

Supplementary Materials

1. Questionnaires

Questionnaire 1: Patient Preference

For each question, please check *one box only*

1. Which treatment do you prefer?

- The treatment received during the first six weeks is better
- The treatment received during the last six weeks is better
- I prefer neither the one nor the other, they are equivalent

2. Which treatment has less side effects?

- The treatment received during the first six weeks has less side effects
- The treatment received during the last six weeks has less side effects
- I prefer neither the one nor the other, they are equivalent

3. Which treatment would you be more willing to take for a long period of time?

- The treatment received during the first six weeks
- The treatment received during the last six weeks
- Neither the one nor the other, they are equivalent

Questionnaire 2: HIV treatment Satisfaction Questionnaire

(Adapted from HIVSQs© Prof. Clare Bradley, Health Psychology Research, Dept of Psychology, University of London, UK)

Source: Woodcock A, Bradley C. Validation of the Revised 10-Item HIV Treatment Satisfaction Questionnaire Status Version and New Change Version. *Value in Health* 2006; Vol. 9; n.5: 320–33

The following questions are concerned with your medical treatment for HIV and your experience over the past few weeks. Please answer each question by circling a number on each of the scales.

1. How satisfied are you with your current treatment?

very satisfied 6 5 4 3 2 1 0 very dissatisfied

2. How satisfied are you with any side effects of your present treatment?

very satisfied 6 5 4 3 2 1 0 very dissatisfied

3. How satisfied are you with the demands made by your current treatment?

very satisfied 6 5 4 3 2 1 0 very dissatisfied

4. How convenient have you been finding your treatment recently?

very convenient 6 5 4 3 2 1 0 very inconvenient

5. Would you recommend your present treatment to someone else with HIV ?

yes, I would 6 5 4 3 2 1 0 no, I would definitely not

definitely recommend
the treatment

recommend the treatment

6. How satisfied would you be to continue with your present form of treatment?

very satisfied 6 5 4 3 2 1 0 very dissatisfied

Questionnaire 3. The Depression Anxiety Stress Scale (DASS)

Source: Lovibond SH, Lovibond PF. *Manual for the Depression Anxiety Stress Scales (DASS)*. Psychology Foundation Monograph. Sydney, Australia: University of New South Wales, 1993.

DASS21				
<p>Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you <i>over the past week</i>. There are no right or wrong answers. Do not spend too much time on any statement.</p> <p><i>The rating scale is as follows:</i></p> <p>0 Did not apply to me at all 1 Applied to me to some degree, or some of the time 2 Applied to me to a considerable degree, or a good part of time 3 Applied to me very much, or most of the time</p>				
1	I found it hard to wind down	0	1	2 3
2	I was aware of dryness of my mouth	0	1	2 3
3	I couldn't seem to experience any positive feeling at all	0	1	2 3
4	I experienced breathing difficulty (e.g., excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2 3
5	I found it difficult to work up the initiative to do things	0	1	2 3
6	I tended to over-react to situations	0	1	2 3
7	I experienced trembling (e.g., in the hands)	0	1	2 3
8	I felt that I was using a lot of nervous energy	0	1	2 3
9	I was worried about situations in which I might panic and make a fool of myself	0	1	2 3
10	I felt that I had nothing to look forward to	0	1	2 3

11	I found myself getting agitated	0	1	2	3
12	I found it difficult to relax	0	1	2	3
13	I felt down-hearted and blue	0	1	2	3
14	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15	I felt I was close to panic	0	1	2	3
16	I was unable to become enthusiastic about anything	0	1	2	3
17	I felt I wasn't worth much as a person	0	1	2	3
18	I felt that I was rather touchy	0	1	2	3
19	I was aware of the action of my heart in the absence of physical exertion (e.g., sense of heart rate increase, heart missing a beat)	0	1	2	3
20	I felt scared without any good reason	0	1	2	3
21	I felt that life was meaningless	0	1	2	3

Questionnaire 4: Assessing sleepiness

Source: Freedman N: Quantifying Sleepiness, in UpToDate ®, assessed December 20, 2007

Johns MW. A new method for measuring daytime sleepiness: the Epworth sleepiness scale. *Sleep* 1991; 14: 540–5.

Hoddes et al., 1973 E. Hoddes, V. Zarcone, H. Smythe, R. Phillips and W.C. Dement, Quantification of sleepiness: a new approach, *Psychophysiology* 10 (1973), pp. 431–436

4a) EPWORTH SLEEPINESS SCALE (ESS) — The ESS subjectively measures sleepiness as it occurs in ordinary life situations. It can be used as a screening test for excessive sleepiness or to follow an individual's subjective response to an intervention.

Eight situations are described on a questionnaire:

- Sitting and reading
- Watching television
- Sitting inactively in a public place
- Riding as a passenger in a car for one hour without a break
- Lying down to rest in the afternoon when circumstances permit
- Sitting and talking with someone
- Sitting quietly after lunch without alcohol
- Sitting in a car as the driver, while stopped for a few minutes in traffic

Each situation receives a score of zero to three, which is related to the likelihood that sleep will be induced:

- 0 = would never doze
- 1 = slight chance of dozing
- 2 = moderate chance of dozing
- 3 = high chance of dozing

Thus, the total ESS score can range from zero to 24, with higher scores correlating with increasing degrees of sleepiness.

