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Original Article

Adherence to long-term non-invasive positive airway pressure therapy

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ABSTRACT

INTRODUCTION. Studies have shown varying patient adherence to long-term non-invasive positive airway pressure therapy (nPAP). We aimed to investigate adherence to long-term nPAP in a Danish cohort of patients with chronic respiratory insufficiency and/or sleep-disordered breathing (SDB) due to neuromuscular disorders (NMD), obesity-hypoventilation syndrome (OHS) or other reasons.

METHODS. This cohort study included all adult patients with association to the Respiratory Center East treated with long-term nPAP: bilevel (BiPAP), automatic (APAP) and continuous (CPAP) or adaptive servo-ventilation (ASV) with a remote monitoring system in April 2022. The primary outcome was adherence, defined as a median use of nPAP ≥ 4 hrs/day in April 2022. A preplanned extended subgroup analysis was conducted for patients with data on adherence from initiation and six months onwards.

RESULTS. The primary analysis included 241 patients, of whom 90% were diagnosed with NMD (54%) or OHS (36%). The nPAP was used ≥ 4 hrs/day by 175 patients (73%), including 22 (100%) with ASV, 129 (72%) with BiPAP and 24 (59%) with APAP/CPAP. Treatment adherence was seen in 75% of patients with NMD, 64% with OHS and 84% with other reasons for SDB. The proportion of adherent subjects in the subgroup analysis of 55 patients was relatively stable throughout the six-month period, ranging from 67% to 75% with slight intraindividual variation.

CONCLUSION. In this retrospective analysis of adults primarily with NMD and OHS, 73% used the prescribed nPAP therapy ≥ 4 hrs/day.

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Long-term non-invasive positive airway pressure therapy (nPAP) is accepted as standard care in patients with chronic respiratory insufficiency and/or sleep-disordered breathing (SDB) due to obstructive sleep apnoea (OSA), neuromuscular disease (NMD), chronic obstructive pulmonary disease (COPD) or obesity hypoventilation syndrome (OHS). The nPAP includes fixed-pressure continuous positive pressure (CPAP) along with automatic positive pressure (APAP), bilevel positive pressure (BiPAP) and adaptive servo-ventilation (ASV), which dynamically adjusts the airway pressure based on the individual respiratory pattern. Studies have shown a significant association between nPAP and reduced disease severity [1] and improved quality of life and survival [2-5].

However, obtaining benefits from therapy relies on using it, and a threshold of at least 4 hrs of treatment per day

has been defined as clinically acceptable [3, 4, 6]. Despite this, studies have shown very different nPAP adherences. A cross-sectional observational study from the Geneva Lake Area of long-term BiPAP showed 92% adherence [7]. In contrast, an Australian study of 86 new BiPAP users reported 62% adherence after six months of therapy [8].

In this study, we aimed to investigate patient adherence to long-term nPAP in a Danish setting followed by the Respiratory Center East. The primary outcome was median use of nPAP ≥ 4 hrs/day. Moreover, we aimed to examine the course during the initiating phase of nPAP for a subgroup of patients.

METHODS

Study design

This study analysed data on consecutively enrolled adults treated at home with nPAP: BiPAP, APAP/CPAP or ASV using a remote monitoring system. The participants were followed by the Respiratory Center East from 1 January 2022 to 1 May 2022.

Patients were eligible for this study only if they were > 18 years old. The exclusion criteria were treatment ending before 1 May 2022 due to death, if subjects had actively requested that their therapy be terminated or if it had started later than 1 April 2022.

Cohort characteristics

Respiratory Center East treats patients across the Capital Region of Denmark, Region Zealand and the Faroe Islands. Patients associated with the department have chronic respiratory insufficiency and/or SDB due to NMD, OHS [9] or other causes, including subjects with central/mixed sleep apnoea syndrome (CSA) or with OSA and comorbidity of significance for treatment complexity. Patients with CSA or OSA without significant respiratory comorbidity or chronic respiratory insufficiency exclusively due to COPD do not meet the referral criteria.

Subjects are referred to our centre from other health services or the community.

