asthma or chronic obstructive pulmonary disease (COPD).
Methods: Participants aged ≥ 18 years, with self-reported, physician-diagnosed asthma or COPD (≥ 1 year) who had been receiving FF/VI (≥ 3 months) were recruited from UK primary

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care. This two-phase, mixed-methods study consisted of a semi-structured, telephone-interview phase (qualitative) and a self-completed online/paper-survey phase (quantitative).
Results: The telephone-interview phase included 50 individuals [asthma, $n = 25$; COPD, $n = 25$; mean age (SD) 56.7 years (13.3); 50% female]. Of these, 21 with asthma reported that their condition was stable/well controlled and 13 with COPD felt their condition was manageable. Most participants found FF/VI easy to use (asthma, 25; COPD, 23), easy to integrate into their daily routine (asthma, 25; COPD, 24), and able to control symptoms for ≥ 24 h (asthma, 14; COPD, 16). During the survey phase, 199 individuals were recruited [asthma, $n = 100$; COPD, $n = 99$; mean age (SD) 63.6 years (15.1); 59.3% female]. Most participants were satisfied/very satisfied with the efficacy of FF/VI in terms of all-day symptom relief (asthma, 84%; COPD, 75%) and found FF/VI easy/very easy to fit into their daily routine (asthma, 99%; COPD, 96%), easy/very easy to use (asthma, 97%; COPD, 92%), and convenient/very convenient to take as instructed (asthma, 95%; COPD, 93%). Significantly more individuals with asthma (87% versus 46%, $P < 0.001$) and numerically more individuals with COPD (84% versus 76%, $P = 0.055$) were satisfied/very satisfied with FF/VI compared with their most recent previous maintenance medication.

Conclusion: The majority of individuals in this study had confidence in FF/VI and were satisfied or very satisfied with various key attributes of the treatment.
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INTRODUCTION

Asthma and chronic obstructive pulmonary disease (COPD) are common respiratory conditions in the UK [1, 2]. Current treatment guidelines for adults with asthma recommend inhaled corticosteroids (ICS) as regular preventer therapy, with "step-up" therapy [such as an inhaled long-acting β_2-agonist (LABA)] as necessary [3]. ICS/LABA treatments are also recommended as an option for patients with COPD [4]. ICS/LABA treatments are typically administered twice daily (e.g., fluticasone propionate/salmeterol) [5].

Both asthma and COPD can significantly affect the lives of people living with these conditions, who may experience substantial limitations in quality of life (QoL) and significant negative emotional impacts [6–9]. Shortness of breath is a key symptom of both asthma and COPD, which individuals typically report as the worst aspect of their condition [10]. Notable physical limitations associated with asthma and COPD include disturbed sleep and a reduced ability to socialize and undertake desired physical activities, while emotional impacts range from embarrassment to depression and fear [10–12]. Key attributes for medication in the treatment of asthma and COPD are the ability to reduce symptom impact and to enable undisturbed sleep [10, 13].

Fluticasone furoate/vilanterol (FF/VI) 100/25 µg is the first once-daily, inhaled ICS/LABA combination for the maintenance treatment of asthma [14, 15] and COPD [16, 17]. FF/VI is delivered via the ELLIPTA inhaler, a device

that has been shown to be preferred and considered easy to use by patients in clinical studies [18–20]. The once-daily administration and 24-h efficacy [21, 22] of FF/VI may be associated with clinical benefits to patients in addition to convenience, such as reduced nocturnal symptoms and related improvements in sleep and QoL. However, patient perceptions of FF/VI and the potential impact of treatment on daily life are not fully understood.

This two-phase study aimed to evaluate participants' experiences with, and perceptions of, FF/VI in the treatment of asthma and COPD.

METHODS

Study Design and Objective

In the first phase, we assessed the experiences of individuals who were receiving treatment with FF/VI via semi-structured interviews. In the second phase, we used a patient satisfaction survey to quantify participants' experiences and preferences with FF/VI on specific aspects of their treatment, including a comparison with their most recent previous inhaler treatment.

The study protocol and all study materials were reviewed and approved by the NHS Health Research Authority, UK (research ethics committee reference 16/LO/0836l; IRAS project ID 206320).

Participants

Participants with asthma or COPD were recruited through UK primary care on the basis of referrals from healthcare professionals (HCPs). Key inclusion criteria were age ≥ 18 years; a diagnosis of asthma, COPD, or asthma–COPD overlap (ACO) from a physician for ≥ 1 year; and current prescription of FF/VI for asthma or COPD and use of FF/VI for ≥ 3 months. Individuals could only participate in one phase of the study.

A broad participant sample for each condition was sought in both phases and based on age, gender, and disease control; asthma control and COPD impact were assessed by the Asthma

Control Test™ (ACT) [23] and the COPD Assessment Test™ (CAT) [24], respectively. In total, 50 participants (asthma, $n = 25$; COPD, $n = 25$) were recruited for phase 1 (interviews) and 200 participants (asthma, $n = 100$; COPD, $n = 100$) were recruited for phase 2 (survey). Written, verbal, or electronic (via tick boxes) informed consent was obtained from all participants.

Phase 1: Qualitative Interviews

Procedure

Prior to the interview, participants were asked socio-demographic questions and completed the ACT [23] or CAT [24]. Any participant with ACO was interviewed about COPD and completed the CAT. The ACT scoring range is 5–25; scores < 20 indicate asthma that has not been controlled during the preceding 4 weeks [25]. The CAT scoring range is 0–40, with scores > 20 representing high disease impact and scores < 10 representing low disease impact [26, 27].

Participants completed individual, 60-min telephone interviews, conducted according to the approved individual interview guides. Question topics included frequency of use of FF/VI, thoughts on FF/VI as a once-daily medication, ease of use of FF/VI, current condition and symptoms, symptom control, length of control, change in QoL, impact of FF/VI on sleep, side effects, and confidence in FF/VI. Some patients were not asked every question.

Safety

This study was non-interventional and therefore presented minimal risk to participants. Any adverse events suspected to be associated with FF/VI were reported to the GSK Central Safety Department.

Analysis

Socio-demographic and ACT/CAT data were summarized using descriptive statistics. Interviews were transcribed verbatim and analyzed using a qualitative software tool, MAXQDA (v11.0.4 or above, VERBI GmbH 2015). A codebook based on the interview guide was developed and used to code transcripts; codes were analyzed using thematic analysis [28]. The most common themes that arose from the qualitative interviews were translated into closed-ended survey questions.

