

## Introduction

OSA is a common sleep disorder characterized by repetitive obstruction of the upper airway during sleep, this disorder displays 24-26% prevalence among adult men and increases with age.

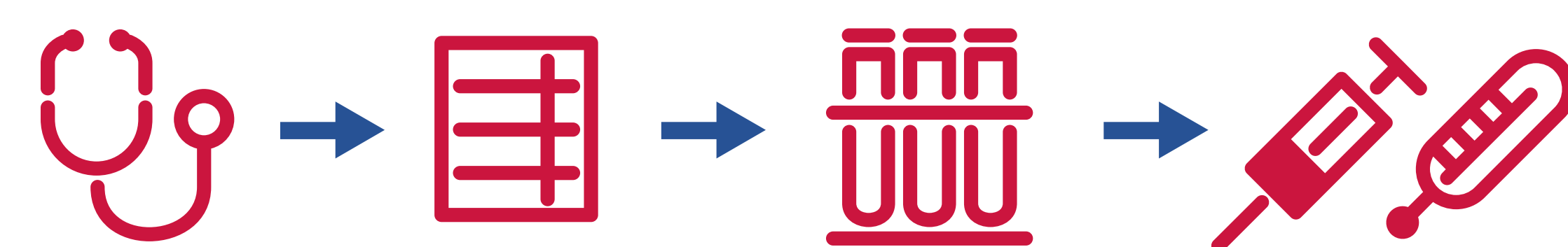
Approximately 60% of OSA diagnoses are position-dependent, and approximately 25% have supine isolated events only when lying in the supine position.



Avoidance of the supine position could represent an effective treatment, improving arterial hypertension, cardio- and cerebrovascular diseases, road accidents and quality of life.

The aim of our study is to know the compliance of our forehead positional therapy and to show a complementary data obtained in RCT of validation using the device during 12 weeks,

## Methods



**Design and settings:** Multicenter, randomized, prospective, parallel controlled trial. The design was distributed in three arms:

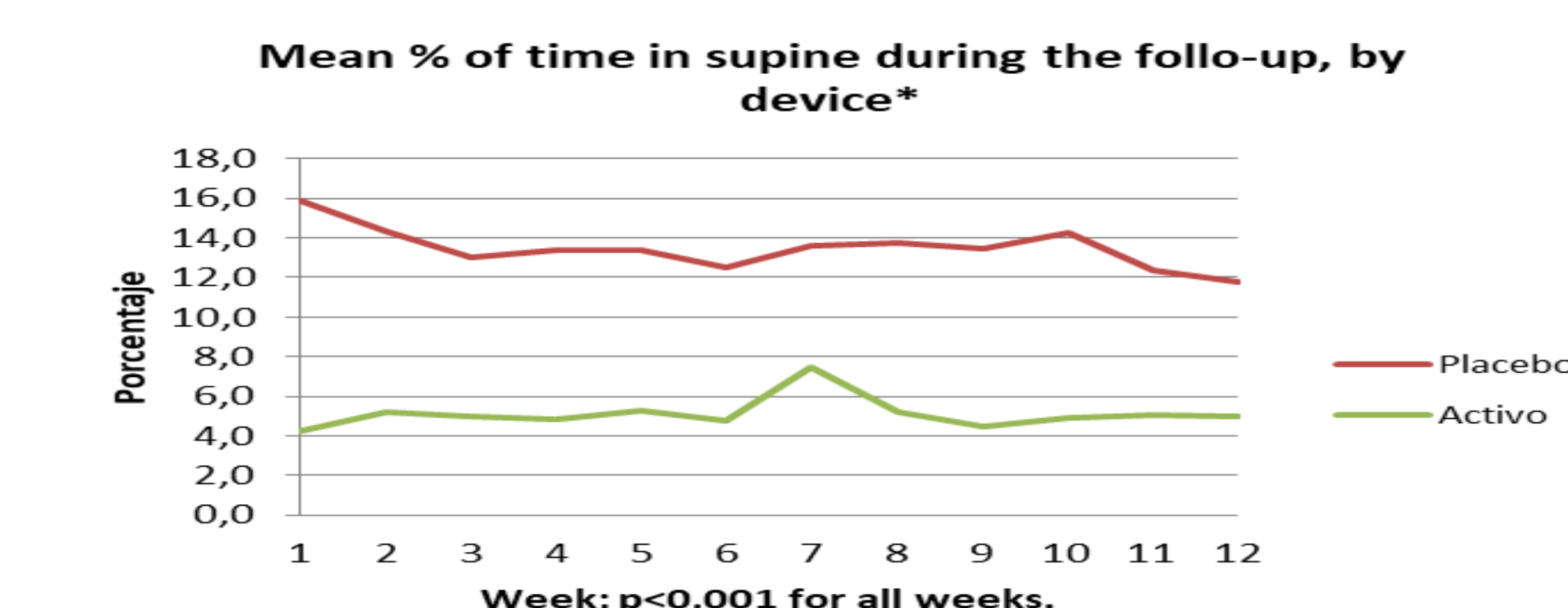
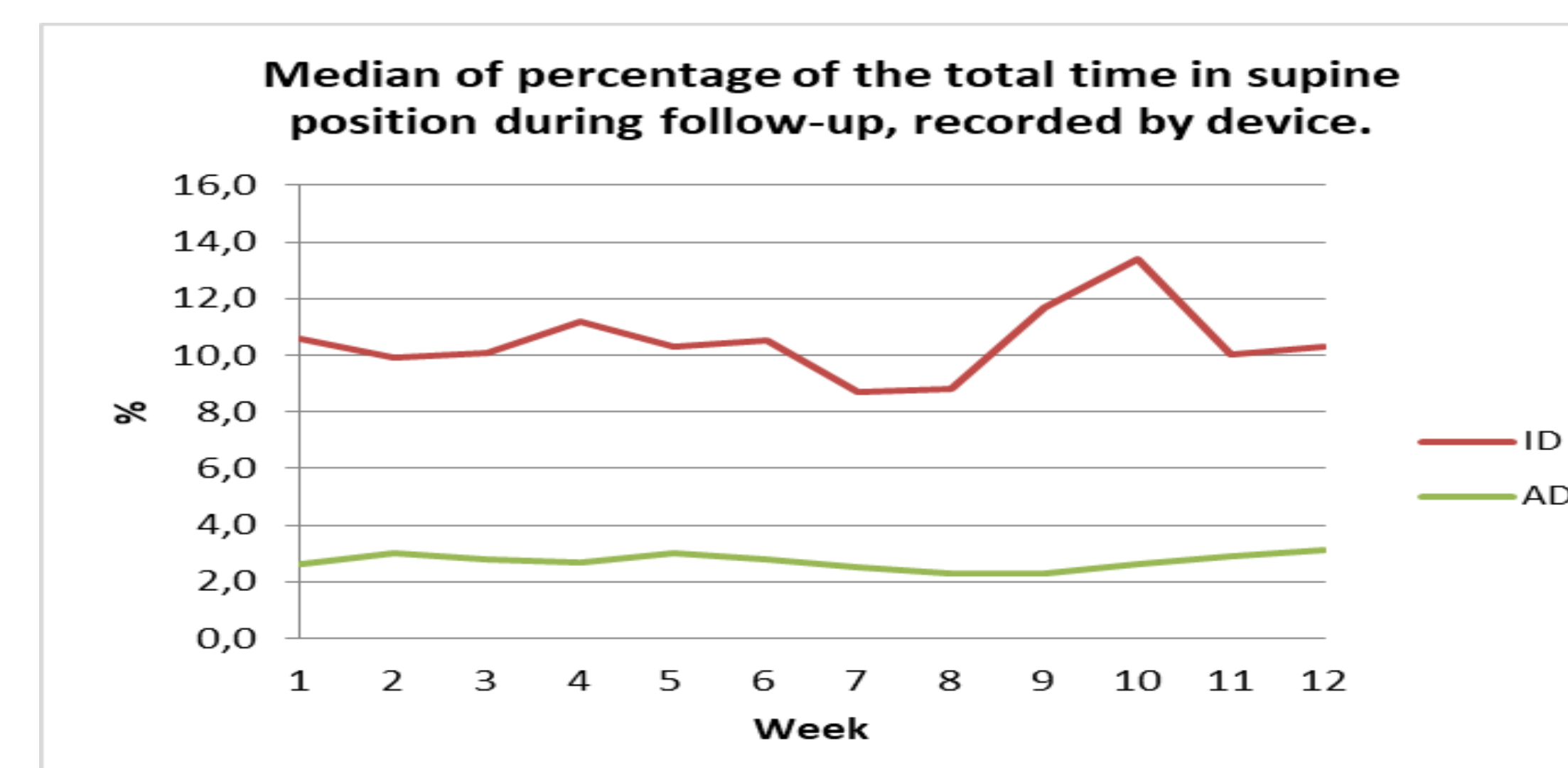
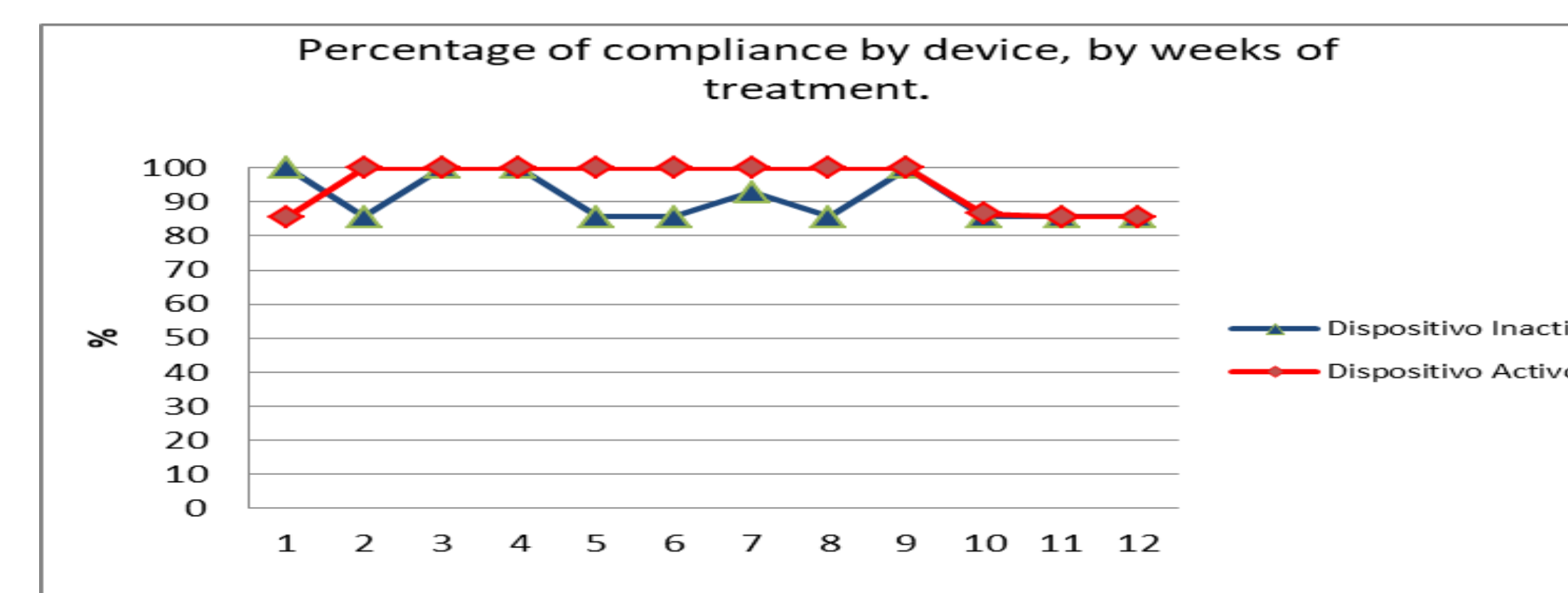
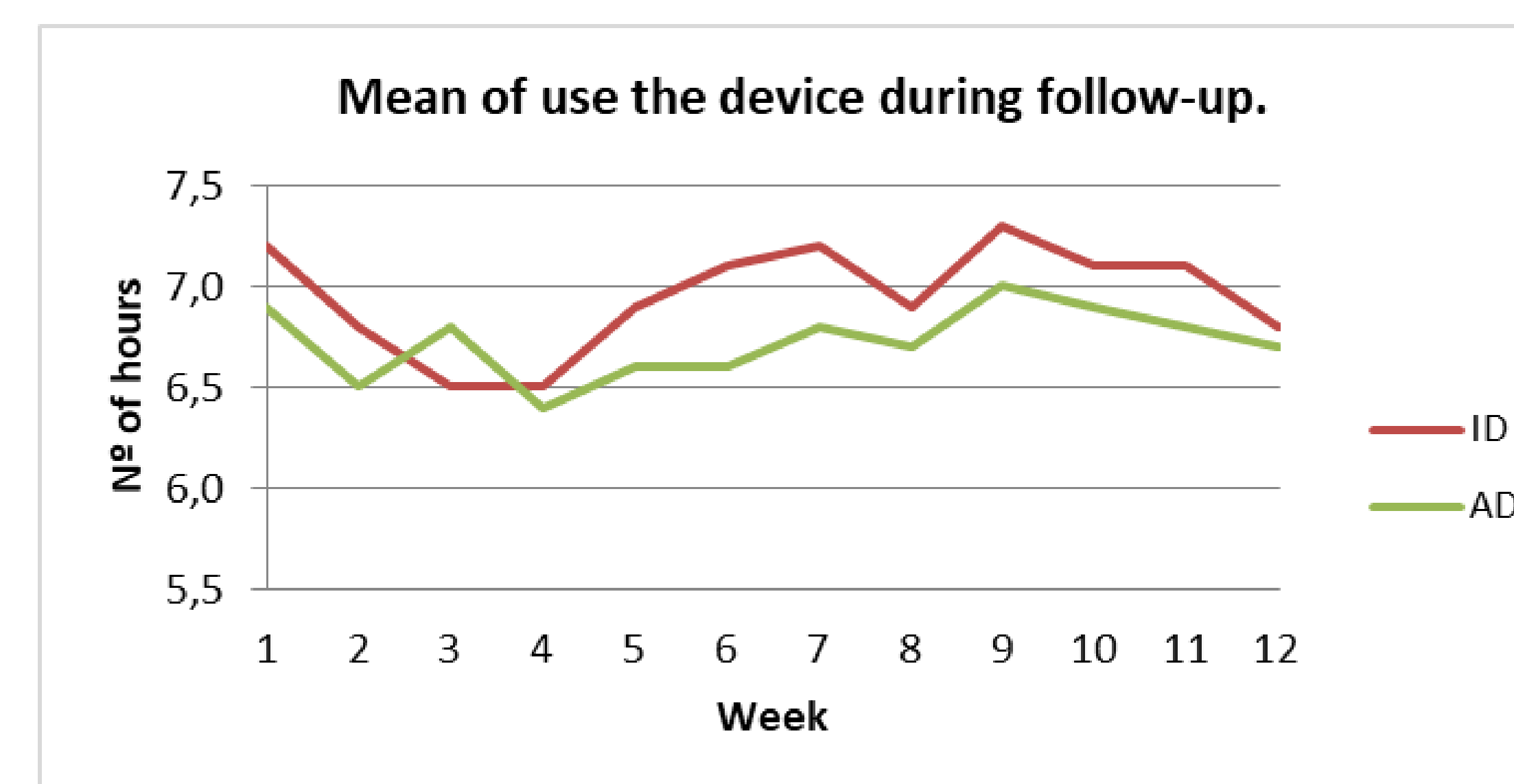
- 1) General recommendations (GR) to avoid supine position
- 2) GR plus inactive device (ID)
- 3) GR plus active device (AD).