The diagnostics for SDB included one night of in-hospital respiratory polygraphy. Here, we determined the apnoea-hypopnoea index, oxygen desaturation index, respiratory rate, heart rate and body movements, transcutaneous CO_2 monitoring and PCO_2 from capillary blood gases during daytime and morning [10]. The decision to start long-term nPAP was based on a combination of the results of these tests and clinical symptoms. This decision was made at the physician's discretion, and no specific criteria were applied. Typically, nPAP is introduced to the patient during a scheduled in-hospital admission lasting 1-2 days with titration of nPAP. Before discharge, all patients receive a standardised education session on using and maintaining the nPAP equipment. Furthermore, we offer a 24-hour telephone support line, supply the patients with a guiding pamphlet and encourage them to contact the department if needed. A follow-up contact, typically a telephone consultation and telemonitoring information, is planned at the physician's discretion.

Ethical approval

The study was approved by the Institutional Review Board at Rigshospitalet (Copenhagen, DK; protocol no. 22024086) and registered with ClinicalTrials.gov (NCT05379309).

Data collected

Two investigators manually entered data from the Epic System for Healthcare and the Airview, Resmed, and PrismaCloud, Löwenstein. Descriptive information, including gender, Body Mass Index and primary diagnosis, was retrieved from the medical charts.

Outcome measures

The primary outcome was median adherence to nPAP ≥ 4 hrs/day for 30 days (April 2022).

The secondary outcome was median adherence during a fixed 30-day period (April 2022) reported in minutes.

Preplanned subgroup analysis

We performed an extended analysis of a subgroup of treatment-naïve patients from whom information regarding adherence to treatment from the day of initiation of therapy and the following six months was available. Respiratory status before the start of nPAP was noted, including forced vital capacity, diagnostic polygraphy results and capillary blood gases. Additionally, information was obtained on whether the nPAP was started during a scheduled admission or due to acute or chronic respiratory failure. We evaluated each patient's median adherence to nPAP in preplanned intervals after initiating nPAP. Moreover, we retrieved information on the time to first contact with the department after starting therapy, if this contact was scheduled and the number of contacts during the first six months.

Analysis

Continuous and ordinal variables are described as median (interquartile range (IQR)) and categorical variables as number (percentages). Outcomes in the subgroup analyses were compared with the Mann-Whitney *U* test, the χ^2 test or Fisher's exact test. A *p*-value of < 0.05 was considered statistically significant. Analyses were performed using SPSS statistics version 28.0.1.0 (IBM).

Trial registration: ClinicalTrials.gov (NCT05379309).

RESULTS

A total of 324 cases were assessed for eligibility. After exclusion, the main cohort for the primary analysis consisted of 241 patients, including 216 (90%) with NMD or OHS. Details of the cohort are included in **Table 1**. Only two patients were prescribed CPAP; 39 patients, APAP.

TABLE 1 Patient characteristics.

	APAP/CPAP ($N_{a/c}$ = 41)	BiPAP (N_b = 178)	ASV (N_a = 22)	Total (N_{tot} = 241)
Age, median (IQR), yrs	61 (45-71)	61 (50-74)	72 (65-82)	63 (50-74)
Males, n (%)	27 (66)	102 (57)	19 (86)	148 (61)
BMI, median (IQR), kg/m²	33 (27-37)	32 (25-40)	31 (25-36)	32 (25-39)
Time since start nPAP, median (IQR), yrs	1 (1-5)	2 (1-5)	6 (4-11)	2 (1-5)
Neuromuscular disease, n (%)	21 (51)	105 (59)	4 (18)	130 (54)
Obesity hypoventilation syndrome, n (%)	14 (34)	69 (39)	3 (14)	86 (36)
Central/mixed sleep apnoea, n (%)	0	0	15 (68)	15 (6)
Obstructive sleep apnoea, other[a], n (%)	6 (15)	4 (2)	0	10 (4)
Comorbidity, n (%)				
COPD	2 (5)	42 (24)	4 (18)	48 (20)
Anxiety or depressive symptoms	5 (12)	10 (6)	0	15 (6)
Cognitive dysfunction	5 (12)	9 (5)	0	14 (6)
Full-face mask, n (%)	25 (61)	135 (76)	19 (86)	179 (53)
Humidifier, n (%)	13 (32)	89 (50)	12 (55)	114 (47)
Personal care assistant, n (%)	3 (7)	22 (12)	2 (9)	27 (11)

APAP = automatic positive airway pressure; ASV = adaptive servo-ventilation; BiPAP = bilevel positive airway pressure; CPAP = continuous positive airway pressure; IQR = interquartile range; nPAP = non-invasive positive airway pressure therapy.
a) Patients with obstructive sleep apnoea who were not diagnosed with neuromuscular diseases or obesity hypoventilation syndrome.

