Electronic Supplementary Material

Patient-Reported Outcomes Through Week 48 of ATLAS-2M: Long-Acting Cabotegravir and Rilpivirine Administered Every Four or Eight Weeks

The Patient

Authors

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Please note: Bold superscript number details affiliation during the conduct of the study.

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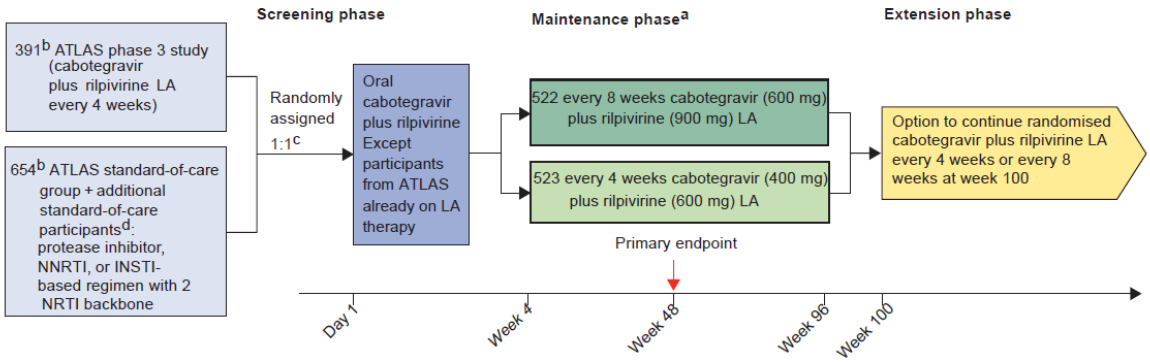
Fig. S1 ATLAS-2M study design



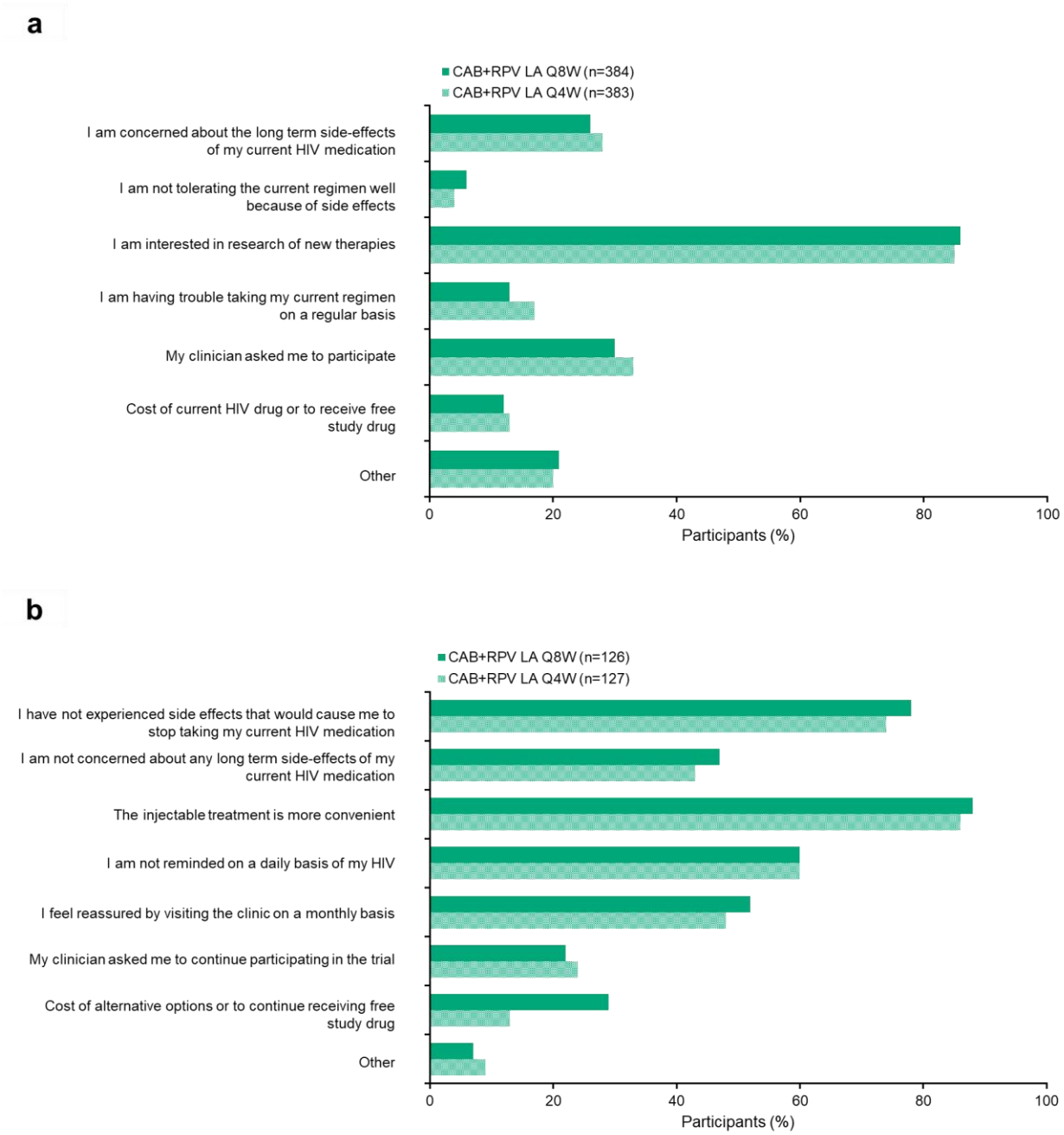
[a]ATLAS participants on every 4 weeks group—transition to ATLAS-2M day 1 onwards: cabotegravir LA (400 mg) plus rilpivirine LA (600 mg) intramuscularly every 4 weeks or cabotegravir LA (600 mg) plus rilpivirine LA (900 mg) intramuscularly every 8 weeks. New ATLAS-2M participants naive to LA at day 1—all participants initiate 4-week oral lead-in followed by LA injections: every 4 weeks group—loading dose of cabotegravir LA (600 mg) plus rilpivirine LA (900 mg) intramuscularly at week 4, then cabotegravir LA (400 mg) plus rilpivirine LA (600 mg) intramuscularly every 4 weeks; every 8 weeks group—initial dose of cabotegravir LA (600 mg) plus rilpivirine LA (900 mg) at week 4 and week 8, then continue same intramuscular dose every 8 weeks. Participants who withdraw from the intramuscular regimen must go into 52-week long-term follow-up if randomized regimen is not yet locally approved and commercially available. Doses were scheduled on the basis of a fixed treatment date, and that target date of the month or every other month was carried forward. For participants transitioning from standard of care in either group and those transitioning from every 4 weeks to every 8 weeks, there was a −7-day dosing window for the second and third intramuscular injections and a ±7-day window thereafter. For those continuing every 4 week dosing from ATLAS, there was a ±7-day window for injections.