**Participants:** Men and women aged  $\geq 18$  years who were diagnosed as having POSA, We defined POSA as having an AHI  $\geq 10$  and the sleep time in supine double than non-supine position.

**Sleep studies:** Full overnight polysomnography was done in the sleep laboratories of the participating centers according to international recommendations, (AASMS 2018) at baseline and 12 weeks after starting the study. Polysomnography recording to be valid for scoring if the total sleep time was longer than 180 minutes.

**Randomization:** Eligible patients were randomized to one of the three groups. An external unit –the Methodological and statistic Unit of Bioaraba Institute - generated the allocation sequence.

## Results



The median use of the device was similar in both groups throughout 12 weeks ( $p > 0.05$  in all weeks, except in week 11,  $p = 0.048$ ), with variations between 6.5h (IQR= 3.3) (week 3) to 7.3 h(1.8) (week 9) in the ID group. In AD group, the use of the device was between 6.4 h (1.8) (week 4) and 7.0h (1.5) (week 9).

The percentage of days that the device was used more than 4 hours a day by our patients, showed a compliance of a 100% (85.7 – 100) in POSA patient with AD at a month and 85,7% at three months  $p=0,896$

The median percentage of time in the supine position was significantly lower in AD group compared to ID group throughout the 12 weeks ( $p < 0.012$  in all weeks in spite of the similar time of using the device.

Also, since the first week the difference of time spent in supine position is noteworthy, reaching a total of 10.6% (14.8) total sleep time in supine position with ID vs. 2.6% (4.2) AD.

The median percentage of time in supine during follow-up showed a significant decrease. Moreover this trend can be showed in all of weeks reaching at 12 weeks a difference of 7.2% ( $p < 0.001$  in all of follow-up weeks).