Primary analysis

A total of 175 patients (73%) used the prescribed nPAP ≥ 4 hrs/day, including 22 of 22 (100%) patients prescribed with ASV, 129 of 178 (72%) with BiPAP, and 24 of 41 (59%) with APAP/CPAP. The non-adherent patients had received therapy for a shorter period (one year (1-2) versus three years (1-6), p < 0.01). They suffered more from anxiety or depressive symptoms than the adherent patients (eight (12%) versus seven (4%), p = 0.03), as illustrated in Table 2.

TABLE 2 Characteristics of patients by use of long-term non-invasive positive airway pressure therapy.

	Use		
	≥ 4 hrs/day ($N_{\geq 4}$ = 175)	< 4 hrs/day ($N_{<4}$ = 66)	p value
Age, median (IQR), yrs	64 (50-74)	60 (51-74)	0.54
Males, n (%)	113 (65)	35 (53)	0.11
Time since start nPAP, median (IQR), yrs	3 (1-6)	1 (1-2)	< 0.01
Neuromuscular disease, n (%)		0.47	
Congenital myopathy and muscular dystrophia	16	2	
Charcot-Marie-Tooth disease	1	1	
Spinal muscular atrophies II & III	5	0	
Pompe disease	1	1	
Amyotrophic lateral sclerosis	17	5	
Demyelinating disease	5	2	
Multiple system atrophy	2	0	
Phrenic nerve paralysis	11	3	
Spinal cord injury	11	4	
Post-polio syndrome	9	3	
Spastic tetraplegy	6	2	
Apoplexia cerebri	5	0	
Arthrogryposis multiplex congenita	1	0	
Scoliosis	5	2	
Myotonic muscular dystrophia	2	8	
Subtotal	97 (55)	33 (50)	
Obesity hypoventilation syndrome, n (%)	57 (33)	30 (45)	0.13
Central/mixed sleep apnoea syndrome, n (%)	15 (9)	0 (0)	0.01
Obstructive sleep apnoea syndrome, other[a], n (%)	6 (3)	4 (6)	0.47
Comorbidity, n (%)			
COPD	30 (17)	18 (27)	0.10
BMI ≥ 30 kg/m²	94 (54)	40 (61)	0.39
Anxiety or depressive symptoms	7 (4)	8 (12)	0.03
Cognitive dysfunction	10 (6)	4 (6)	1.0
Type of therapy, n (%)			
BiPAP	129 (74)	49 (74)	1.0
APAP/CPAP	24 (14)	17 (26)	0.03
ASV	22 (13)	0	< 0.001
Full-face mask, n (%)	132 (75)	47 (71)	0.51
Humidifier, n (%)	85 (49)	29 (44)	0.57
Personal care assistant, n (%)	25 (14)	2 (3)	0.01

APAP = automatic positive airway pressure; ASV = adaptive servo-ventilation; BiPAP = bilevel positive airway pressure; CPAP = continuous positive airway pressure; IQR = interquartile range; nPAP = non-invasive positive airway pressure therapy.
a) Patients with obstructive sleep apnoea who were not diagnosed with neuromuscular diseases or obesity hypoventilation syndrome.

Secondary analysis

Overall median use of nPAP was 427 (205-511) min./day with 450 (390-510) min./day in patients prescribed with ASV, 368 (30-469) min./day with BiPAP and 368 (30-469) min./day with APAP/CPAP.

Subgroup analysis

A total of 55 patients were included in the subgroup, which included treatment-naive patients with available data from the start of treatment until six months after initiation.