Phase 2: Quantitative Patient Surveys

The survey comprised quantitative questions on use of FF/VI (including frequency, administration timings, and ease/convenience) and satisfaction with the impacts of FF/VI [including efficacy (speed of onset, duration of symptom relief) and impacts on work, sleep, and QoL]. Satisfaction was rated on a 5-point scale (ranging from very dissatisfied to very satisfied). Participants also stated their most recent previous asthma/COPD maintenance medication prior to FF/VI and, unless FF/VI was their first medication, answered the same set of questions as for FF/VI. The order of the FF/VI and recent medications sections were randomized to control for any order effects relating to the interview questions. Additionally, three open-ended questions were included at the end of the FF/VI section that asked if there was anything the participant would rate as more positive/negative about FF/VI, and whether they would like to continue taking FF/VI and why. The content of the survey was developed using the results of the phase 1 qualitative interviews conducted with asthma and COPD patients prescribed FF/VI. A pilot version of the survey was tested in cognitive interviews; further details are available in the online supplement.

Main Survey Procedure

In addition to questions about FF/VI and recent inhaler medication, participants were asked socio-demographic questions and completed the ACT or CAT [23, 24]. To ensure a broad sample, participants were grouped by disease control/impact according to ACT score [uncontrolled asthma (< 15); not well or partly controlled asthma [15–19]; controlled asthma (≥ 20)] or CAT score [high-impact COPD (> 20); medium-impact COPD [10–20]; low-impact COPD (< 10)], with patients recruited proportionately to each group whenever possible. Participants completed the survey online or at

their primary care site via tablet. Paper versions were available for individuals who were unable to travel or access the online survey.

Analysis

Demographic data, ACT/CAT scores, and survey responses were summarized using descriptive statistics. Quantitative analysis was undertaken using SPSS v19.0 and v24.0, with independent group comparisons (asthma versus COPD, site-complete versus self-complete) made using chi-squared statistics with testing for linear trend. Wilcoxon matched pairs signed-rank tests were used to compare aspects of FF/VI and recent maintenance medication within asthma and COPD groups.

Responses to the three free-text items were analyzed using a qualitative software tool, MAXQDA (v11.0.4 or above, VERBI GmbH 2015). Each item was analyzed using thematic analysis.

Compliance with Ethics Guidelines

This was a non-interventional observational study that did not alter the use or dosage of any treatment or alter participant perspectives in any way, and was not required to be registered on a public database. The study is posted on the GSK Clinical Study Register https://www.gsk-clinicalstudyregister.com/ Study No. 204888. All patients provided informed consent immediately before beginning the survey using the paper or online method that they used for the survey. The cognitive interview stage of the survey was reviewed and approved by an institutional review board (Salus IRB; protocol number 0018-0681). The survey stage of the study was approved by the NHS Health Research Authority (research ethics committee reference 16/LO/0836l; IRAS project ID 206320).

RESULTS

Phase 1: Qualitative Interviews

Participants

In total, 50 participants completed the qualitative interviews [asthma, $n = 25$; COPD, $n = 25$

(COPD population includes one participant with ACO)]. The mean [standard deviation (SD)] age of participants with asthma or COPD was 52.6 (14.4) and 63.1 (9.8) years, respectively. Participants' mean (SD) disease durations were 20.84 (15.85) years for asthma and 10.42 (6.78) years for COPD; 24% of participants with asthma and 48% with COPD were current smokers (Table 1).

The mean (SD) CAT score for participants with COPD was 22.40 (9.50), indicating a high impact of disease. The mean (SD) ACT score for participants with asthma was 19.72 (4.61), with 15 patients (60%) having ACT scores > 19.

Participants had been prescribed FF/VI for mean (SD) of 0.99 (0.45) years. Ventolin/salbutamol was the next most commonly taken medication. Table S1 contains a full list of current and previous medications.

Participants' Usage of FF/VI

All but one participant took FF/VI once daily (Table 2). One participant with asthma took FF/VI twice daily on the basis of a recommendation from their doctor, but reported that once-daily dosing would be preferable. Most considered FF/VI easy to use (asthma, $n = 25$; COPD, $n = 23$) and felt that FF/VI could be integrated into their daily routine without disruption (asthma, $n = 24$; COPD, $n = 25$). Many participants (asthma, $n = 19$; COPD, $n = 15$) indicated that they preferred taking a once-daily maintenance medication rather than a more frequent dosage.

Nine participants (asthma, $n = 5$; COPD, $n = 4$) considered that a physical aspect of FF/VI affected their frequency of use (Table 2), with the most frequently reported response being that the medication left a powdery taste in the mouth (asthma, $n = 1$; COPD, $n = 3$).

Three participants with asthma and five with COPD reported feeling the effects of FF/VI immediately; however, 12 participants with asthma and four participants with COPD could not feel the medication taking effect (Table 2).

Participant Perceptions of FF/VI: Symptoms and Disease Control

The majority of participants with asthma ($n = 21$) considered that their condition was

Table 1 Participant demographics and clinical characteristics

Characteristic	Phase 1: qualitative interviews			Phase 2: patient survey		Total (N = 199)
	Participants with asthma (N = 25)	Participants with COPD (N = 25)	Total (N = 50)	Participants with asthma (N = 100)	Participants with COPD (N = 99)	
Mean age, years (SD)	52.6 (14.4)	63.1 (9.8)	56.7 (13.3)	57.2 (17.0)	70.0 (9.2)	63.6 (15.1)
Female, n (%)	15 (60.0)	10 (40.0)	25 (50.0)	63 (63.0)	55 (55.6)	118 (59.3)
White-British ethnicity, n (%)	25 (100.0)	25 (100.0)	50 (100.0)	92 (92.0)	98 (99.0)	190 (95.5)
Marital status, n (%)						
Single	4 (16.0)	4 (16.0)	8 (16.0)	22 (22.0)	11 (11.1)	33 (16.6)
Married	14 (56.0)	12 (48.0)	26 (52.0)	53 (53.0)	54 (54.5)	107 (53.8)
Partnership	1 (4.0)	1 (4.0)	2 (4.0)	8 (8.0)	4 (4.0)	12 (6.0)
Divorced/ separated	3 (12.0)	7 (28.0)	10 (20.0)	8 (8.0)	13 (13.1)	21 (10.6)
Widowed	2 (8)	1 (4)	3 (6)	9 (9.0)	17 (17.2)	26 (13.1)
Other	1 (4)	0	1 (2)	0	0	0
Employment, n (%)						
Employed full-time	9 (36.0)	1 (4.0)	10 (20.0)	31 (31.0)	5 (5.1)	36 (18.1)
Employed part-time	2 (8.0)	4 (16.0)	6 (12.0)	7 (7.0)	4 (4.0)	11 (5.5)
Self-employed	1 (4.0)	0	1 (2.0)	2 (2.0)	–	2 (1.0)
Student	1 (4.0)	0	1 (2.0)	1 (1.0)	–	1 (0.5)
Retired	9 (36.0)	14 (56.0)	23 (46.0)	39 (39.0)	75 (75.8)	114 (57.3)
Unemployed	2 (8.0)	0	2 (4.0)	7 (7.0)	2 (2.0)	9 (4.5)
Long-term sickness	1 (4.0)	3 (12.0)	4 (8.0)	7 (7.0)	8 (8.1)	15 (7.5)
Registered disabled	0	2 (8.0)	2 (4.0)	0	0	0
Seeking work	0	0	0	2 (2.0)	2 (2.0)	4 (2.0)
Unpaid carer	0	0	0	3 (3.0)	3 (3.0)	6 (3.0)
Stay at home	0	0	0	1 (1.0)	–	1 (0.5)
Other	0	1 (4.0)	1 (2.0)	0	0	0
Smoker, n (%)						
Yes	6 (24.0)	12 (48.0)	18 (36.0)	14 (14.0)	23 (23.2)	37 (18.6)
No	11 (44.0)	1 (4.0)	12 (24.0)	46 (46.0)	10 (10.1)	56 (28.1)
Former	8 (32.0)	12 (48.0)	20 (40.0)	40 (40.0)	66 (66.7)	106 (53.3)