[b]Intention-to-treat exposed population.

[c]1149 participants were screened, and 1049 participants were randomly assigned. However, four participants did not receive study drug and were therefore not part of the intention-to-treat exposed population.

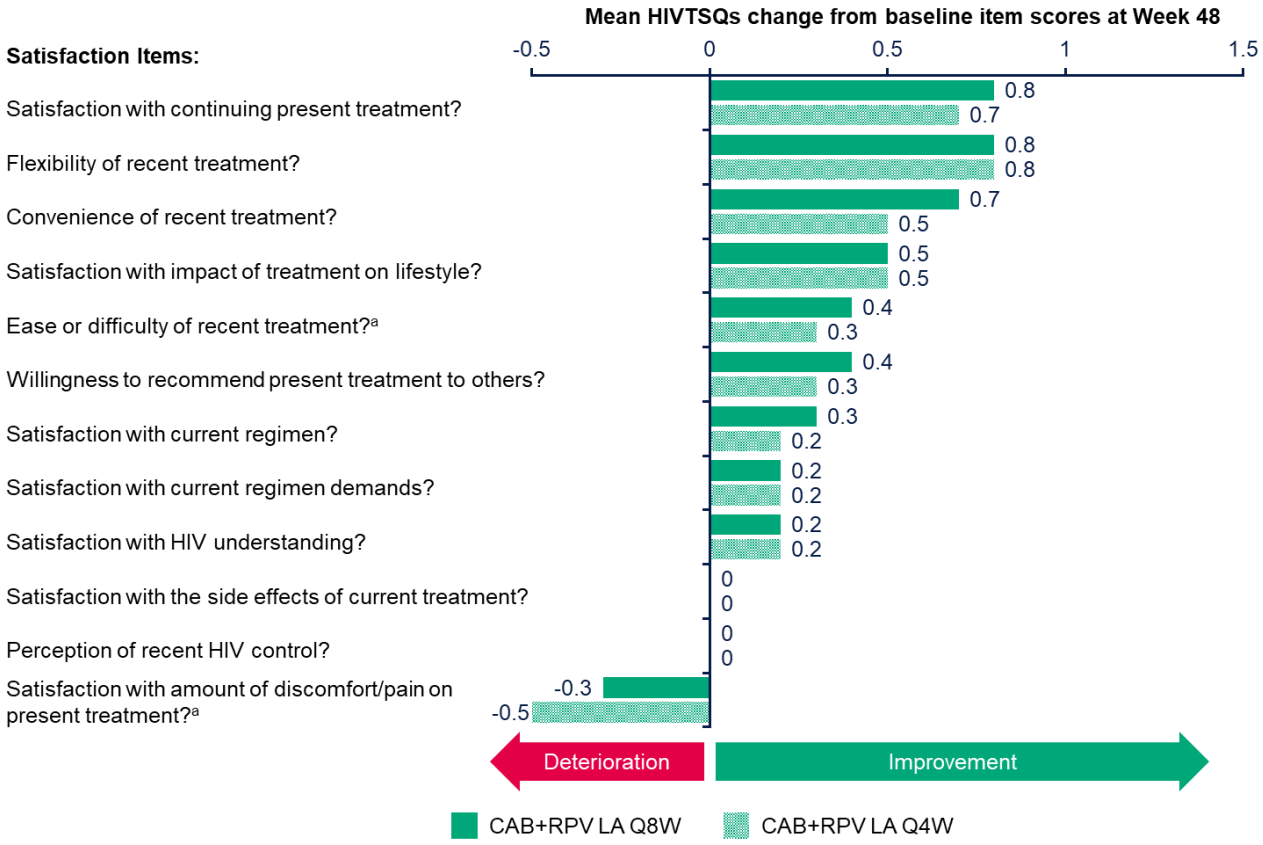
[d]Standard-of-care participants not transitioning from the ATLAS study were to be on uninterrupted current regimen (either the initial or second combined ART regimen) for at least 6 months before screening. Documented evidence was required of at least two plasma HIV-1 RNA measurements <50 copies per mL in the 12 months before screening: one within the 6–12-month window, and one within 6 months before screening. Participants were excluded if they had a history of virological failure; evidence of viral resistance based on the presence of any resistance-associated major INSTI or NNRTI mutation (except K103N) from previous genotype assay results; or current or previous history of etravirine use.