After six months of therapy, 39 patients (71%) used the prescribed nPAP ≥ 4 hrs/day. This group tended to experience more severe respiratory symptoms before initiating nPAP, as illustrated in **Table 3**. The time to first contact with the department after initiating nPAP was 23 (11-34) days versus 32 (17-46) days in the adherent and non-adherent group, respectively (p = 0.121). First contact was prescheduled by 14 patients (36%) in the adherent group and seven patients (44%) in the non-adherent group (p = 1.0). The most frequent reason for the inquiry was interface issues, with eight out of 15 in the adherent group and three out of six in the non-adherent group. There was no significant difference in the number of contacts to the department between the two groups. Pressure adjustments during the first six months were needed by 38% of patients in the adherent group and 44% in the nonadherent group (p = 0.908).

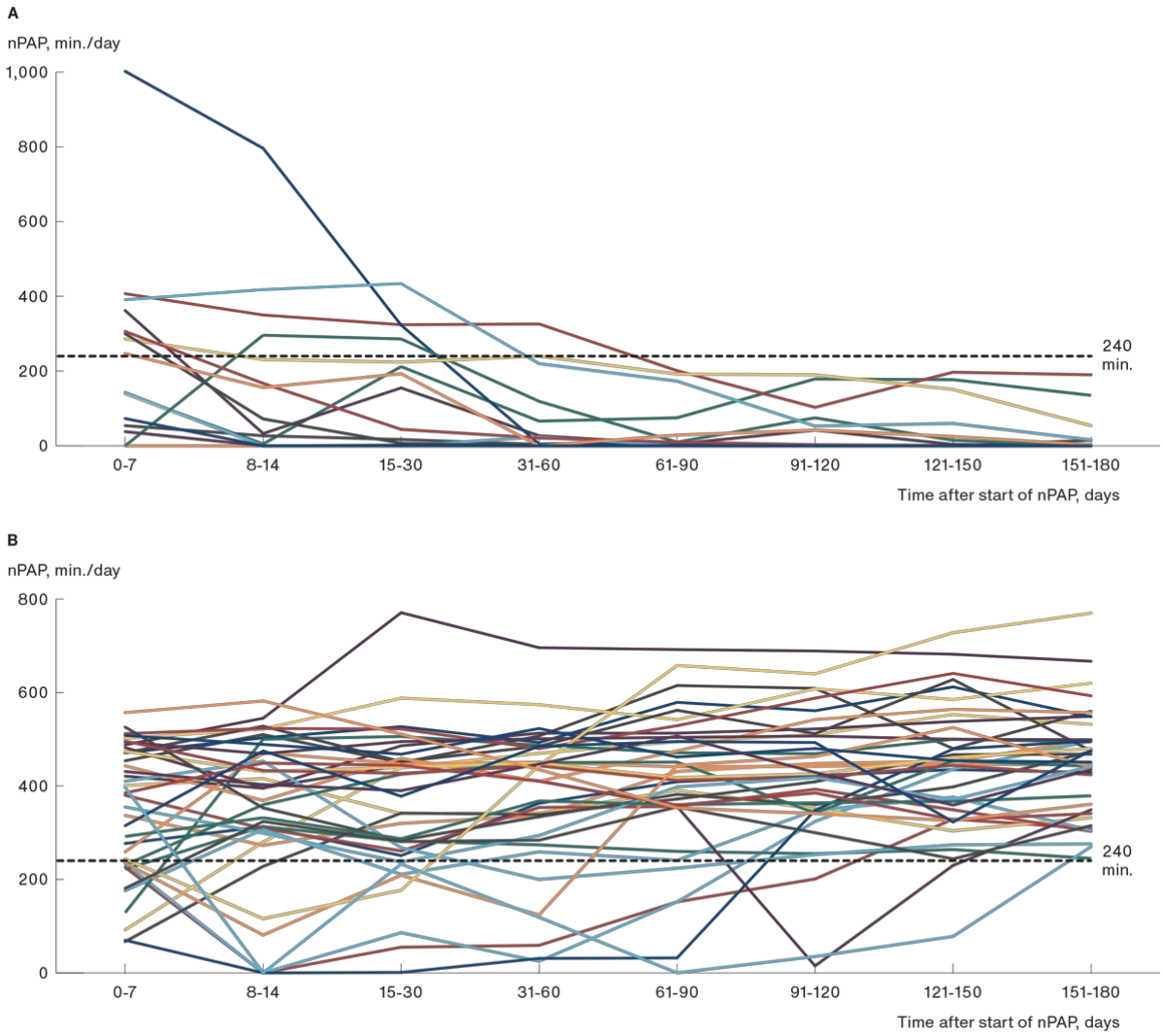
TABLE 3 Demographics and pretherapy characteristics of a subgroup of treatment naïve patients followed for six months after initiation of long-term non-invasive positive airway pressure therapy.