Table 1 continued

Characteristic	Phase 1: qualitative interviews			Phase 2: patient survey		Total (N = 199)
	Participants with asthma (N = 25)	Participants with COPD (N = 25)	Total (N = 50)	Participants with asthma (N = 100)	Participants with COPD (N = 99)	
Pet owner, n (%)						
Yes	15 (60.0)	12 (48.0)	27 (54.0)	42 (42.0)	36 (36.4)	78 (39.2)
No	3 (12.0)	6 (24.0)	9 (18.0)	39 (39.0)	28 (28.3)	67 (33.7)
Former	7 (28.0)	7 (28.0)	14 (28.0)	19 (19.0)	35 (35.4)	54 (27.1)
Currently taking rescue medication, n (%)	–	–	–	72 (72.0)	92 (92.9)	164 (82.4)
Mean (SD) disease duration, years	20.84 (15.9)[a]	10.42 (6.8)[a]	–	23.9 (19.4)[b]	8.1 (8.3)[b]	15.9 (16.9)
Mean (SD) ACT score	19.7 (4.6)	–	–	19.0 (4.6)	–	–
ACT score category, n (%)						
≤ 19 (uncontrolled)	10 (40.0)	–	–	44 (44.0)	–	–
> 19 (controlled)	15 (60.0)	–	–	56 (56.0)	–	–
Mean (SD) CAT score	–	22.40 (9.50)	–	–	17.7 (9.5)	–
CAT score category, n (%)						
< 10 (low impact)	–	2 (8.0)	–	–	22 (22.2)	–
10–20 (medium impact)	–	9 (36.0)	–	–	39 (39.4)	–
≥ 21 (high impact)	–	14 (56.0)	–	–	38 (38.4)	–

ACT Asthma Control Test[TM], *CAT* COPD Assessment Test[TM], *COPD* chronic obstructive pulmonary disease, *SD* standard deviation

[a] Based on interview data (missing data, n = 6 for each group)

[b] Based on available medical records (asthma, n = 90; COPD, n = 94)

currently well managed and controlled, whereas only 13 participants with COPD considered their current condition and symptoms to be manageable (Table 2).

A high proportion of participants (asthma, n = 18; COPD, n = 16) reported that their symptoms were controlled after taking one dose of FF/VI. Of those whose asthma symptoms were not fully controlled, all seven indicated that they felt an improvement in symptom control since beginning treatment with FF/VI. Of the seven patients with COPD that were asked, five felt their symptoms were controlled better after a dose of FF/VI compared with

Table 2 Symptom control and frequency of FF/VI use in participants with asthma and COPD (phase 1: qualitative interviews)

Parameter, n^a	Participants with asthma (N = 25)	Participants with COPD (N = 25)
Time of treatment		
Morning (once-daily dosing)	20	23
Evening (once-daily dosing)	4	2
Morning and evening (twice-daily dosing)	1	0
Previously missed dose	14	7
Physical aspects of medication affect frequency of use		
Yes	5	4
No	17	13
Speed of FF/VI effect		
Immediate	3	5
"A few" minutes	4	0
5–15 min	4	5
30 min	0	3
45 min	1	0
1–2 h	0	2
Did not notice/know or could not feel medication taking effect	12	4
Current symptom control		
Manageable and controlled	21	13
Varied	0	2
Not very good	0	5
Worsening	0	2
Controlled symptoms after a dose of FF/VI	18	16

Table 2 continued

Parameter, n^a	Participants with asthma (N = 25)	Participants with COPD (N = 25)
Improvement in symptom control since beginning treatment with FF/VI	7	5
Duration of symptom control		
> 24 h	3	0
All day	11	16
Up to 24 h	4	0
Morning	0	1
1 h	0	1
Didn't keep track	1	4
Consistency of symptom control		
Same length of time	18	13
Consistent throughout the day	15	6

COPD chronic obstructive pulmonary disease, *FF/VI* fluticasone furoate/vilanterol

^{a} Not all participants responded to every question

previous treatments (Table 2). When asked about their symptoms since starting on FF/VI, one participant with asthma stated, "I know that I feel better in myself, I know that I'm breathing easier and I know it's only since I started taking [FF/VI] so I can only assume it's the [FF/VI] that's done this". Another participant noted, "I do still have episodes of feeling chesty, what I class as chesty and I still cough a lot which is another symptom of asthma so there are things that still go on as part of the asthma, they never 100% go away".

Eleven participants with asthma and 16 with COPD felt that their symptoms were controlled all day, while three participants with asthma felt their symptoms were possibly controlled for longer than 24 h (Table 2). Seventeen participants with asthma and 11 with COPD considered that the length of symptom control was

"better" with FF/VI compared with previous medications, although five participants with COPD considered that symptom control with FF/VI was the same. Some COPD participants were not sure whether their symptoms were controlled after a dose of FF/VI ($n = 2$), felt their symptoms were sometimes controlled ($n = 1$), reported that FF/VI treatment "doesn't really make a lot of difference" to symptom control ($n = 1$), and felt unable to compare FF/VI with their previous treatment because of the number of other medications they were taking ($n = 2$).

Medications mentioned in comparison to FF/VI via the ELLIPTA inhaler included Becotide, Seretide, Symbicort, Clenil, beclomethasone, Qvar, and salbutamol by asthma patients, and Seretide, Genuair, Spiriva, and Fostair by COPD patients.

