

Physical Activity and Bleed Prevention for People With Severe Haemophilia A Treated With Once-Weekly Efanesoctocog Alfa: A Plain-Language Summary of 12-Month Interim Results From the FREEDOM Study

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What was our aim?

To show results on physical activity and bleeding episodes from the first year of efanesoctocog alfa treatment in the two-year FREEDOM study.

What are our conclusions?

During the first year of treatment, people with severe haemophilia A remained highly active on once-weekly efanesoctocog alfa.

Despite being very physically active, participants were well protected against bleeding episodes.

What is the study background?

Efanesoctocog alfa is a factor VIII replacement therapy that is injected once weekly to protect people with haemophilia A against bleeding episodes.¹

Adults and adolescents with haemophilia A receiving efanesoctocog alfa can maintain factor VIII levels in a normal or close-to-normal range, i.e. above 40%, for the first four days after each injection, and above 15% during the rest of the week.¹

FREEDOM (NCT05817812) is an ongoing clinical study evaluating physical activity and joint health in people with severe haemophilia A receiving efanesoctocog alfa for 24 months.² People aged 12 years and above with previous use of factor VIII prophylaxis could join the study to receive efanesoctocog alfa 50 IU/kg once a week.

What were the characteristics of the participants?

In total, 93 males with severe haemophilia A were enrolled across 32 sites in 14 European countries.

How is the study being carried out?

Physical activity data (activity tracker):

- Fitbit worn ≥8 hours daily between 06:00–23:00 on at least 12 days per month (including ≥1 weekend day).
- Data shown are the percentages of total time while wearing the tracker spent doing:
 - Light activity
 - Moderate–vigorous activity

Safety data:

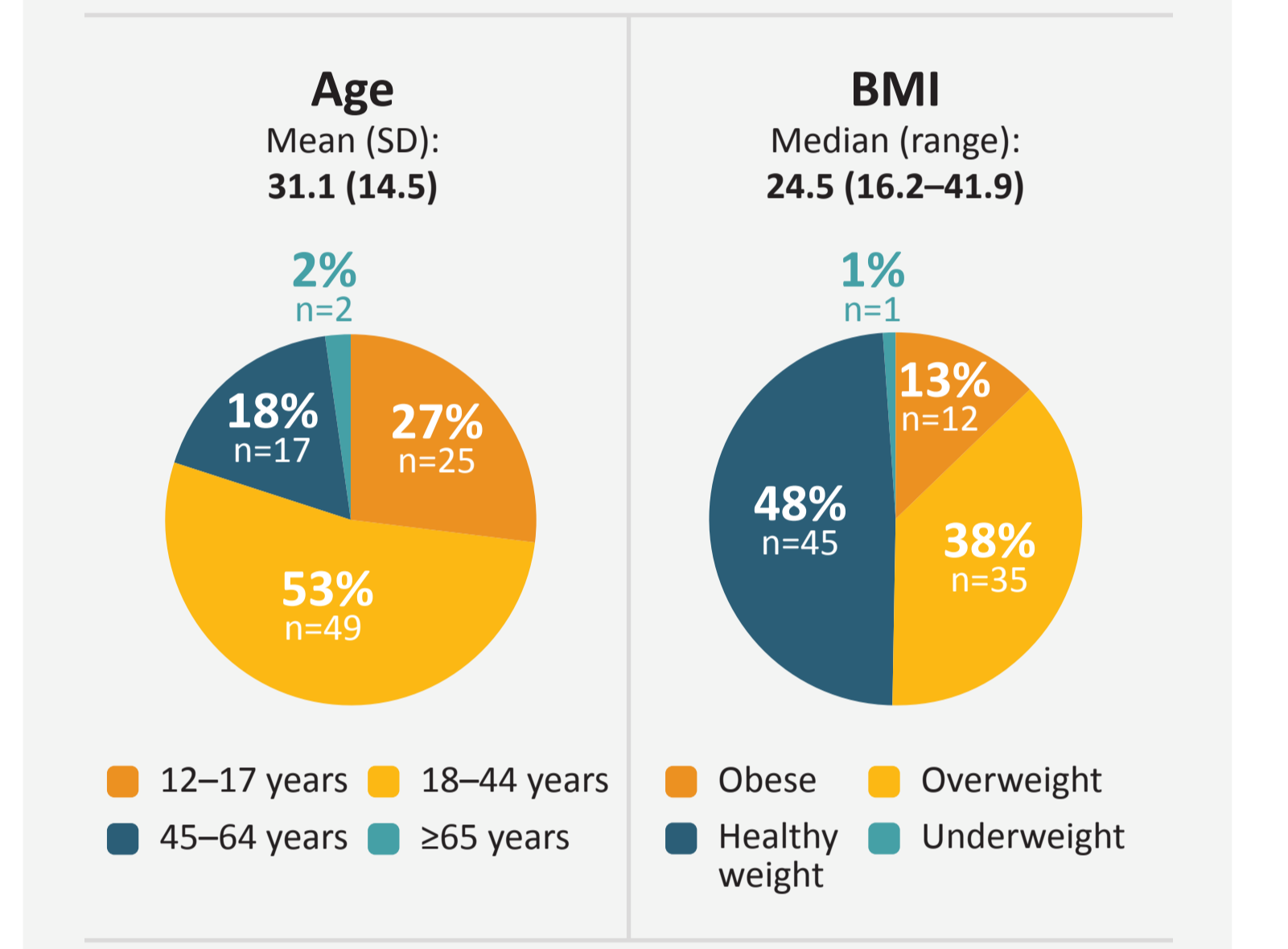
- All side effects were reported.