	Use		
	≥ 4 hrs/day ($N_{\geq 4}$ = 39)	< 4 hrs/day ($N_{<4}$ = 16)	p value
Age, median (IQR), yrs	63 (55-76)	56 (42-65)	0.02
Males, n (%)	24 (62)	7 (44)	0.77
Primary diagnosis, n (%)			
Neuromuscular disease:	20 (51)	8 (50)	1.00
Amyotrophic lateral sclerosis	9 (23)	3 (19)	
Obesity hypoventilation syndrome	18 (46)	6 (38)	0.77
Central/mixed sleep apnoea	0	0	-
Obstructive sleep apnoea, other[a]	1 (3)	2 (13)	0.20
Pretherapy values, median (IQR)			
PCO_2, kPa:			
Day	6.6 (5.9-7.6)	5.7 (5.3-6.6)	0.02
Morning	7.4 (6.6-8.7)	6.3 (5.9-7.3)	0.02
FVC, % of predicted value	61 (39-73)	67 (53-80)	0.21
AOS, %	89 (82-92)	92 (86-95)	0.04
AHI, n/hr	28 (14-57)	25 (12-49)	0.94
ODI, n/hr	30 (19-62)	36 (14-57)	0.90
Transcutaneous CO_2, kPa	7.1 (6.2-7.7)	6.3 (5.6-7.1)	0.09
Comorbidity, n (%)			
COPD	10 (26)	4 (25)	1.00
BMI ≥ 30 kg/m²	23 (59)	10 (63)	1.00
Anxiety or depressive symptoms	1 (3)	3 (13)	0.07
Cognitive dysfunction	1 (3)	1 (6)	0.50
Live alone[b], n (%)	15 (38)	8 (50)	0.76
Type of therapy, n (%)			
BiPAP	32 (82)	8 (50)	0.02
APAP	7 (18)	8 (50)	0.02
ASV	0	0	-
Full-face mask, n (%)	30 (77)	12 (75)	1.00
Humidifier, n (%)	19 (49)	5 (31)	0.31
nPAP initiated acutely, n (%)	7 (18)	2 (13)	1.00

AHI = apnoea-hypopnoea index; AOS = average oxygen saturation; APAP = automatic positive airway pressure; ASV = adaptive servo-ventilation; FVC = forced vital capacity; IQR = interquartile range; nPAP = non-invasive positive airway pressure therapy; ODI = oxygen desaturation index.
a) Patients with obstructive sleep apnoea who were not diagnosed with neuromuscular diseases or obesity hypoventilation syndrome.
b) Living status missing in 3 subjects.

The proportion of adherent patients remained relatively stable throughout the six months, ranging from 67% to 75%. After 30 days, the intraindividual variation between groups was slight, with 89% (31 of 35) of those adhering to the treatment at day 15-30 remaining adherent at day 151-180. In the non-adherent group, 80% (16 of 20) of those who had not been adherent at 15-30 days remained non-adherent at day 151-180. The nPAP treatment courses for each patient during the first six months are illustrated in **Figure 1** A and B.

FIGURE 1 Median daily use of non-invasive positive airway pressure therapy (nPAP) 0-180 days after treatment initiation. Each line represents one patient. **A**. Patients with low treatment adherence (< 4 hrs/day). **B**. Patients with high treatment adherence (≥ 4 hrs/day).



DISCUSSION

In this study, 73% of 241 subjects used the prescribed long-term nPAP ≥ 4 hrs/day in a cohort of adults treated with nPAP primarily due to NMD and OHS.