Effects of FF/VI on Participants' QoL

The effect of FF/VI on participants' daily activities varied across the two conditions, ranging from unchanged ($n = 2$) to improved ($n = 2$; because of reduced reliance on reliever inhaler) in the asthma group and worsening ($n = 2$; because of COPD deterioration) to improved ($n = 3$) in the COPD group. The majority of participants questioned about physical activities reported improvements (asthma, $n = 13$; COPD, $n = 15$), whereas six asthma and seven COPD participants reported no change since starting treatment with FF/VI. Specific improvements included positive impact on walking, exercise, climbing the stairs, and the ability to take up new physical activities; generally, participants with asthma were able to do more and/or for longer, while participants with COPD found physical activities easier than before starting treatment with FF/VI. One participant with COPD stated, "if I take [FF/VI] in the morning […] I can do my normal activities for the day, that I wouldn't be able to do normally anyway with my condition". Nine participants with asthma and one participant with COPD felt that FF/VI had a positive impact on their social life; those with asthma felt more confident when socializing as they were either less concerned about having an asthma attack or less tired and breathless, and the participant with COPD reported that FF/VI made them feel

safe and secure. Seven asthma and 10 COPD participants, respectively, reported no change in their social life since starting treatment with FF/VI.

More participants with asthma than COPD considered that their sleep quality had improved with FF/VI treatment (asthma, $n = 13$; COPD, $n = 4$), largely owing to a reduction in the number of nighttime awakenings due to symptoms. Nine participants with asthma and 12 with COPD reported no change in their sleep quality, two of whom reported still waking during the night. One participant with COPD considered that their sleep quality had worsened since commencing FF/VI treatment.

The majority of participants with asthma ($n = 18$) and COPD ($n = 15$) did not report any side effects associated with treatment with FF/VI. Of the side effects that were reported, the most frequent were dry mouth (asthma, $n = 4$; COPD, $n = 7$) and thrush (asthma, $n = 3$; COPD, $n = 2$), none of which were reported as serious adverse events. When questioned further, seven participants with asthma and five with COPD indicated that avoiding side effects was important to them.

The majority of participants in both groups (asthma, $n = 24$; COPD, $n = 23$) felt confident with FF/VI treatment and, furthermore, 17 participants with asthma reported feeling "very confident" in their treatment. The most frequent reasons for confidence in FF/VI were the control of symptoms (asthma, $n = 12$; COPD, $n = 14$), reduced usage of their reliever medication (asthma, $n = 3$), increase in personal confidence (asthma, $n = 3$), and ease of use/convenience (COPD, $n = 3$). Two participants with COPD reported not feeling confident in FF/VI treatment because they did not feel the treatment had made a difference to their condition ($n = 1$) or as a result of medication side effects ($n = 1$). In general, however, participants reported a positive experience with FF/VI, with 20 participants with asthma and 15 with COPD considering FF/VI to be favorable compared with previous treatments. Further results of the impact of FF/VI in phase 1 are included in Table 2 and the online supplement.

Phase 2: Quantitative Survey

Participants

Two hundred participants completed the patient survey [asthma, $n = 100$; COPD, $n = 100$ (COPD population includes four participants with ACO)], of whom 197 (98.5%) completed the survey either online ($n = 152$) or via a tablet at their clinical site ($n = 45$). Two participants (1.5%) completed a paper version of the survey. Data from one participant with COPD (0.5%) who completed the paper survey was excluded from analysis because they received assistance from a family member in completing the survey; all other participants read and responded to either the online or paper survey themselves. Forty-seven participants (23.6%) completed the survey with assistance from the research team [asthma, $n = 15$ (15.0%); COPD $n = 32$ (32.3%)]; these individuals were generally older than those who self-completed the survey (mean age 69.5 versus 61.7 years, respectively). In total, data from 199 participants were analyzed (asthma, $n = 100$; COPD, $n = 99$).

The demographics and clinical characteristics of participants are shown in Table 1. The mean (SD) age of participants with asthma or COPD was 57.2 (17.0) and 70.0 (9.2) years, respectively. Participants with asthma had a mean (SD) disease duration of 23.9 (19.4) years, and those with COPD had a duration of 8.1 (8.3) years; 14.0% of participants with asthma and 23.2% with COPD were current smokers. The mean (SD) ACT score for participants with asthma was 19.0 (4.6), and 56.0% had an ACT score ≥ 20 (controlled). The mean (SD) CAT score for participants with COPD was 17.7 (9.5), and 22.2% had a CAT score < 10 (low impact). At the time of the survey, rescue medication was being taken by a higher number of individuals with COPD (92.9%) compared with asthma (72.0%).

Participants' Usage of FF/VI

Participants with asthma had been taking FF/VI for a mean (SD) of 1.4 (1.0) years and those with COPD for 1.9 (1.9) years (Table 3). The majority of participants in both groups reported taking FF/VI once daily (asthma, 86.0%; COPD, 82.8%) and as part of their morning routine (asthma, 87.0%; COPD, 93.9%). Almost all participants reported that FF/VI was easy or very easy to use (asthma, 97.0%; COPD, 91.7%) and fit into their daily routine (asthma, 99.0%; COPD, 96.0%), and the majority found it convenient or very convenient to take as instructed (asthma, 95.0%; COPD, 92.9%).

Participants' Satisfaction with FF/VI

Most participants reported being satisfied or very satisfied with the frequency at which FF/VI was taken (asthma, 92.0%; COPD, 80.8%) and its ability to control their symptoms (asthma, 91.0%; COPD, 74.7%). The majority of participants were satisfied or very satisfied with the speed of onset (asthma, 89.0%; COPD, 74.7%) and duration of FF/VI's effect (asthma, 90.0%; COPD, 75.8%), and were confident or very confident that it would relieve their symptoms all day (asthma, 84.0%; COPD, 70.7%). In almost all cases, the percentage of participants reporting satisfaction with the attributes of FF/VI was higher among participants with asthma than with COPD; some of these differences were statistically significant (Table 3).

Over three quarters of participants with asthma were satisfied or very satisfied with their ability to sleep through the night while taking FF/VI (78.0%) and with the level of impact FF/VI had on their ability to do physical or social activities (77.0% and 87.0%, respectively). For patients with COPD, 56.6% were satisfied or very satisfied with their ability to sleep through the night while taking FF/VI, with similar levels of satisfaction observed regarding the level of impact that FF/VI had on their ability to do physical or social activities (54.6% and 59.6%, respectively) (Table 3).

The majority of participants in both disease groups reported being satisfied or very satisfied with their overall experience of using FF/VI (asthma, 90.0%; COPD, 84.8%) (Table 3).

Most patents (asthma, 93.0%; COPD, 92.9%) reported that they would like to continue using FF/VI. Sample free-text responses to questions on participants' experience of FF/VI are included in the supplementary materials.

