

HOW DO PARTICIPANTS EXPERIENCE ANALYTICAL TREATMENT INTERRUPTION TRIALS: LESSONS LEARNED FROM THE HIV-STAR STUDY

Background:

In HIV cure research, analytical treatment interruption (ATI) trials have become a very important tool to evaluate new latency reversing agents (and other molecules that aim to reduce the viral reservoir). Furthermore, these trials can give us broader insights on the origin of

viral rebound and can help with the identification of potential biomarkers to predict viral rebound post-treatment. Although recent data supports the safety of these interventions, little is known about participants experience and satisfaction.

Results:

Overall satisfaction was high (90%), resulting in zero drop-outs and a high N of participants who would reenter this trial (90%). Participants had very realistic expectations concerning outcome and benefits related to their participation (90%). However, most of the participants underestimated the treatment interruption phase, especially on a psychological level.

Description:

Participants of the HIV-STAR study (NCT02641756) answered two self-designed questionnaires. The first (32 questions) at inclusion (T1) focused on expectations, motivation and fears. The second at the final study visit (T5), in average 3 months after the ATI (23 questions). Here, we mostly assessed the overall satisfaction and experience.

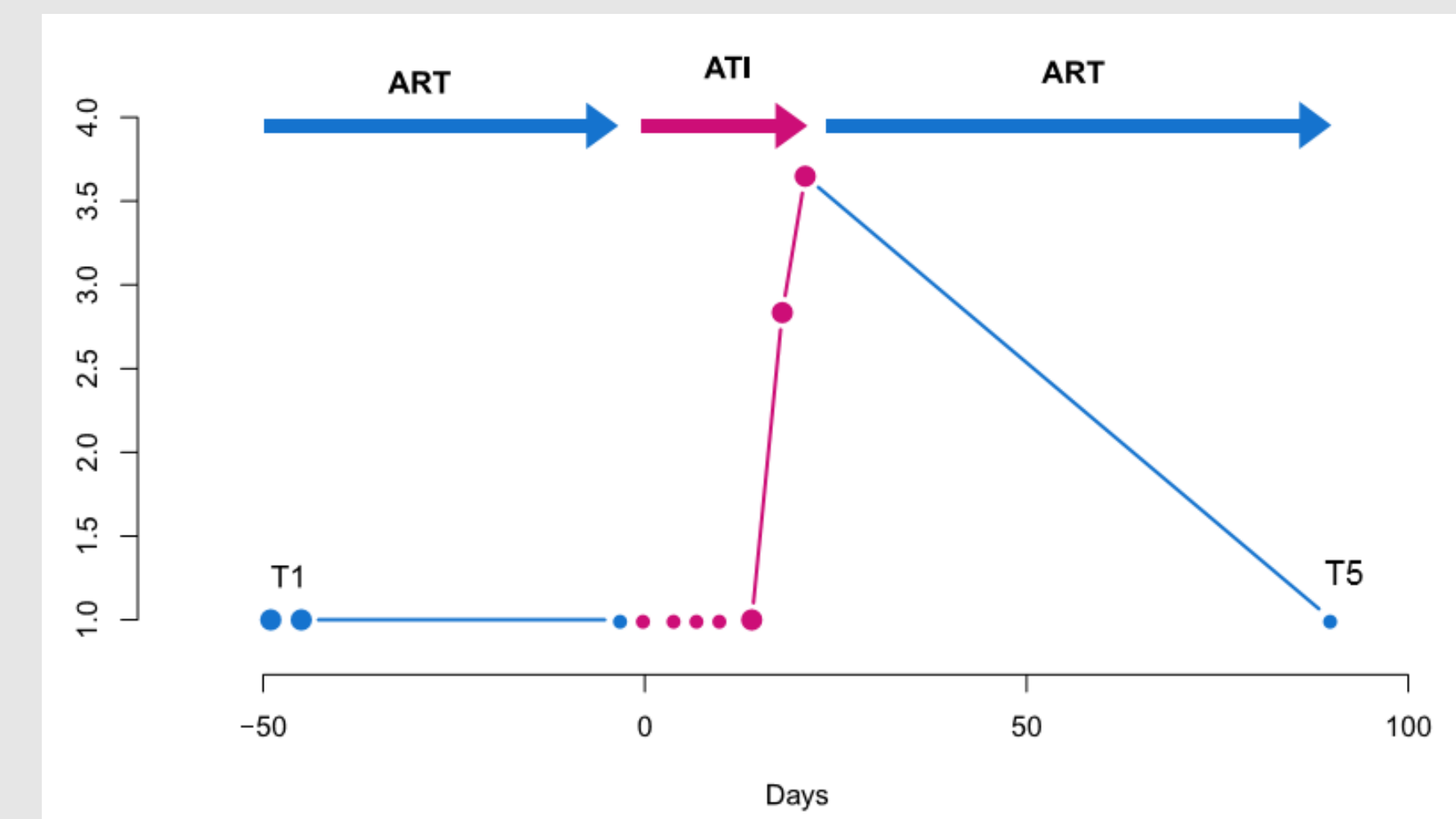


Fig 1: Flowchart representing the study flow and time points of sampling

Although initial screening revealed mostly fear of the extensive sampling interventions (63%), this did not appear to be a major burden at final evaluation (9%).

