

## Background

- Patient-reported outcome measures (PROMs) are of increasing relevance in the assessment of patients' health-related quality of life and in identification of unnoticed symptoms.
- In this post-hoc analysis of the DUALIS study<sup>1</sup>, we focus on mental health, in particular depression, in people with HIV (PWH) on stable suppressive ART at time of enrollment in the DUALIS study.
- DUALIS was a phase IIIb, open-label randomized clinical trial demonstrating non-inferiority of a switch to darunavir/ritonavir+dolutegravir (2DR) versus continuous darunavir/ritonavir+2NRTI (3DR) in virologically suppressed people PWH with week 48 virologic response rates of 86% (2DR) and 88% (3DR), respectively.<sup>1</sup>

## Methods

- The Hospital Anxiety and Depression Scale (HADS) was used to screen for anxiety and depression (main outcome measure). For corresponding subscales HADS/A and HADS/D (range 0-21 each), cut-offs of  $\geq 8$  (moderate to severe depression/anxiety) and  $\geq 11$  (severe depression/anxiety) were used.
- The 'mental health' dimension of the Medical Outcomes Study HIV Health Survey (MOS-HIV) was utilized to correlate with HADS/D outcomes, allowing for a comparison of these measures.
- The prevalence of depression (HADS/D  $\geq 8$ ) was evaluated with respect to sociodemographic (age, gender, HIV disclosure status, partnership, employment) and clinical variables (stage of HIV disease, presence of comorbidities).

## Results

### Characteristics of the analysis population

- The analysis population consisted of 259 (out of 263) DUALIS participants who completed the HADS questionnaire.
- The majority of participants were male (90%), 40% were  $\geq 50$  years of age.
- At time of HIV-diagnosis, 26% already had advanced HIV disease (clinical AIDS, i.e. stage CDC C); in 46%, CD4 nadir was  $<200/\mu\text{L}$ .
- Median CD4 cell count (IQR, interquartile range) at baseline was 598 cells/ $\mu\text{L}$  (423-818).
- 51% of participants were in stable partnership, 75% indicated either a full- or part-time job.
- Overall, 10% of participants had disclosed their HIV status to an extended circle of people, 80% only to very close people; for a further 10%, only healthcare providers knew about it.

