Medication adherence in the DREAMING study: a pragmatic randomized placebo controlled trial in insomnia patients

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Background

The DREAMING study aims to assess the effectiveness of the use of low-dose amitriptyline and mirtazapine for 16 weeks in participants with insomnia disorder (18-85 years) in general practice. It is of particular interest to study medication adherence and early discontinuation.

Objective

To assess adherence of insomnia patients to low dose amitriptyline and mirtazapine in the DREAMING trial.

Methods

- Design: randomized placebo controlled trial, descriptive analysis
- Setting: adults diagnosed with insomnia disorder in general practices
- Treatment (1-2 tablets): amitriptyline (10/20 mg) or mirtazapine (7.5/15 mg) or placebo for 16 weeks (figure 1)
- Measurements: adherence based on pill count (percentage of days covered; PDC, calculated as (No. tablets – Pill count) / (Expected no. tablets used according to protocol) and questionnaires (figure 1).

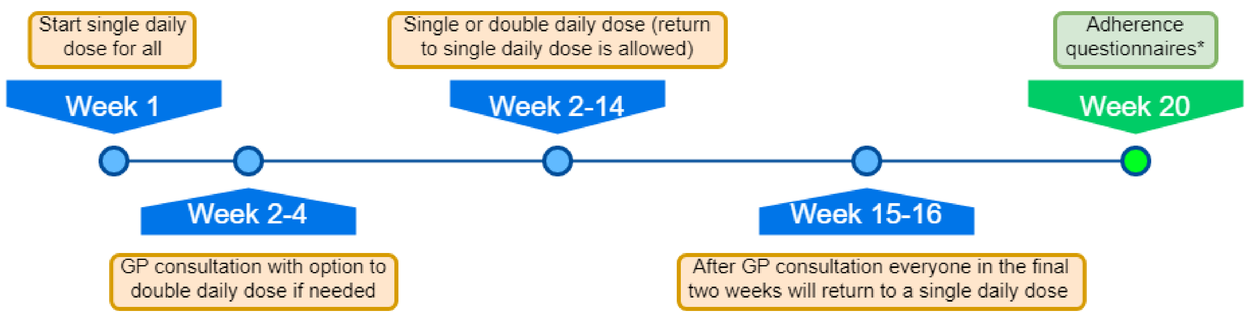

Figure 1. Participant time line. *Adherence questionnaires were taken in week 6 or week 12 for participants who discontinued early.

Results

- Five of 80 participants were lost to follow-up, 16 participants discontinued study medication early and 59 participants finished the 16 weeks medication period.
- PDC could only be calculated for 56 finishers and 9 discontinuers over their period in the trial.
- For 15 participants PDC could not be calculated due to missing information on dose prescription or pill count.
- The mean PDC was 99.2 ± 16.7 (n=65).
- Figures 2,3. show the results regarding PDC and the adherence.

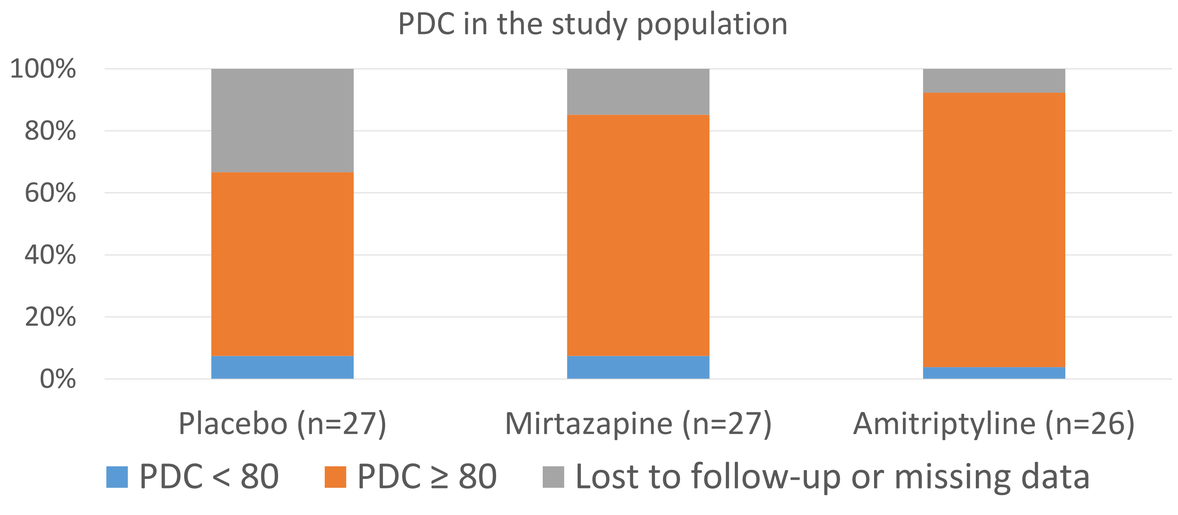

Figure 2. The percentage of participants with a calculated PDC below and above or equal to 80% in the total study population (n=80).

