

Effectiveness of Baricitinib for Nasal, Genital, and Beard Hair Regrowth in Patients With Severe Alopecia Areata: 12-Month Outcomes From a Prospective Observational Study



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OBJECTIVE

To complement findings from the BRAVE-AA clinical trial, the objective of this real-world study was to evaluate the effectiveness of baricitinib for regrowth of nasal, genital, and beard hair

CONCLUSIONS

Among adults with severe alopecia areata (AA), high baseline bothersomeness from nasal and beard hair loss was reported (scores of 8 out of 10, with 10 being the worst imaginable bothersomeness), indicating that these hair-bearing sites should be assessed alongside scalp, eyebrow, and eyelash hair when evaluating AA

Overall, baricitinib therapy was associated with clinically meaningful regrowth in nasal (52% of participants), genital (44% of participants), and beard hair (53% of participants) as well as reduced bothersomeness from hair loss at these sites

These data inform on holistic treatment outcomes across high-impact sites for adults with severe AA receiving baricitinib

BACKGROUND

- AA causes hair loss across hair-bearing sites, including nasal, genital, and beard hair, which is often under-recognized
- Despite the functional and cultural importance, treatment response at these sites remains poorly understood, particularly in routine clinical settings
- Baricitinib is an efficacious selective JAK inhibitor indicated for the treatment of adults with severe AA

METHODS

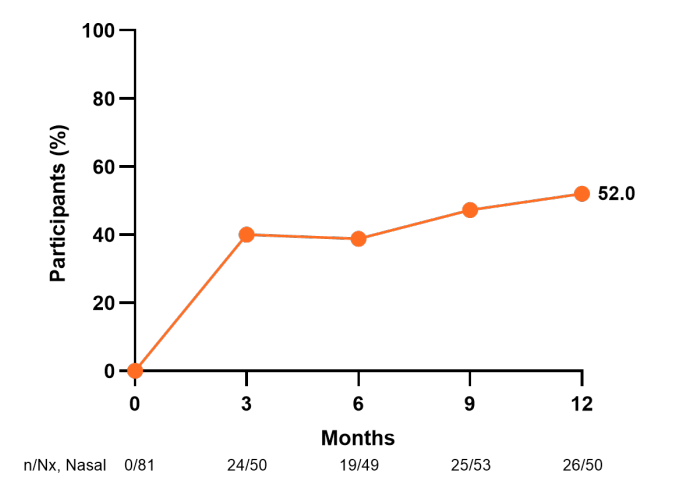
Study Population

- Adult patients who were participating in the US Baricitinib Patient Support Program for the treatment of severe AA, who had agreed to be contacted for future research studies, were invited to participate in this prospective, observational study
- Participants were surveyed approximately every 3 months after initiation of therapy with baricitinib as the first JAK inhibitor in the previous 60 days

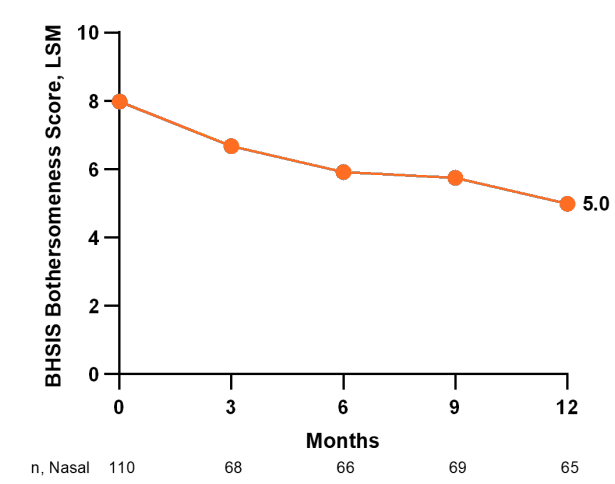
KEY RESULTS

52% of Participants Achieved Nasal Hair Regrowth After Baricitinib Treatment With Accompanying Improvement in Bothersomeness Score