Physical activity data (IPAQ long version):

- The self-reported questionnaire assessed participants' physical activity levels over the last 7 days using four sets of questions.
- The total score of these is then converted into MET-mins per week (a measure of energy expenditure).

Bleed data:

- The number of bleeding events that occurred in a year and the proportion of participants that experienced no bleeds are reported.

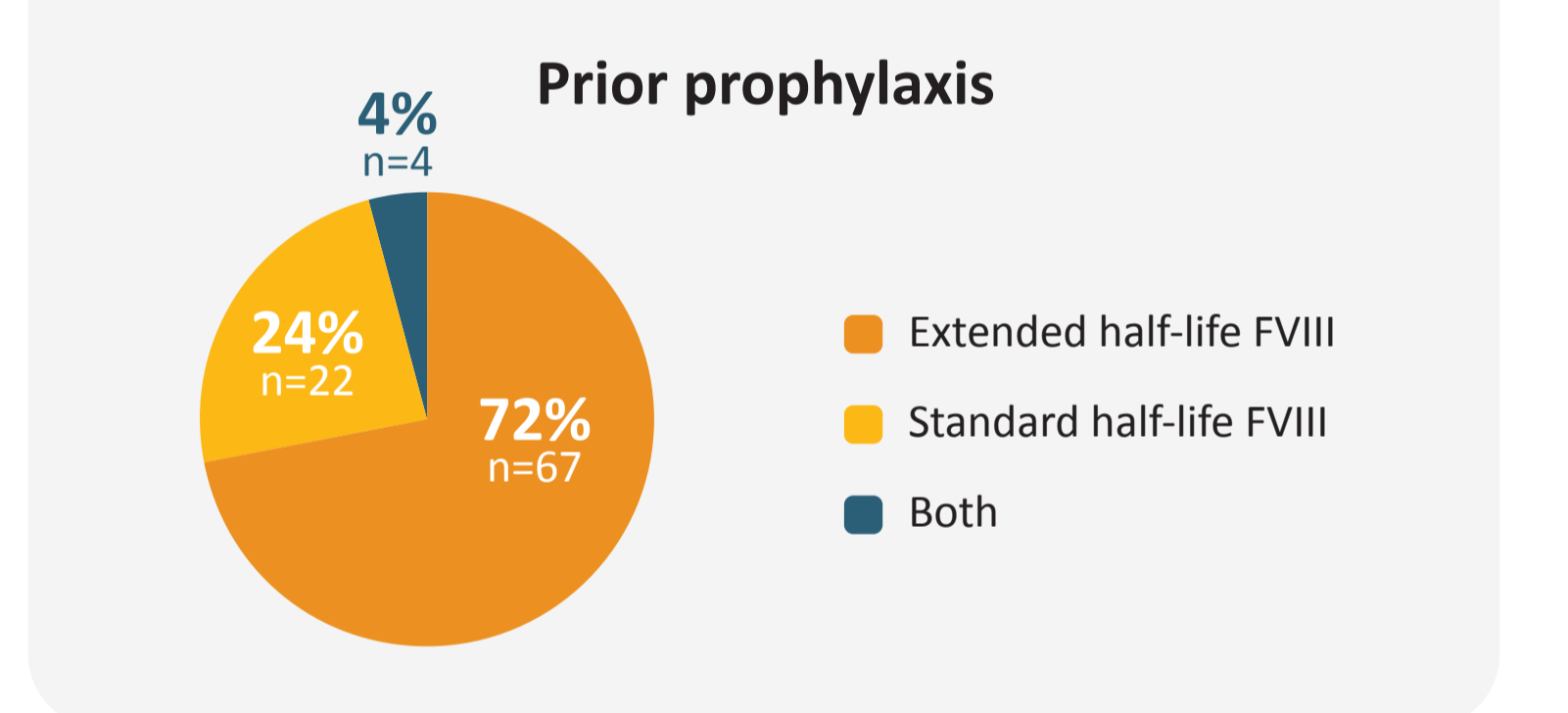


Interim data cut: 21 July 2025. IPAQ data were collected at enrolment and every 6 months after that; activity tracker data were collected 30–45 days pre-baseline and throughout the study.

What did we find?

During the first year, participants had an average of 0.3 bleeds and 84% had no treated bleeding episodes