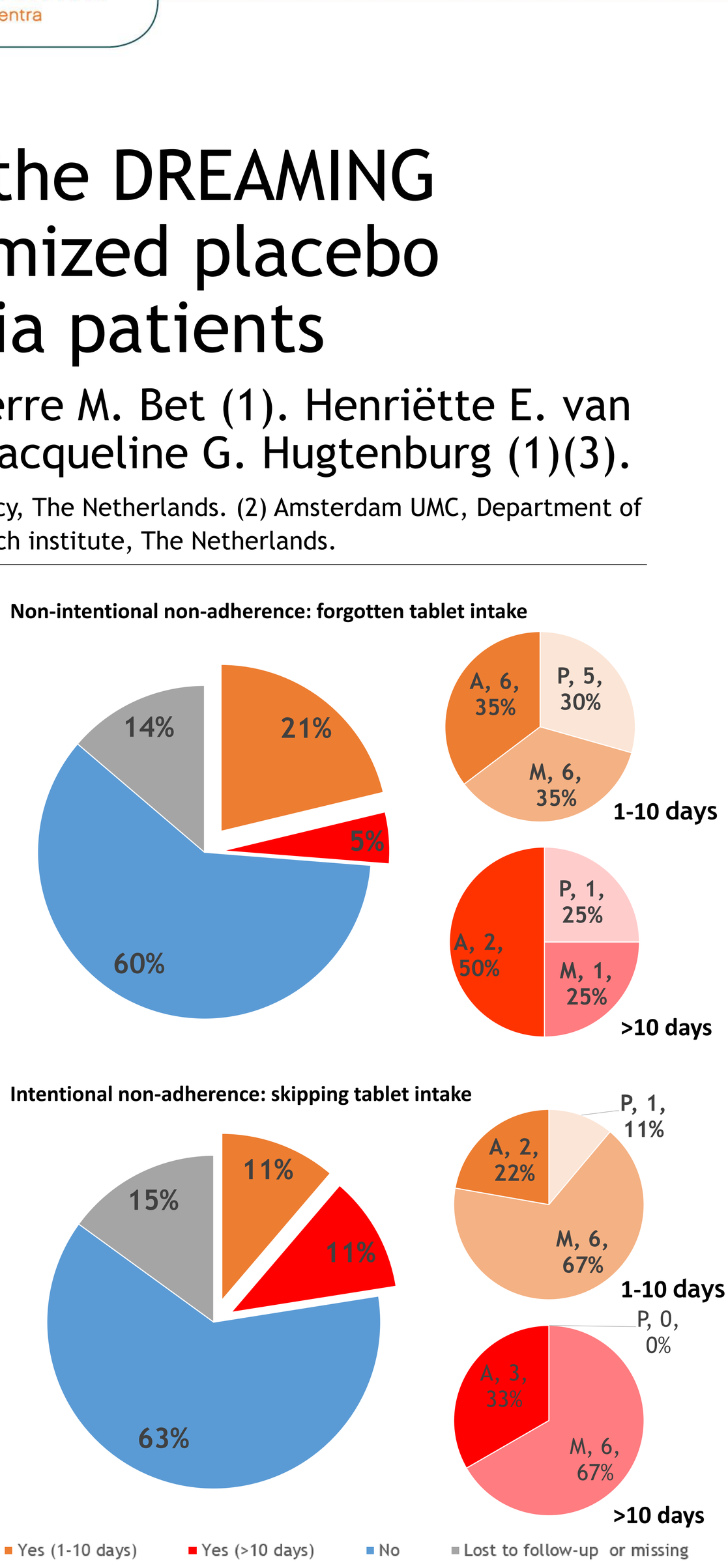

Figure 3. Patient reported adherence in total study population (n=80). P = placebo; A = amitriptyline; M = mirtazapine.

- Reasons for skipping medication were: Not needed anymore (n=5), driving (n=3), side effects (n=3), using other medication (n=2), stopped using (n=1), insufficient effect (n=1), not specified (n=2)
- Reasons for discontinuation were: side effects (n=8) and insufficient effect (n=8)

Conclusion

Both non-intentional and intentional medication non-adherence and early discontinuation occurred. Overall, adherence was reasonably good.

Discussion

Non-adherent patients may be less inclined to participate in clinical trials.