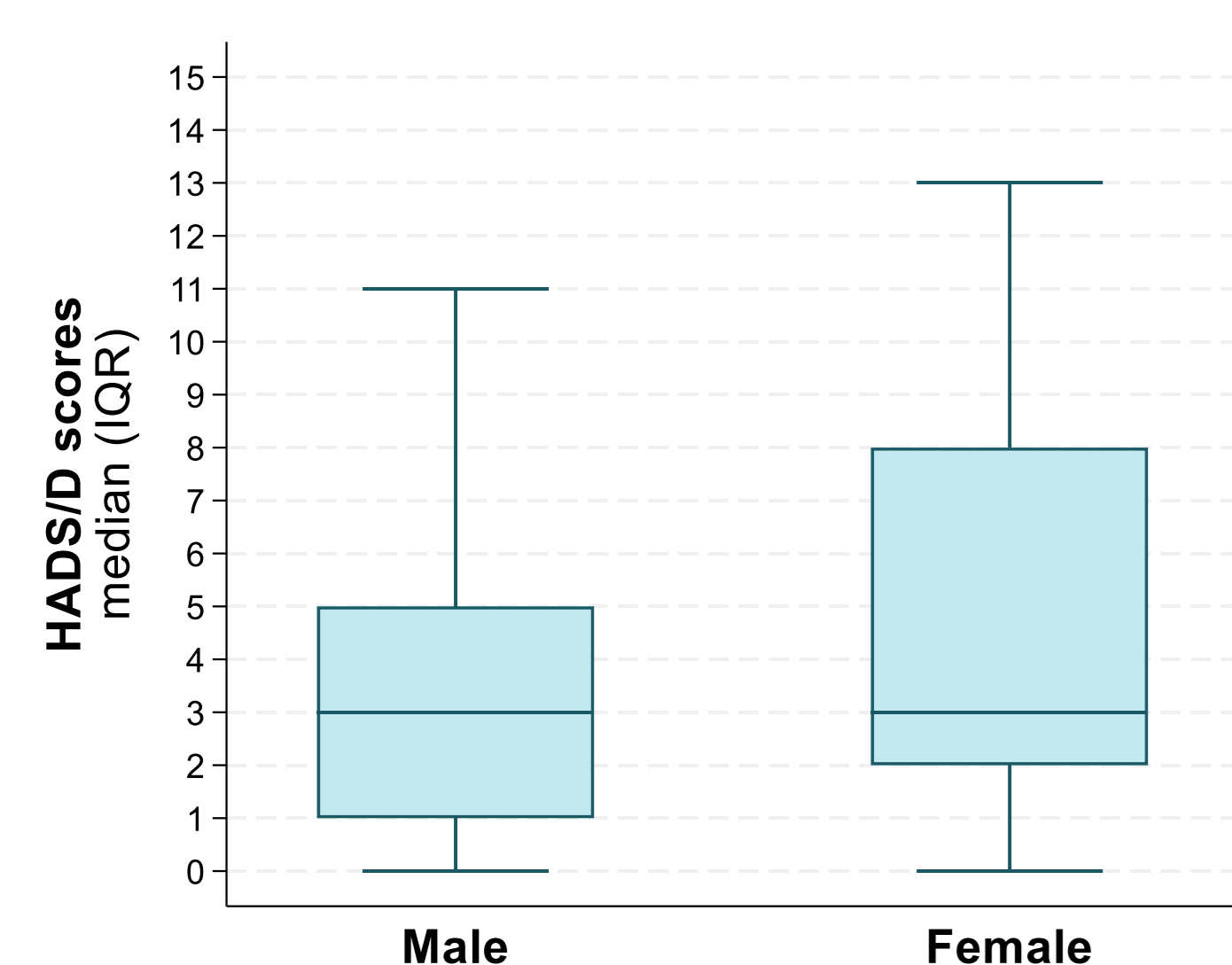
### HADS/D scores at time of inclusion (baseline)

- At baseline, the median HADS/D score (IQR) was 3 (1-6).
- The prevalence of at least moderate or of severe depression using HADS/D scores of  $\geq 8$  and  $\geq 11$ , was 17% ( $n=44/259$ ) and 5% ( $14/259$ ), respectively.
- 15% of PWH ( $38/255$ ) received psychotherapy or psychotropic treatment/pharmacotherapy, 36% of those with HADS/D $\geq 8$  ( $15/42$ ), 11% of those with HADS/D $<8$  ( $23/213$ ).