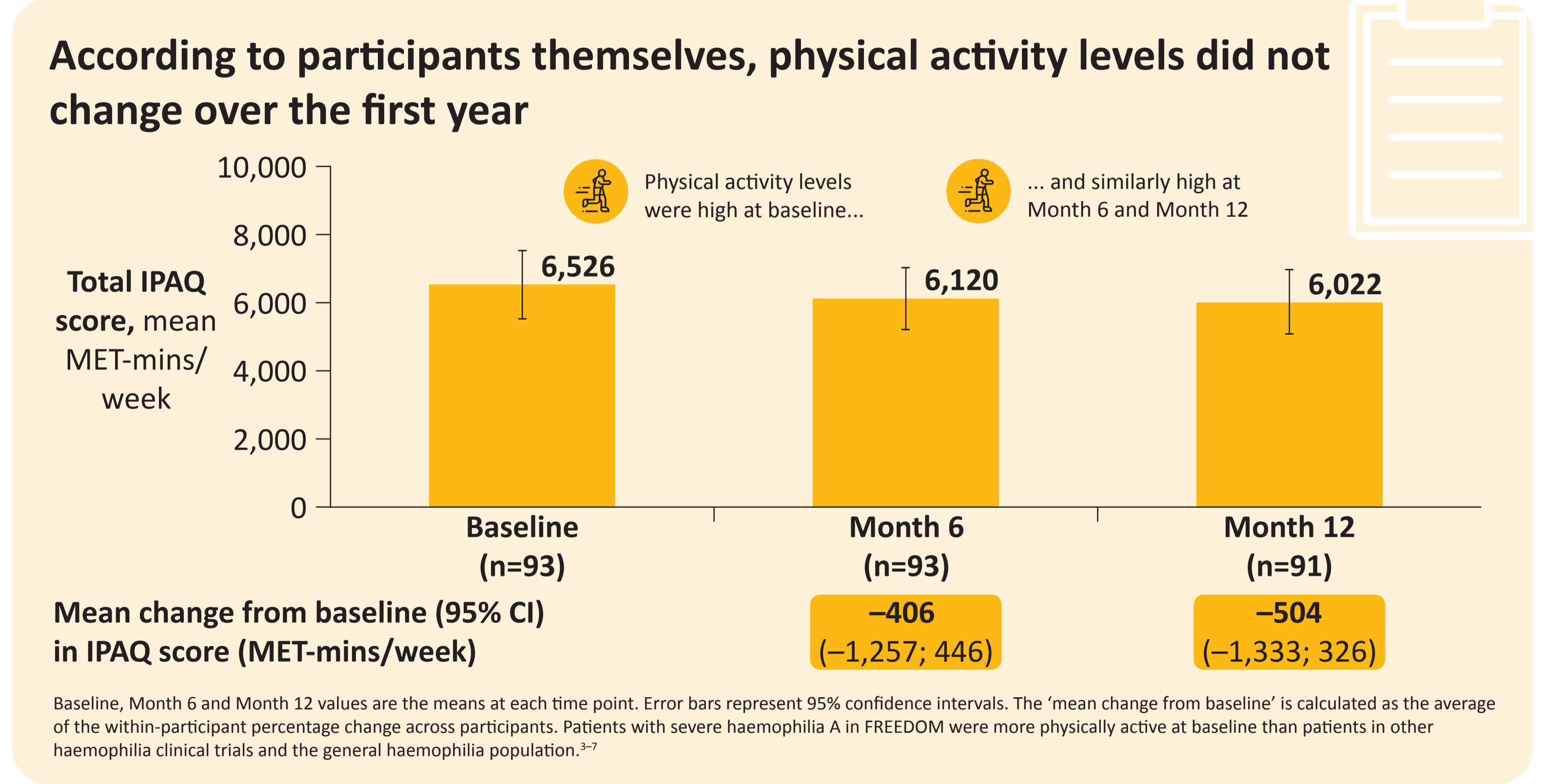
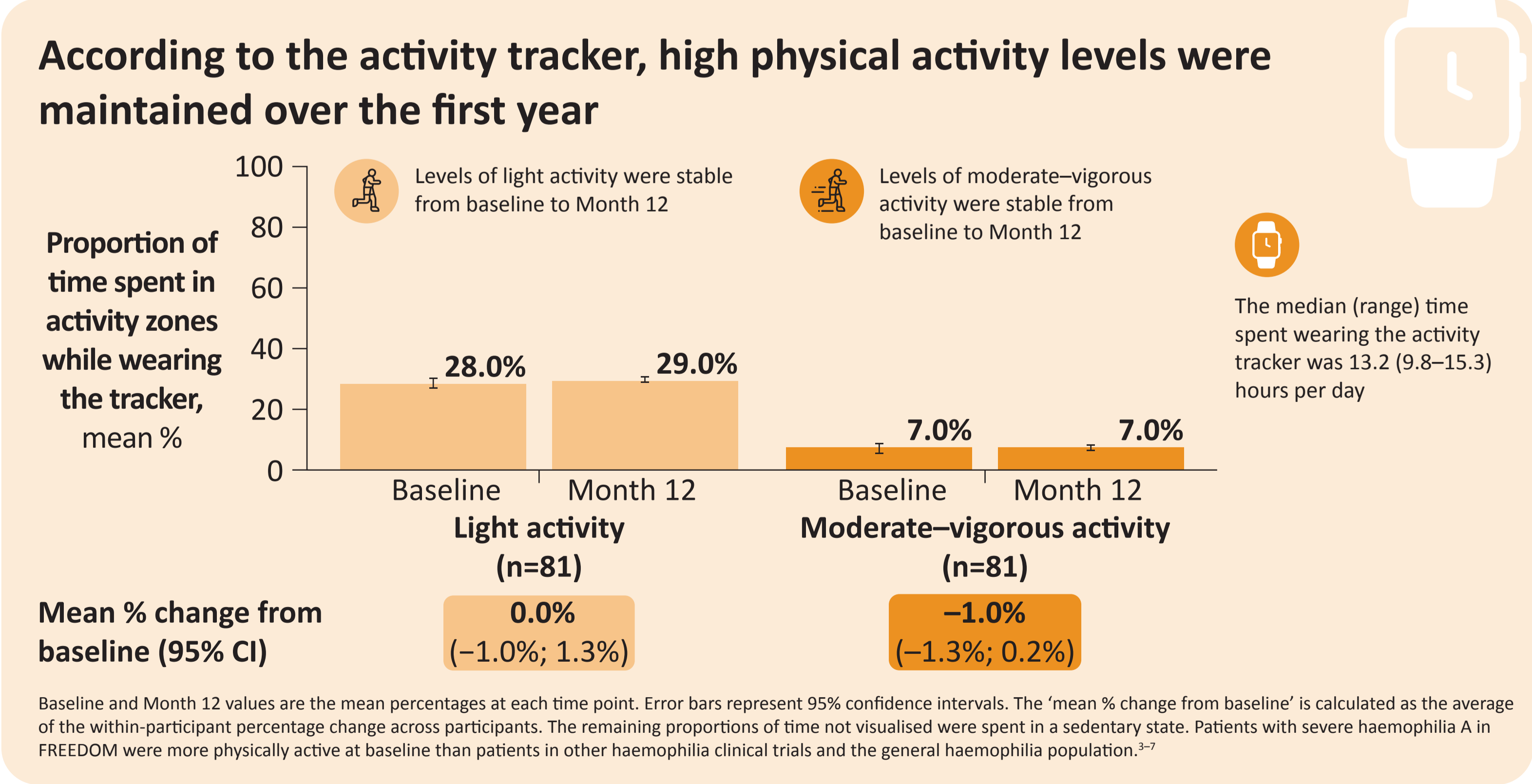
Category	Mean (SD)	Median (IQR)	Zero treated bleeds (%)	Patients (n)
Number of spontaneous bleeds per year	0.19 (0.77)	0 (0–0)	90.3%	84/93 patients
Overall number of bleeds per year	0.31 (0.87)	0 (0–0)	83.9%	78/93 patients
Number of traumatic bleeds per year	0.12 (0.42)	0 (0–0)	91.4%	85/93 patients