Fig. S2 Reasons for switch at baseline for participants transitioning from oral SoC in the routine clinic or the SoC arm in ATLAS (a) and for participants transitioning from the CAB+RPV LA Q4W arm in ATLAS (b)



CAB, cabotegravir; LA, long-acting; Q4W, every 4 weeks; Q8W, every 8 weeks; RPV, rilpivirine; SoC, standard of care.

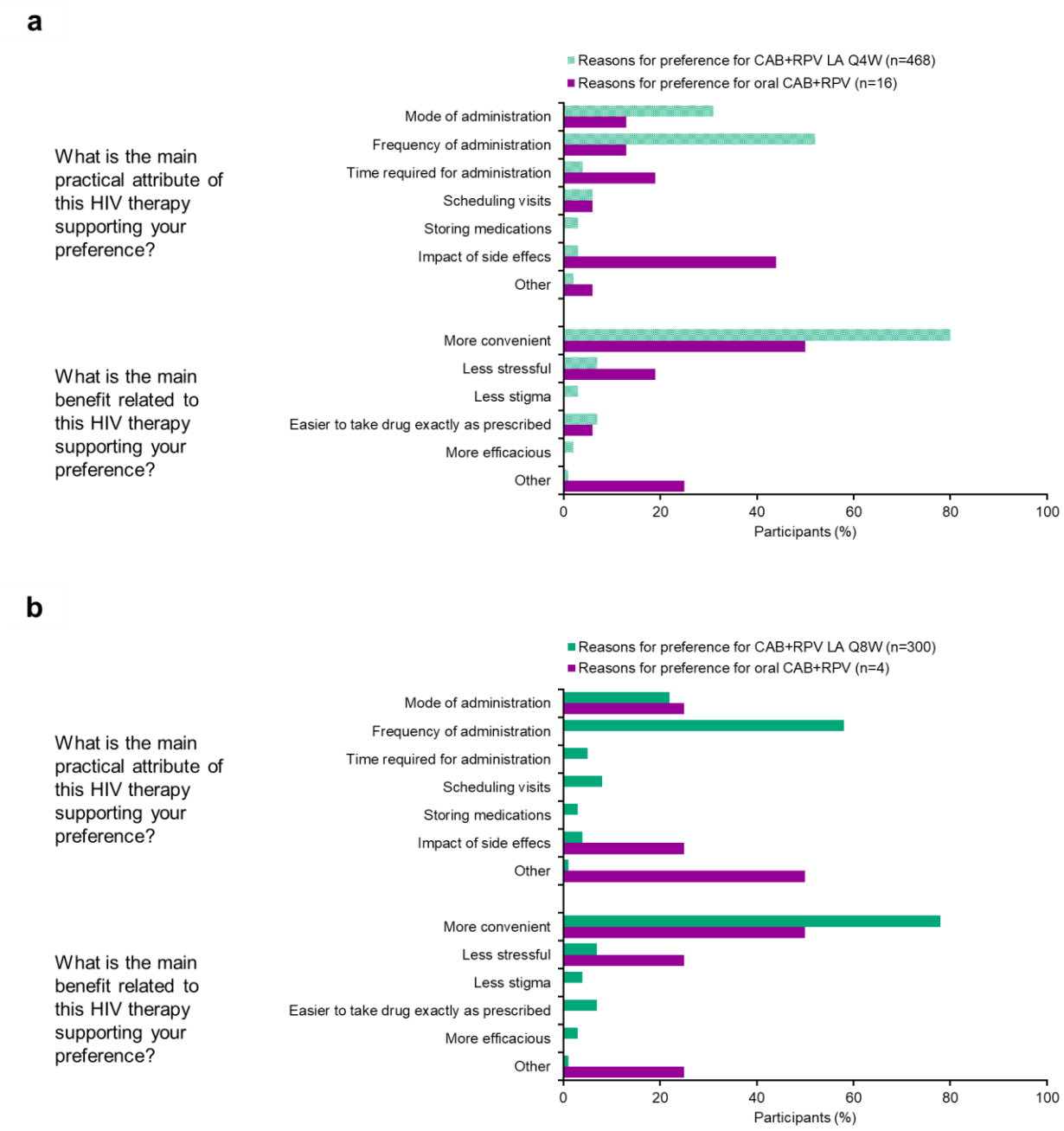
Fig. S3 Mean HIVTSQs change from baseline for individual items in participants without prior CAB+RPV exposure