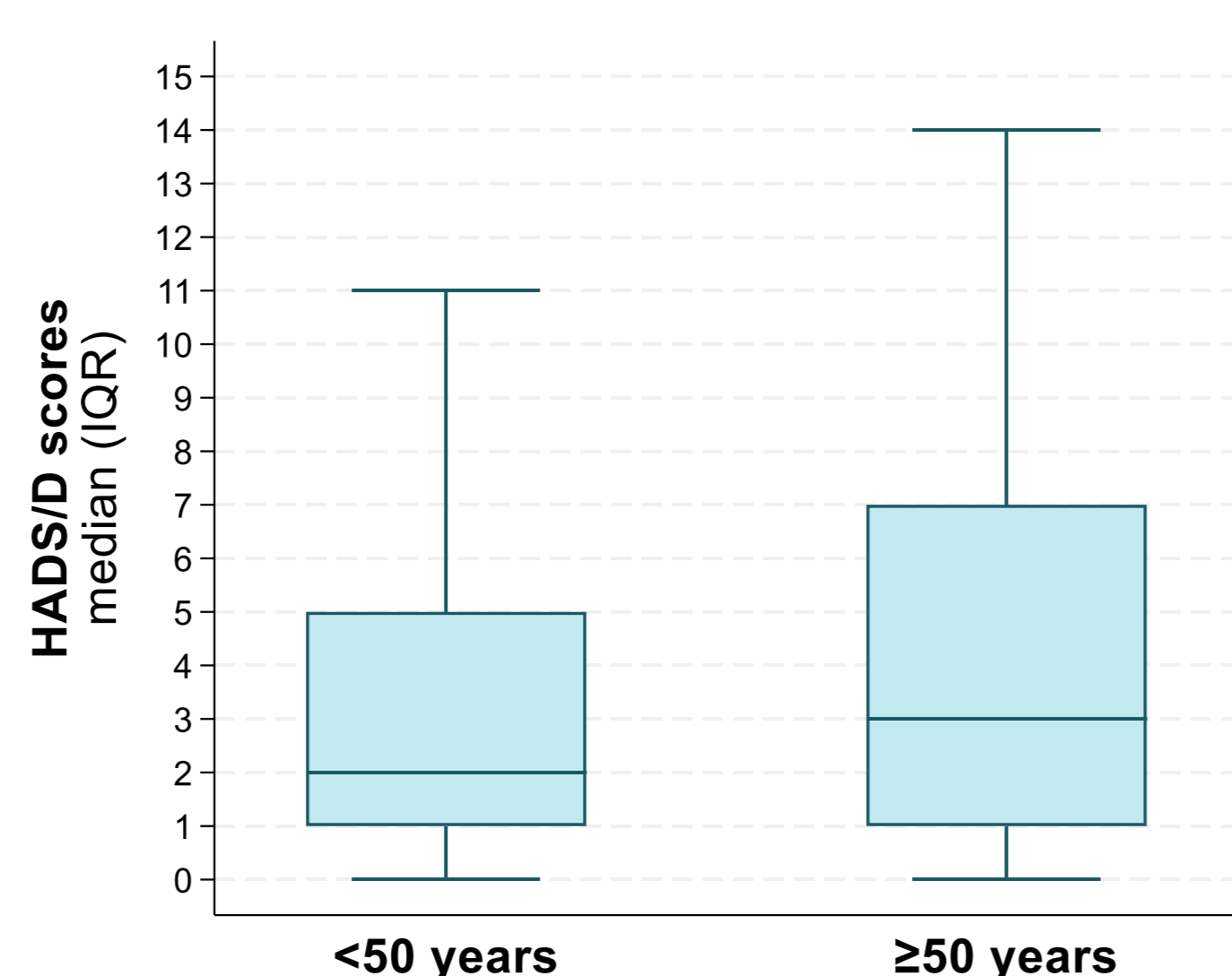
**Table 1. Characteristics of the analysis population and HADS/D categories at baseline\***

	Overall (N=259)	HADS/D <8 (N=215)	HADS/D $\geq 8$ (N=44)
Female; n (%)	25 (10)	17 (8)	8 (18)
Age [years]; median (IQR)	47 (39-53)	47 (39-52)	51 (43-57)
Age $\geq 50$ years; n/N (%)	104 (40)	80 (37)	24 (55)
CDC C stage at HIV-diagnosis	68 (26)	55 (26)	13 (30)
Absolute CD4 nadir $<200/\mu\text{L}$ ; n/N (%)	99/213 (46)	81/176 (46)	18/37 (49)
At least concomitant disease at baseline; n/N (%)	177 (68)	145 (67)	32 (73)
Psychotropic treatment/pharmacotherapy; n/N (%)	28/255 (11)	15/213 (7)	13/42 (31)
Psychotherapy; n/N (%)	25/255 (10)	16/213 (8)	9/42 (21)
Stable partnership; n/N (%)	131/255 (51)	114/213 (54)	17/42 (40)
Full-/part-time employment or education; n/N (%)	192/257 (75)	166/215 (77)	26/42 (62)
Disclosure	(N=257)	(N=215)	(N=42)
of HIV status to an extended circle of people; n (%)	25 (10)	20 (9)	5 (12)
of HIV status to very close people; n (%)	207 (80)	173 (81)	34 (81)
of HIV status to healthcare providers only; n (%)	25 (10)	22 (10)	3 (7)