Table 3 Participants' experience and satisfaction with using FF/VI (phase 2: quantitative survey results)

Parameter	Participants with asthma ($N = 100$)	Participants with COPD ($N = 99$)	Chi-squared P value asthma versus COPD (trend)
Mean (SD) time taking FF/VI (self-reported), years	1.4 (1.0)	1.9 (1.9)	–
How often do you take FF/VI?[a], n (%)			–
Less than once a day	3 (3.0)	11 (11.1)	
Once a day	86 (86.0)	82 (82.8)	
Twice a day	12 (12.0)	6 (6.1)	
More often than twice a day	–	–	
When do you usually take FF/VI?[a], n (%)			–
As part of my morning routine	87 (87.0)	93 (93.9)	
Around lunchtime	–	2 (2.0)	
In the afternoon	–	–	
Around dinner time	1 (1.0)	–	
In the evening (after evening meal)	6 (6.0)	1 (1.0)	
Just before bedtime	18 (18.0)	7 (7.1)	
During the night	–	–	
How easy or difficult is it to use your FF/VI inhaler? n (%)			0.169 (0.012)
Very difficult	–	1 (1.0)	
Difficult	–	1 (1.0)	
Neutral	3 (3.0)	6 (6.1)	
Easy	63 (63.0)	70 (70.7)	
Very easy	34 (34.0)	21 (21.2)	
How easy or difficult is it to fit taking your FF/VI medication into your daily routine? n (%)			0.060 (0.007)
Very difficult	–	–	
Difficult	–	1 (1.0)	
Neutral	1 (1.0)	3 (3.0)	
Easy	67 (67.0)	78 (78.8)	
Very easy	32 (32.0)	17 (17.2)	
How convenient or inconvenient is it to take your FF/VI medication as instructed? n (%)			0.459 (0.133)
Very inconvenient	1 (1.0)	1 (1.0)	
Inconvenient	–	1 (1.0)	
Neutral	4 (4.0)	5 (5.1)	
Convenient	67 (67.0)	74 (74.7)	
Very convenient	28 (28.0)	18 (18.2)	

Table 3 continued

Parameter	Participants with asthma ($N = 100$)	Participants with COPD ($N = 99$)	Chi-squared P value asthma versus COPD (trend)
How satisfied or dissatisfied are you with the frequency you need to take FF/VI? n (%)			0.070 (0.010)
Very dissatisfied	1 (1.0)	1 (1.0)	
Dissatisfied	4 (4.0)	9 (9.1)	
Neutral	3 (3.0)	9 (9.1)	
Satisfied	63 (63.0)	64 (64.6)	
Very satisfied	29 (29.0)	16 (16.2)	
How satisfied or dissatisfied are you with the ability of FF/VI to control your symptoms? n (%)			0.002 (< 0.001)
Very dissatisfied	–	–	
Dissatisfied	4 (4.0)	10 (10.1)	
Neutral	5 (5.0)	15 (15.2)	
Satisfied	61 (61.0)	62 (62.6)	
Very satisfied	30 (30.0)	12 (12.1)	
How satisfied or dissatisfied are you with the amount of time it takes FF/VI to start working? n (%)			0.093 (0.010)
Very dissatisfied	–	1 (1.0)	
Dissatisfied	1 (1.0)	5 (5.1)	
Neutral	10 (10.0)	19 (19.2)	
Satisfied	74 (74.0)	63 (63.6)	
Very satisfied	15 (15.0)	11 (11.1)	
How satisfied or dissatisfied are you with the length of time your symptoms are controlled after taking a dose of FF/VI? n (%)			0.006 (0.001)
Very dissatisfied	–	–	
Dissatisfied	4 (4.0)	8 (8.1)	
Neutral	6 (6.0)	16 (16.2)	
Satisfied	65 (65.0)	65 (65.7)	
Very satisfied	25 (25.0)	10 (10.1)	
How confident or unconfident are you that FF/VI will relieve your symptoms all day? n (%)			0.211 (0.031)
Very unconfident	–	1 (1.0)	
Unconfident	6 (6.0)	13 (13.1)	
Neutral	10 (10.0)	15 (15.2)	
Confident	71 (71.0)	59 (59.6)	
Very confident	13 (13.0)	11 (11.1)	

Table 3 continued

Parameter	Participants with asthma (N = 100)	Participants with COPD (N = 99)	Chi-squared P value asthma versus COPD (trend)
How satisfied or dissatisfied are you with your ability to sleep through the night while taking FF/VI? n (%)			0.010 (0.001)
Very dissatisfied	–	–	
Dissatisfied	3 (3.0)	10 (10.1)	
Neutral	19 (19.0)	33 (33.3)	
Satisfied	66 (66.0)	49 (49.5)	
Very satisfied	12 (12.0)	7 (7.1)	
How satisfied or dissatisfied are you with the impact FF/VI has on your ability to do physical activities (e.g., ability to exercise, going up and down stairs, walking up hills or inclines)? n (%)			0.004 (0.005)
Very dissatisfied	–	–	
Dissatisfied	10 (10.0)	13 (13.1)	
Neutral	13 (13.0)	32 (32.3)	
Satisfied	66 (66.0)	49 (49.5)	
Very satisfied	11 (11.0)	5 (5.1)	
How satisfied or dissatisfied are you with the impact FF/VI has on your ability to do social activities (e.g., ability to visit family, socialize with friends, joining social clubs)? n (%)			< 0.001 (< 0.001)
Very dissatisfied	–	–	
Dissatisfied	5 (5.0)	5 (5.1)	
Neutral	8 (8.0)	35 (35.4)	
Satisfied	73 (73.0)	54 (54.5)	
Very satisfied	14 (14.0)	5 (5.1)	
How satisfied or dissatisfied are you with your overall experience of using FF/VI? n (%)			0.155 (0.048)
Very dissatisfied	1 (1.0)	1 (1.0)	
Dissatisfied	4 (4.0)	5 (5.1)	
Neutral	5 (5.0)	9 (9.1)	
Satisfied	54 (54.0)	64 (64.6)	
Very satisfied	36 (36.0)	20 (20.2)	

COPD chronic obstructive pulmonary disease, *FF/VI* fluticasone furoate/vilanterol, *SD* standard deviation

[a] Not mutually exclusive, participants could select more than one option

Participants' Satisfaction with FF/VI Compared with Their Most Recent Inhaled Medication

Fifty-four participants with asthma (54.0%) reported recent use of another maintenance inhaler medication for a mean (SD) duration of 5.8 (5.0) years. Sixty-three participants with COPD (63.6%) reported recent use of another maintenance inhaler medication for a mean (SD) duration of 4.2 (4.6) years. The most recent medications taken, most of which participants reported taking twice daily (asthma, 68.5%; COPD, 25.4%), are provided in Table 4.