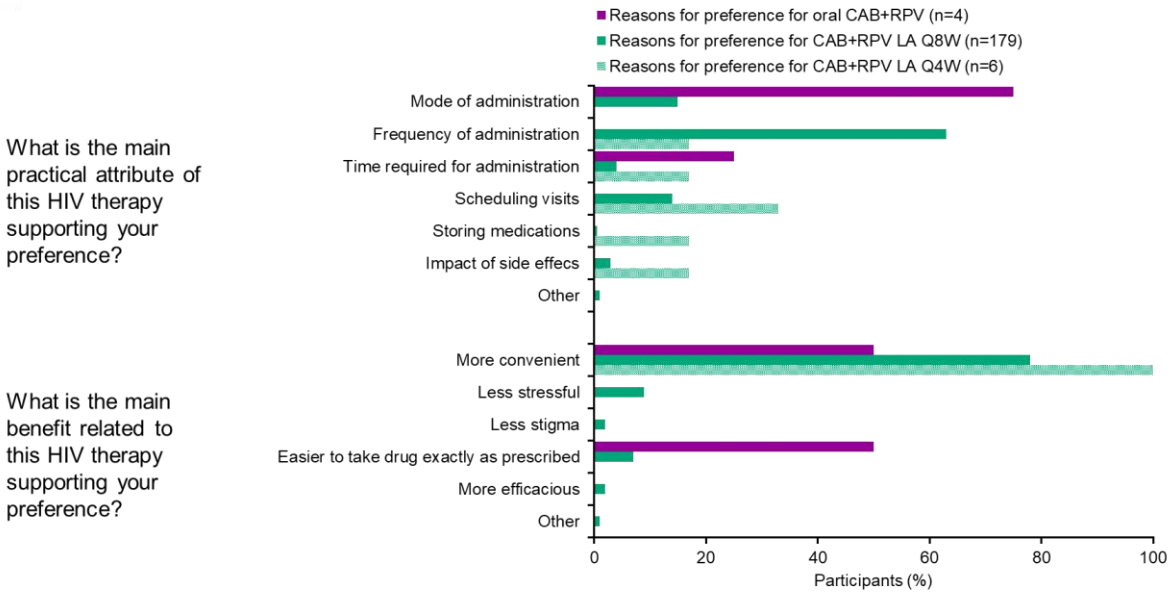
[a]HIVTSQ was adapted to include two additional questions relating to injectable treatment.

CAB, cabotegravir; HIVTSQs, HIV Treatment Satisfaction Questionnaire (status version); LA, long-acting; Q4W, every 4 weeks; Q8W, every 8 weeks; RPV, rilpivirine.

Fig. S4 Reasons for preference for participants in the Q4W group (a), for participants in the Q8W group without prior CAB+RPV exposure (b), and for participants in the Q8W group with prior CAB+RPV exposure (c)



c



CAB, cabotegravir; LA, long-acting; Q4W, every 4 weeks; Q8W, every 8 weeks; RPV, rilpivirine.