A score greater than ten is consistent with excessive sleepiness. This threshold between normal and abnormal subjective sleepiness is derived from an observational study of 180 adults. The mean ESS score was approximately six among healthy adults, compared to 16 or greater among patients with narcolepsy, idiopathic hypersomnia, or moderate to severe OSAH (defined as a respiratory disturbance index [RDI] greater than 15 events per hour).

The ESS can be performed in the examination room or waiting room. It is relatively simple and generally takes only a few minutes to complete. It should be repeated at subsequent visits to assess for change.

Advantages — The ESS is widely available, reliable for assessing subjective sleepiness, and can be performed easily and quickly.

Disadvantages — The ESS cannot be used on multiple occasions throughout the day and is not a good measure of short-term acute sleep loss. Although the ESS score tends to increase with the severity of OSAH and most patients with moderate to severe OSAH have an ESS score greater than ten, the ESS should not be used to screen for OSAH because it is neither sensitive nor specific for this purpose.

STANFORD SLEEPINESS SCALE (SSS) — The SSS is the best validated subjective measure of sleepiness. It is typically used as a research tool to measure the impact of short-term acute sleep loss on subjective sleepiness. During the SSS, one of seven statements is chosen that best describes an individual's level of sleepiness:

- 1 = feeling active, vital, alert, wide awake
- 2 = functioning at a high level, not at peak, able to concentrate
- 3 = relaxed, awake, not at full alertness, responsive
- 4 = a little foggy, not at peak, let down
- 5 = fogginess, losing interest in remaining awake, slowed
- 6 = sleepiness, prefer to be lying down, fighting sleep, woozy
- 7 = almost in reverie, sleep onset soon, losing struggle to remain awake

Individuals who choose the fourth, fifth, sixth, or seventh statement at a time when they should be feeling alert, may have excessive sleepiness.

Advantages of the SSS are that it can be administered multiple times throughout the day and night and it correlates with standard measures of performance. In addition, it correlates well with acute total sleep deprivation (but, less well with chronic partial sleep deprivation). This may be related to an individual's perception of their ability to get used to chronic sleep loss.

The major disadvantage of the SSS is its inability to differentiate sleep deprived normal subjects from individuals with sleep disorders. There also appears to be some discordance between gross behavioral indicators of sleep (eg, closed eyes) and the first and second choices. Finally, the SSS only conveys information about a patient's state of sleepiness at single points in time.

4b: The Groningen Sleep Quality Score (GSQS, 17)

Source: Meijman TF, de Vries-Griever AH, de Vries G. *The evaluation of the Groningen Sleep Quality Scale*. Groningen: Heymans Bulletin (HB 88-13-EX), 1988

1. I had a deep sleep last night
2. I feel that I slept poorly last night
3. It took me more than half an hour to fall asleep last night
4. I woke up several times last night
5. I felt tired after waking up this morning
6. I feel that I didn't get enough sleep last night
7. I got up in the middle of the night
8. I felt rested after waking up this morning
9. I feel that I only had a couple of hours' sleep last night
10. I feel that I slept well last night
11. I didn't sleep a wink last night
12. I didn't have trouble falling asleep last night
13. After I woke up last night, I had trouble falling asleep again

14. I tossed and turned all night last night

15. I didn't get more than 5 hours' sleep last night

All items are scored true / false

The first question does not count for the total score

One point if answer is 'true': questions 2, 3, 4, 5, 6, 7, 9, 11, 13, 14, 15

One point if answer is 'false': questions 8, 10, 12

Maximum score 14 points, indicating poor sleep the night before

2. Table of questionnaires results

Scores of questionnaires	ETR period at W6 or W12	EFV period at W6 or W12	Change between ETR and EFV periods	Group effect P values	Treatment effect P values
	n=55	n=55	n=55		
	median (IQR)	median (IQR)	median (IQR)		
DASS* Scores :					
Stress	6 (2; 14)	8 (2; 16)	0 (-6; 2)	0.345	0.222
Anxiety	2 (0; 8)	4 (0; 10)	0 (-6; 2)	0.100	0.075
Depression	2 (0; 10)	6 (0; 12)	0 (-2; 2)	0.254	0.421
GSQS** Scores :	1 (1; 2)	1 (1; 2)	0 (0; 0)	0.2528	0.515
ESS*** Scores :	5 (3; 9)	6 (3; 9)	0 (-2;1)	0.9109	0.3197
SSS**** Scores :					
Score at 10 AM	1 (1; 2)	1 (1; 2)	0 (0; 0)	0.253	0.515
Score at 12 AM	2 (1; 4)	2 (2; 3)	0 (-1; 0)	0.837	0.494
Score at 14 PM	2 (1; 2)	2 (1; 3)	0 (-1; 0)	0.070	0.682
Score at 22 PM	3 (2; 5)	4 (2; 6)	0 (-1; 1)	0.792	0.166

*Depression Anxiety Stress Scales questionnaire

**Groningen Sleep Quality Scale questionnaire

***Epworth Sleepiness Scale questionnaire

****Stanford Sleepiness Scale questionnaire