Most patients (74%) were treated with BiPAP of whom 72% used the device ≥ 4 hrs/day. This is markedly lower than in the Geneve Lake study [7]. However, nonadherent and less adherent patients who may have terminated their treatment before three months were not included in the latter, which may have led to attrition bias. Also, the median duration of therapy was 37 months in the Geneva Lake Study compared with 24 months in our study. The proportion of adherent users among the 17% who had been prescribed APAP/CPAP in our study was 59%, which is comparable to previous studies [11, 12]. Only 9% were prescribed ASV, but all were adherent. ASV was superior to CPAP for compliance in CSA patients [13]. However, a recent Cochrane review could not draw any definitive conclusions regarding BiPAP for treating adults with CSA [14]. Notably, the patients in our study who were prescribed ASV tended to be older, which may have biased the results as younger age has been associated

with reduced adherence [15].

We found differences in adherence among the different diagnoses. Subjects with dystrophia myotonica type 1 had markedly lower adherence to treatment than patients with other diagnoses. nPAP has previously been described as a complex treatment in this group due to cognitive and behavioural impairment and because they tend to experience fewer benefits from the therapy [16, 17]. In the subgroup analysis, we found that the pretherapy respiratory status, measured by FVC and PCO_2, tended to be more affected in adherent than in non-adherent users. A higher need for therapy may lead to a subjectively greater treatment effect and may, therefore, be associated with better compliance. This may also be the case for the patients with dystrophia myotonica as the FVCs for the two patients with dystrophia myotonica, who were included in the subgroup analysis, were reduced only by approximately 15% compared to the expected values. The adherent group tended to have their first consultation with the department earlier than the nonadherent group. Our department has no guideline on follow-up timing after nPAP initiation. Clinicians may prioritise patients with a more affected respiratory function, reducing the time to the first scheduled consultation. This is important as our results also suggest that an adherence pattern may be established soon after initiating long-term nPAP, with most users establishing a pattern of use within the first month of therapy. We found that 80-89% of the patients were in the same adherence group 151-180 days after initiating nPAP as they had been 15-30 days after initiating nPAP. This aligns with the results of a study by Chao et al., who also showed stationary adherence assessed six months after initiating BiPAP, including 65% of patients with NMD [8].

Several other factors may affect adherence to nPAP. Evidence suggests that nasal interface and heated humidification, using educational troubleshooting, and intervening by use of telemonitoring may increase adherence to nPAP in OSA [1]. We did not see any significant difference in the choice of interface or humidifier. An Italian pilot study of a small cohort of patients affected by NMD indicated that psychological factors such as depression, family support and positive physician-subject relationship interaction are also of importance to treatment adherence [18]. This confirms our finding that more non-adherent than adherent patients suffered from anxiety or depressive symptoms. The results of a Cochrane review from 2020 of CPAP-naive subjects with OSA also indicated with high certainty that behavioural interventions yield a clinically significant increase in CPAP usage compared to usual care [19]. Our results suggest that these interventions must be used within the first month.

The analyses of this study were based on routine clinical practice with data from accurate, prospective telerecording. The protocol, including outcome definitions, was finalised and registered at clinicaltrials.gov before data retrieval and analysis. A key strength of this study was the ability to track adherence in a subgroup of patients during the initial treatment phase.

We excluded patients who died in the six-month follow-up period after 1 May 2022 from the subgroup analysis. This may have led to attrition bias. Moreover, we included all subjects treated at the department with nPAP regardless of diagnoses, phenotypes and type of nPAP, which makes the cohort heterogeneous and more challenging to compare to other studies. Thirdly, adherence was predefined as use of nPAP ≥ 4 hrs/day. Others use this definition to describe acceptable adherence [4, 6, 8]. However, it is probably more appropriate to adopt a "more is better" approach to most patients, depending on the diagnosis, stage of the disease and outcome of interest [3, 11].

In the future, studies should focus on improving treatment adherence for the different diagnoses and phenotypes – including optimal time to follow-up, and the use of artificial intelligence within a personalised approach to treatment [20].

CONCLUSION

In this retrospective analysis of nPAP therapy in a Danish population of adults primarily with NMD and OHS, 73% used the prescribed therapy ≥ 4 hrs/day. Considerable differences were observed in the proportions of adherent patients between the diagnoses. The results of the subgroup analysis add to mounting evidence that adherence patterns may be established early after commencing long-term nPAP therapy but also that adherence may depend on disease severity.

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