No patients initially thought treatment interruption would be an emotional challenge and only 27% were preoccupied by the viral rebound whereas this was assessed as the more difficult phase of the study at evaluation (36%).

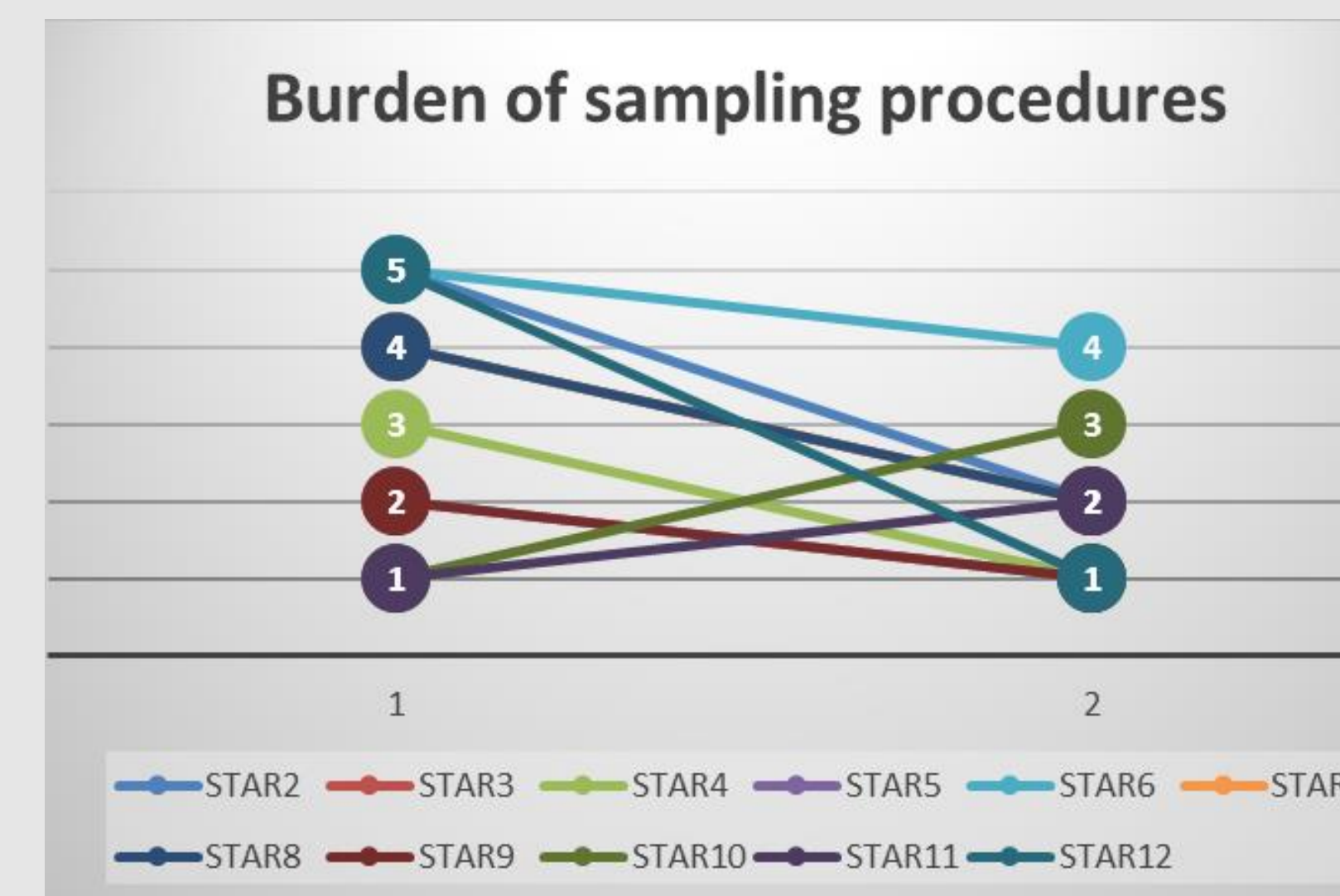


Fig 2: Slopegraph showing the expected and experienced burden of sampling procedures before (1) and after the study (2) respectively. The colors represent the different patients. Scores are from 1->5 at time point 1 and 1-> 4 at timepoint 4, where 1 is the lowest intensity and 4-5 represent the highest intensity.