Compared with their previous maintenance medication, significantly more participants with asthma were satisfied with the frequency of use of FF/VI ($P = 0.001$) and reported that FF/VI fitted more easily into their daily routine ($P = 0.001$), was more convenient to take as instructed ($P = 0.009$), and easier to use ($P = 0.003$), and that they forgot to take FF/VI less often ($P = 0.003$). Conversely, participants with COPD did not report significant advantages for FF/VI over their most recent medication; however, a numeric trend towards an advantage was observed (Table 5).

Participants with asthma were also significantly more satisfied with the efficacy of FF/VI compared with their recent maintenance medication, including time to onset of effect, symptom control, and post-dose duration of effect, and they felt confident that their symptoms would be relieved all day (all $P < 0.001$). Participants with asthma were also significantly more satisfied with the QoL impacts of FF/VI compared with their recent maintenance medication in terms of the impacts on their ability to perform physical and social activities, and their ability to sleep through the night (all $P < 0.001$) (Table 5).

Compared with their previous medication, participants with COPD were significantly more satisfied with the speed of onset of effect of FF/VI ($P = 0.008$), its impact on sleep quality ($P = 0.031$), the protection it conferred against triggers of exacerbations/flare-ups ($P = 0.003$), and how anxious/depressed they felt about their condition ($P = 0.035$). There was,

Table 4 Maintenance/preventer medication taken most recently before FF/VI

Recent medication, n (%)	Asthma (N = 54)	COPD (N = 63)	Total (N = 117)
Becotide	5 (9.3)	5 (7.9)	10 (8.5)
Clenil	1 (1.9)	–	1 (0.9)
Flixotide (fluticasone propionate)	2 (3.7)	–	2 (1.7)
Fostair	8 (14.8)	2 (3.2)	10 (8.5)
Seebri (glycopyrronium)	–	1 (1.6)	1 (0.9)
Onbrez (indacaterol)	–	1 (1.6)	1 (0.9)
Pulmicort (budesonide)	1 (1.9)	–	1 (0.9)
Qvar	1 (1.9)	–	1 (0.9)
Seretide	27 (50.0)	10 (15.9)	37 (31.6)
Serevent	–	4 (6.3)	4 (3.4)
Spiriva (tiotropium bromide)	1 (1.9)	19 (30.2)	20 (17.1)
Symbicort	5 (9.3)	1 (1.6)	6 (5.1)
Other – Incruse ELLIPTA	1 (1.9)	20 (31.7)	21 (17.9)
Other – DuoResp/Spiromax	2 (3.7)	–	2 (1.7)

COPD chronic obstructive pulmonary disease, *FF/VI* fluticasone furoate/vilanterol

Table 5 Participants' satisfaction with FF/VI compared with their most recent inhaler (phase 2: quantitative survey results)

Parameter	Participants with asthma (N = 54)			Participants with COPD (N = 63)		
	FF/VI	Recent medication	P value[a]	FF/VI	Recent medication	P value[a]
Frequency of taking?[b] n (%)			–			–
Less than once a day	1 (1.9)	2 (3.7)		8 (12.7)	3 (4.8)	
Once a day	47 (87.0)	10 (18.5)		51 (81.0)	42 (66.7)	
Twice a day	6 (11.1)	37 (68.5)		4 (6.3)	16 (25.4)	
More often than twice a day	–	5 (9.3)		–	2 (3.2)	
When taken?[b] n (%)			–			–
As part of my morning routine	47 (87.0)	49 (90.7)		60 (95.2)	60 (95.2)	
Around lunchtime	–	–		1 (1.6)	2. (3.2)	
In the afternoon	–	3 (5.6)		–	1 (1.6)	
Around dinner time	1 (1.9)	3 (5.6)		–	1 (1.6)	
In the evening (after evening meal)	1 (1.9)	6 (11.1)		1 (1.6)	2 (3.2)	
Just before bedtime	11 (20.4)	33 (61.1)		3 (4.8)	16 (25.4)	
During the night	–	2 (3.7)		–	–	
Easy or difficult to use? n (%)			0.003			0.233
Very difficult	–	1 (1.9)		1 (1.6)	–	
Difficult	–	5 (9.3)		1 (1.6)	2 (3.2)	
Neutral	3 (5.6)	2 (3.7)		3 (4.8)	5 (7.9)	
Easy	28 (51.9)	36 (66.7)		48 (76.2)	52 (82.5)	
Very easy	23 (42.6)	10 (18.5)		10 (15.9)	4 (6.3)	
Easy or difficult to fit into your daily routine? n (%)			0.001			0.160
Very difficult	–	1 (1.9)		–	–	
Difficult	–	4 (7.4)		–	–	
Neutral	–	2 (3.7)		2 (3.2)	3 (4.8)	
Easy	33 (61.1)	37 (68.5)		53 (84.1)	56 (88.9)	
Very easy	21 (38.9)	10 (18.5)		8 (12.7)	4 (6.3)	
Convenient or inconvenient to take as instructed? n (%)			0.009			0.102
Very inconvenient	1 (1.9)	–		1 (1.6)	–	
Inconvenient	–	5 (9.3)		–	–	
Neutral	4 (7.4)	5 (9.3)		3 (4.8)	7 (11.1)	
Convenient	35 (64.8)	39 (72.2)		48 (76.2)	56 (88.9)	
Very convenient	14 (25.9)	5 (9.3)		11 (17.5)	4 (6.3)	