\*data as observed



**Figure 1a. HADS/D scores, stratified by gender**

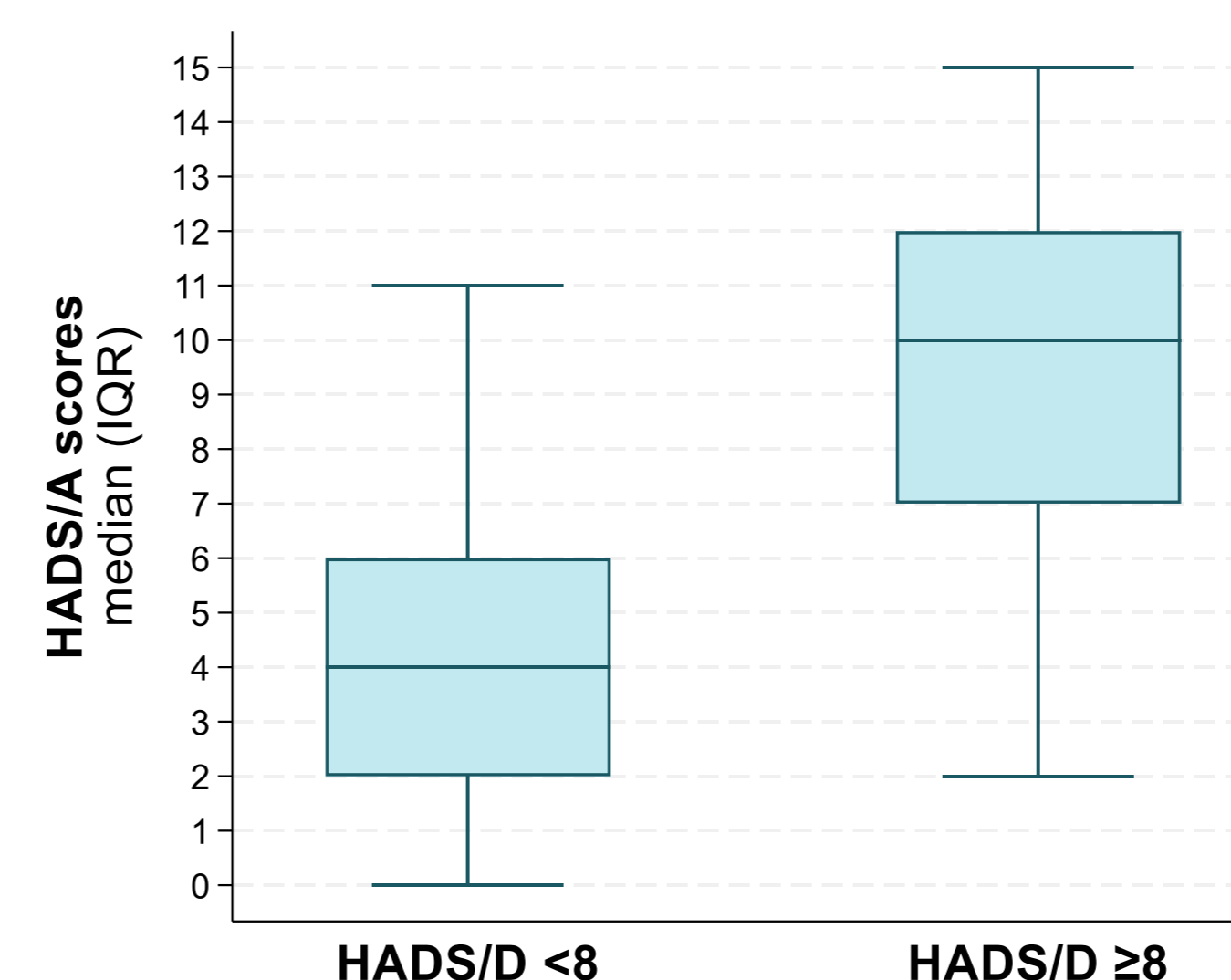


**Figure 1b. HADS/D scores, stratified