No new safety concerns were found

- 67 participants reported at least one side effect; 5 were considered related to treatment (1 serious side effect was considered related to treatment).
- No side effects led to death or stopping efanesoctocog alfa treatment.

The most common side effects (n [%]) were joint pain (15 [16.1%]), common cold (13 [14.0%]) and headache (9 [9.7%]). Five side effects were considered related to efanesoctocog alfa treatment (joint pain, muscle pain, misuse of drug delivery system, headache and eye pain). One serious side effect was considered related to efanesoctocog alfa treatment (a small blood clot in an abnormal vein near the surface of the skin).



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Disclosures
AB: Received honoraria as a member of advisory board and speaker for Bayer, CSL Behring, Novo Nordisk, Octapharma, Pfizer, Roche, Sobi and Takeda. KT: Received support to attend educational meetings from Sobi, Chugai, Novo Nordisk and Roche; honoraria as a member of advisory board and speaker for Sobi. IPZ: Received honoraria for speaking and support for education from Sobi, Roche and Novo Nordisk. PVDV: Received speaker fees from Baxter, paid to the institute. JB, ES, MF: Employees of Sobi and may hold shares and/or stock options in the company. JA: Received grant/research support from Bayer, CSL Behring and Sobi; honoraria as member of advisory boards and speaker for Bayer, BioMarin, CSL Behring, Novo Nordisk, Octapharma, Pfizer, Roche, Sanofi, Sobi and Takeda.

Abbreviations
BMI: body mass index; CI: confidence interval; IPAQ: International Physical Activity Questionnaire; IQR: interquartile range; IU: international units; MET: metabolic equivalent of task; SD: standard deviation.

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