Table 5 continued

Parameter	Participants with asthma ($N = 54$)			Participants with COPD ($N = 63$)		
	FF/VI	Recent medication	P value[a]	FF/VI	Recent medication	P value[a]
Ever forget to take? n (%)			0.003			0.076
Always	–	1 (1.9)		–	2 (3.2)	
Most of the time	2 (3.7)	1 (1.9)		–	–	
Sometimes	10 (18.5)	17 (31.5)		6 (9.5)	7 (11.1)	
Rarely	12 (22.2)	15 (27.8)		10 (15.9)	12 (19.0)	
Never	30 (55.6)	20 (37.0)		47 (74.6)	42 (66.7)	
Satisfied or dissatisfied with the frequency of taking? n (%)			0.001			0.280
Very dissatisfied	1 (1.9)	1 (1.9)		–	2 (3.2)	
Dissatisfied	3 (5.6)	12 (22.2)		6 (9.5)	8 (12.7)	
Neutral	3 (5.6)	8 (14.8)		4 (6.3)	4 (6.3)	
Satisfied	26 (48.1)	29 (53.7)		43 (68.3)	40 (63.5)	
Very satisfied	21 (38.9)	4 (7.4)		10 (15.9)	9 (14.3)	
Satisfied or dissatisfied with the ability to control symptoms? n (%)			< 0.001			0.726
Very dissatisfied	–	1 (1.9)		–	2 (3.2)	
Dissatisfied	3 (5.9)	18 (33.3)		5 (7.9)	7 (11.1)	
Neutral	4 (7.4)	11 (20.4)		11 (17.5)	4 (6.3)	
Satisfied	27 (50.0)	22 (40.7)		39 (61.9)	44 (69.8)	
Very satisfied	20 (37.0)	2 (2.7)		8 (12.7)	1 (1.6)	
Satisfied or dissatisfied with the length of time symptoms are controlled after taking a dose? n (%)			< 0.001			0.055
Very dissatisfied	–	2 (3.7)		–	2 (3.2)	
Dissatisfied	3 (5.9)	19 (35.2)		3 (4.8)	7 (11.1)	
Neutral	4 (7.4)	9 (16.7)		11 (17.5)	9 (14.3)	
Satisfied	31 (57.4)	22 (40.7)		42 (66.7)	44 (69.8)	
Very satisfied	16 (29.6)	2 (3.7)		7 (11.1)	1 (1.6)	
Satisfied or dissatisfied with the amount of time it takes to start working?			< 0.001			0.008
Very dissatisfied	–	2 (3.7)		–	1 (1.6)	
Dissatisfied	–	11 (20.4)		7 (11.1)	6 (9.5)	
Neutral	10 (18.5)	11 (20.4)		17 (27.0)	17 (27.0)	
Satisfied	34 (63.0)	28 (51.9)		33 (52.4)	37 (58.7)	
Very satisfied	10 (18.5)	2 (3.7)		6 (6.5)	2 (3.2)	

Table 5 continued

Parameter	Participants with asthma ($N = 54$)			Participants with COPD ($N = 63$)		
	FF/VI	Recent medication	P value[a]	FF/VI	Recent medication	P value[a]
Confident or unconfident that symptoms will be relieved all day? n (%)			< 0.001			0.217
Very unconfident	–	3 (5.6)		–	2 (3.2)	
Unconfident	4 (7.4)	22 (40.7)		8 (12.7)	8 (12.7)	
Neutral	9 (16.7)	5 (9.3)		9 (14.3)	11 (17.5)	
Confident	31 (57.4)	20 (37.0)		38 (60.3)	39 (61.9)	
Very confident	10 (18.5)	4 (7.4)		8 (12.7)	3 (4.8)	
Satisfied or dissatisfied with impact on quality of sleep? n (%)			0.002			0.031
Very dissatisfied	–	3 (5.6)		–	1 (1.6)	
Dissatisfied	3 (5.6)	11 (20.4)		7 (11.1)	11 (17.5)	
Neutral	13 (24.1)	15 (27.8)		19 (30.2)	19 (30.2)	
Satisfied	26 (48.1)	20 (37.0)		33 (52.4)	29 (46.0)	
Very satisfied	12 (22.2)	5 (9.3)		4 (6.3)	3 (4.8)	
Satisfied or dissatisfied with your ability to sleep through the night? n (%)			< 0.001			0.151
Very dissatisfied	–	3 (5.6)		–	1 (1.6)	
Dissatisfied	3 (5.6)	13 (24.1)		7 (11.1)	11 (17.5)	
Neutral	13 (24.1)	18 (33.3)		19 (30.2)	18 (28.6)	
Satisfied	27 (50.0)	15 (27.8)		33 (52.4)	29 (46.0)	
Very satisfied	11 (20.4)	5 (9.3)		4 (6.3)	4 (6.3)	
Satisfied or dissatisfied with the impact on your ability to do physical activities (e.g., ability to exercise, going up and down stairs, walking up hills or inclines)? n (%)			< 0.001			0.143
Very dissatisfied	–	4 (7.4)		–	3 (4.8)	
Dissatisfied	6 (11.1)	20 (37.0)		6 (9.5)	8 (12.7)	
Neutral	3 (14.8)	9 (16.7)		22 (34.9)	21 (33.3)	
Satisfied	30 (55.6)	20 (37.0)		32 (50.8)	28 (44.4)	
Very satisfied	10 (18.5)	1 (1.9)		3 (4.8)	3 (4.8)	

Table 5 continued

Parameter	Participants with asthma (N = 54)			Participants with COPD (N = 63)		
	FF/VI	Recent medication	P value[a]	FF/VI	Recent medication	P value[a]
Satisfied or dissatisfied with the impact on your ability to do social activities (e.g., ability to visit family, socialize with friends, joining social clubs)? n (%)			< 0.001			0.278
Very dissatisfied	–	–		–	1 (1.6)	
Dissatisfied	4 (7.4)	12 (22.2)		3 (4.8)	5 (7.9)	
Neutral	6 (11.1)	13 (24.1)		21 (33.3)	22 (34.9)	
Satisfied	34 (63.0)	27 (50.0)		36 (57.1)	32 (50.8)	
Very satisfied	10 (18.5)	2 (3.7)		3 (4.8)	3 (4.8)	
Satisfied or dissatisfied with overall experience? n (%)			< 0.001			0.055
Very dissatisfied	1 (1.9)	5 (9.3)		–	2 (3.2)	
Dissatisfied	4 (7.4)	17 (31.5)		3 (4.8)	7 (11.1)	
Neutral	2 (3.7)	7 (13.0)		7 (11.1)	6 (9.5)	
Satisfied	21 (38.9)	20 (37.0)		40 (63.5)	41 (65.1)	
Very satisfied	26 (48.1)	5 (9.3)		13 (20.6)	7 (11.1)	

COPD chronic obstructive pulmonary disease; *FF/VI* fluticasone furoate/vilanterol

[a] Wilcoxon matched pairs signed-rank test

[b] Not mutually exclusive, participants could select more than one option for FF/VI

however, no significant difference in level of satisfaction with the ability of both medications to control symptoms, duration of symptom control, or level of confidence that symptoms would be relieved (all $P \geq 0.055$) (Table 5).

A significantly greater percentage of participants with asthma were satisfied or very satisfied with their overall experience of FF/VI, compared with their recent previous maintenance inhaler (87.0% versus 46.3%, respectively; $P < 0.001$) (Table 5). For those with COPD, there was no significant difference in participant satisfaction between FF/VI and participants' previous medication in terms of QoL impacts, including ability to sleep through the night ($P \geq 0.151$) and impact on ability to do physical and social activities ($P = 0.143$ and $P \geq 0.151$, respectively). Consequently, there was no significant difference in the number of COPD participants who reported being satisfied

or very satisfied with their overall experience of FF/VI compared with their recent previous maintenance inhaler (84.1% versus 76.2%; $P = 0.055$).