by age <50 vs  $\geq 50$  years**

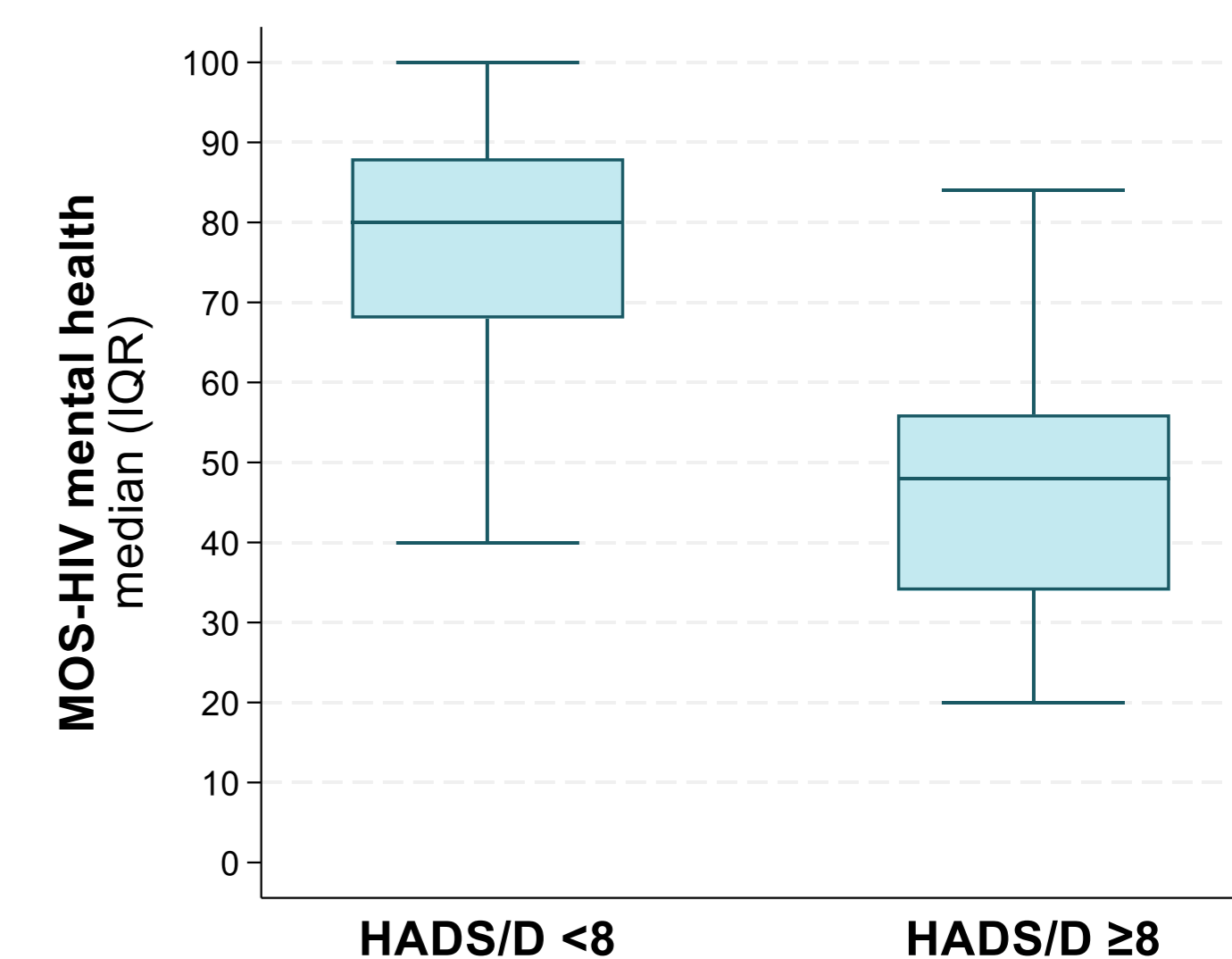
### HADS/A and MOS-HIV mental health scores and correlation with HADS/D scores