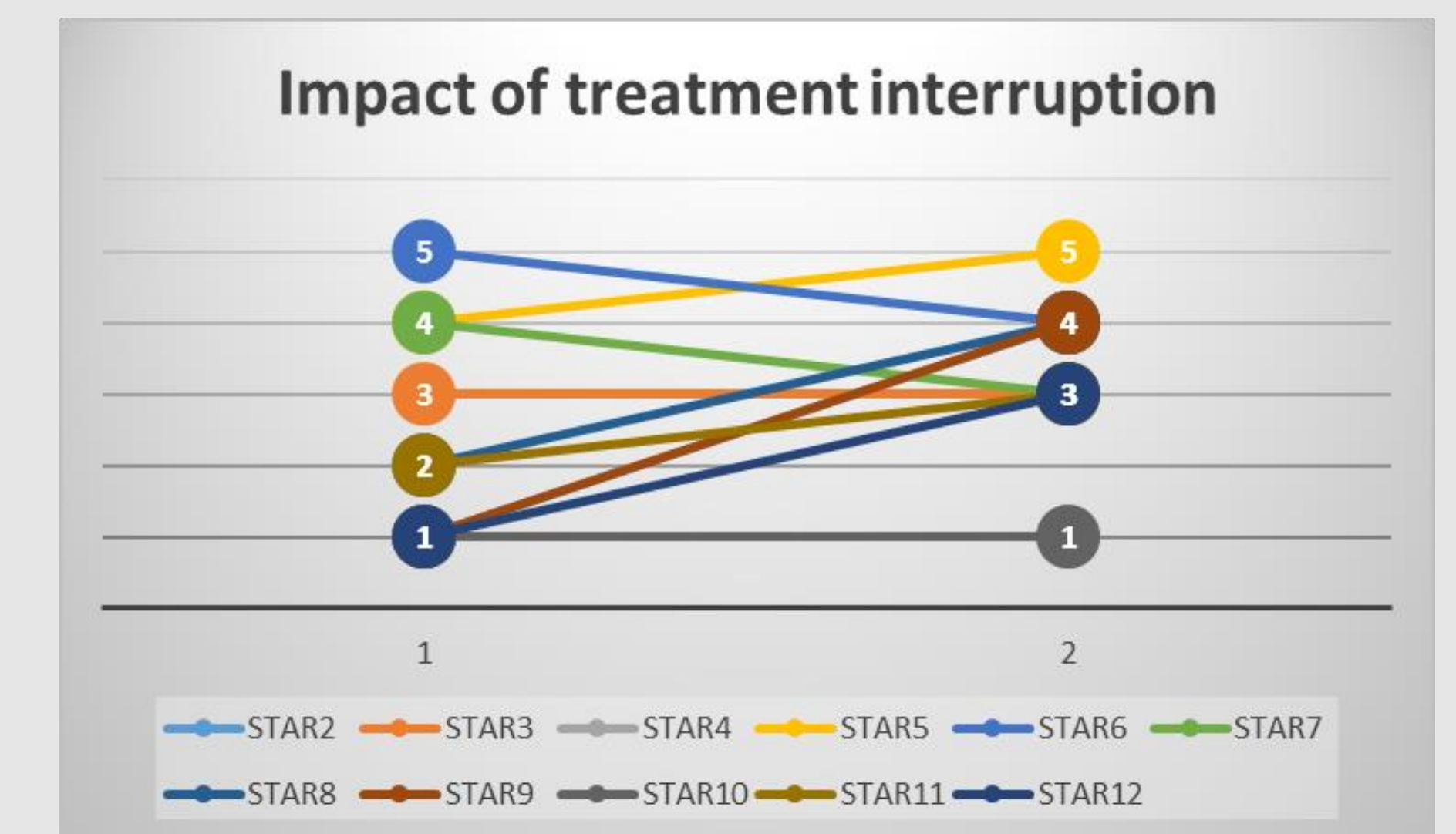


Fig 3: Slopegraph showing the impact of treatment interruption before (1) and after the study (2). The colored lines represent the different patients. Scores are from 1->5 at timepoint 1 and 1-> 4 at timepoint 4, where 1 is the lowest intensity and 4-5 represent the highest intensity.

Conclusions: ATI and extensive sampling were positively evaluated by the participants of the HIV-STAR study, resulting in zero drop-outs, high overall satisfactory scores (90%) and an increased interest and contribution in research projects. However, we believe that a strict inclusion policy, individual guidance and fierce organization play a major role in participants satisfaction. Qualitative assessment is ongoing and results will be reported shortly.

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