DISCUSSION

This two-phase study evaluated patients' experiences with, and perceptions of, FF/VI in the treatment of asthma and COPD. In the qualitative interviews, nearly all patients had confidence in FF/VI as a treatment for their condition, primarily due to its efficacy. Most patients were satisfied with the once-daily dosage frequency of FF/VI and found the treatment easy to use. In general, participants reported a positive experience with FF/VI when compared with their previous treatments, most of which were twice-daily medications. In the

quantitative survey, there was a high level of satisfaction with FF/VI among participants from both disease groups. Most participants were satisfied with the efficacy of FF/VI, with patients with asthma reporting greater satisfaction with the QoL impacts of FF/VI versus those with COPD. Individuals with asthma reported significantly more satisfaction with all aspects of FF/VI's efficacy and QoL impacts compared with their recent previous maintenance medication, whereas participants with COPD only reported significantly more satisfaction with FF/VI's speed of onset, protection against exacerbations, and impacts on sleep quality, and any anxiety/depression they felt about their condition.

Symptom control is one of the key considerations in the treatment of asthma and COPD [4]. In phase 1, most participants reported that FF/VI controlled their symptoms for at least 24 h. In phase 2, the majority of participants were satisfied with both the level and duration of disease control afforded by FF/VI, and most were confident that FF/VI would relieve their symptoms all day. These findings are consistent with previous studies, which have shown improvements in symptom control and health status with FF/VI compared with other treatments for asthma and COPD, with evidence of a 72-h duration of bronchodilator effect [14, 15, 29–31].

Compared with participants with COPD, participants with asthma were significantly more satisfied with the ability of FF/VI to control their symptoms; they were also significantly more confident that their symptoms would be relieved all day versus their previous inhaler, which was not the case for participants with COPD. The difference in perceptions between participants with asthma and those with COPD may be related to the chronic and persistent nature of COPD symptoms, with asthma symptoms potentially being more variable [3, 4].

Differences in the baseline characteristics of participants with COPD and those with asthma may also have influenced whether they considered their symptoms to be well managed. For example, participants with COPD were older (phase 1, 63.1 years; phase 2, 70.0 years) than

participants with asthma (phase 1, 52.6 years; phase 2, 57.2 years) and took a higher mean number of medications (phase 1, 3.28 versus 2.12 medications). Additionally, more participants with controlled asthma versus uncontrolled asthma were recruited in phase 2, whereas fewer participants with low-impact COPD were included compared with any other COPD severity category. This imbalance in condition severity between the two disease arms resulted from a relative scarcity of candidates with uncontrolled asthma or low-impact COPD during recruitment. The lack of potential candidates in these disease categories suggests that the current sample may be representative of patients being prescribed FF/VI in primary care.

It should be noted that although most participants considered that their symptoms were controlled with FF/VI, relatively few participants in phase 1 (seven with asthma and five with COPD) reported an improvement in their symptoms since commencing this treatment. Almost all participants across both study phases reported that FF/VI was easy to use and easy to integrate into their daily routine, consistent with previous research that demonstrated that participants found the ELLIPTA inhaler easy and convenient to use [18–20]. Previous studies have shown that more patients with asthma and COPD preferred ELLIPTA over comparator inhalers [32–34].

In addition to the convenience of a once-daily regimen, the 24-h continuous efficacy profile of FF/VI has been shown to improve nocturnal asthma symptoms [35], which may consequently improve sleep quality and provide benefits in terms of greater daytime productivity and ability to conduct various activities. Compared with their most recent inhaler, participants in both disease groups were significantly more satisfied with FF/VI in terms of its impact on sleep quality. However, only participants with asthma were significantly more satisfied with the effect of FF/VI on their ability to sleep through the night versus their previous medication. These results are in agreement with previous studies, which have shown that asthma is associated with a negative impact on sleep quality [36], while for COPD, having 24-h symptoms is associated with worse dyspnea,

health status, and sleep quality, and higher levels of anxiety and depression [37].

Medication side effects were included in the phase 1 interview questions. Over 70% of participants with asthma and over 60% of those with COPD did not report experiencing side effects with FF/VI. Moreover, any side effects that were reported were common for the treatment class.

Strengths of phase 1 of the study included the use of an interview guide, and questions that were designed to be non-leading, reducing the potential for interviewer bias, as well as the reasonably large sample size for a qualitative study ($N = 50$). Moreover, by its nature, the study aimed to uncover and increase our understanding of individuals' experiences of their condition and associated treatments. This is important since these experiences are likely to impact on the effectiveness of the treatment and also reveal potential unmet individual needs and preferences.

There are some limitations to the current study, including the lack of randomization, preventing comparisons between FF/VI and previous treatments, and the fact that only participants who were currently taking FF/VI were recruited (minimum time on FF/VI was 3 months). This may have resulted in a participant sample that was weighted toward those with positive opinions about the treatment, given that individuals who had previously ceased treatment with FF/VI might have switched to a different medication because they were not satisfied with FF/VI. Furthermore, as participants were already taking FF/VI at study recruitment, it is not possible to determine whether their ACT or CAT scores had improved as a result of FF/VI treatment. Additionally, while current prescription of FF/VI was based on medical records, previous maintenance medications were self-reported and thus subject to recall bias. Future research including participants who have been switched away from FF/VI may therefore provide additional context to the patient preferences reported here. The focus on FF/VI during the interviews and survey may have also impacted the answers given by the participants, potentially encouraging participants to provide a positive portrayal of FF/VI. However, participants did not always report positive opinions about all aspects of FF/VI, and some participants, particularly those with COPD, presented negative views, perhaps as a consequence of the progressive nature of their disease.

Despite the number of participants in the study, ethnic diversity was limited; caution is therefore warranted when generalizing these findings to the wider population, particularly since the average age for participants with asthma was higher than average for adults with asthma in the UK [38]. Moreover, in phase 2, almost one quarter of the sample (23.6%) had difficulties understanding the survey, and therefore completed it with assistance from the research team. Statistically significant differences were evident between individuals with COPD who had assistance versus those who completed the survey alone; participants who required assistance were on average almost 21 years older and had lower satisfaction with FF/VI compared with those who self-completed. Although this suggests heterogeneity between the assisted and self-completing participants, as both groups still represent views from individuals using FF/VI, it would have been misleading to exclude these participants from the analysis simply because they found the survey difficult to navigate and complete. Future studies should aim to ensure that the characteristics of participants involved in pilot or test phases of a study are reflective of those who will take part in the main study, particularly given that statistical measures such as chi-squared do not account for the influence of factors such as age or gender.

In conclusion, this study showed that participants were generally satisfied with the level of symptom control provided by FF/VI and felt confident with this treatment. Many participants experienced 24-h symptom control, with limited side effects, and frequently reported improvements in physical activities with FF/VI.

ACKNOWLEDGEMENTS

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