- The baseline prevalence of anxiety using an HADS/A score  $\geq 8$  [ $\geq 11$ ] was 24% ( $n=63/259$ ) [9% ( $n=23/259$ )].
- Anxiety was highly correlated with depression: in those with HADS/D $\geq 8$ , median HADS/A score (IQR) was 10 (7-12) (in comparison to 4 (2-6) in those with HADS/D $<8$ ).
- Median (IQR) score for MOS-HIV mental health\* was 80 (60-88).

\*Overall range (0-100); higher scores representing better outcomes



**Figure 2a. HADS/A scores, stratified by HADS/D scores <8 vs  $\geq 8$**



**Figure 2b. MOS-HIV mental health scores, stratified by HADS/D scores <8 vs  $\geq 8$**

### Independent factors associated with HADS/D scores $\geq 8$

In PWH entering the DUALIS study, independent factors associated with HADS/D scores  $\geq 8$  in logistic regression analysis\* were

- female gender (OR 3.3; 95% CI 1.2-9.5;  $p=0.03$ )
- age  $\geq 50$  years (OR 2.6; 95% CI 1.2-5.5;  $p=0.01$ ).

There was a trend towards higher depression scores for people

- without stable partnership (OR 2.0; 95% CI 0.9-4.3,  $p=0.07$ ).

HIV disclosure status, employment and clinical variables were not associated with HADS/D scores  $\geq 8$ .

\*  $p<0.2$  for remaining in the model

### HADS/D and HADS/A scores stratified by study arms at week 48

HADS/D and HADS/A scores did not change significantly from baseline to week 48, neither in the continuous ART study arm (darunavir/ritonavir+2NRTI), nor in the interventional arm with switch to darunavir/ritonavir+dolutegravir.

**Table 2. HADS/D and HADS/A scores at baseline and at week 48**

	2DR (N=128)	3DR (N=131)
HADS/D scores at baseline; median (IQR)	3 (1-6)	2 (1-5)
HADS/D scores at week 48; median (IQR)	3 (1-6)	2 (0-6)
HADS/D scores $\geq 8$ at week 48; n/N (%)	23/120 (19)	20/121 (17)
Change in HADS/D scores at week 48 from baseline; median (IQR)	0 (-2-+1)	0 (-1-+2)
HADS/A scores at baseline; median (IQR)	6 (3-8)	4 (2-7)
HADS/A scores at week 48; median (IQR)	5 (2-9)	4 (2-7)
HADS/A scores $\geq 8$ at week 48; n/N (%)	36/118 (31)	25/121 (21)
Change in HADS/A scores at week 48 from baseline; median (IQR)	0 (-2-+1)	0 (-2-+2)

## Conclusions

- ▶ In the DUALIS study, the prevalence of elevated baseline HADS/D and HADS/A scores indicating anxiety and depression were 17% and 24%, respectively.
- ▶ HADS scores remained largely unchanged over 48 weeks while on either continuous darunavir/ritonavir+2NRTI-based ART or on darunavir/ritonavir+dolutegravir.
- ▶ In this selected group of people with HIV, only higher age and female gender were significantly associated with higher depression scores. Disease related and sociodemographic variables did not show a significant association.
- ▶ Patient-reported outcome measures may help identifying people with HIV in need for therapeutic intervention.

### References

<sup>1</sup>Spinner C., et al. Open Forum Infect Dis.2020;7(9):ofaa356)

### Funding

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