Proportion of Participants Who Achieved Limited/No Nasal Hair Loss^a

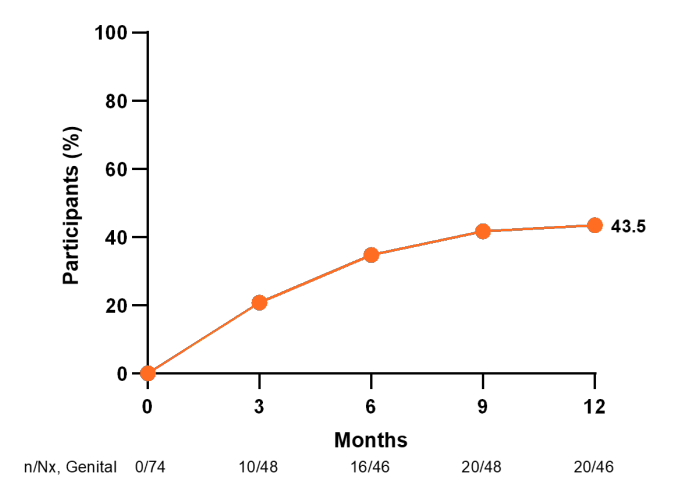


Mean Change in Nasal Bothersomeness Score^b

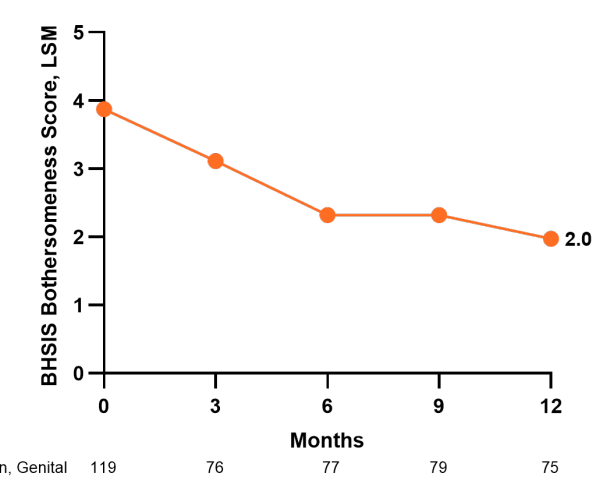


44% of Participants Achieved Genital Hair Regrowth After Baricitinib Treatment With Accompanying Improvement in Bothersomeness Score

Proportion of Participants Who Achieved Limited/No Genital Hair Loss^a

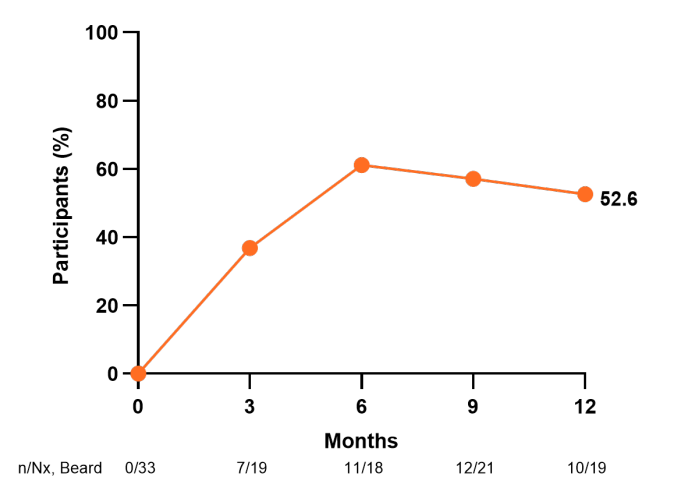


Mean Change in Genital Bothersomeness Score^b

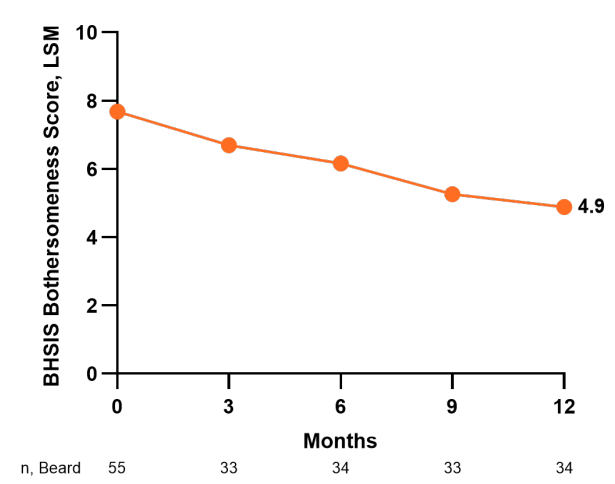


53% of Participants Achieved Beard Hair Regrowth After Baricitinib Treatment With Accompanying Improvement in Bothersomeness Score

Proportion of Participants Who Achieved Limited/No Beard Hair Loss^a



Mean Change in Beard Bothersomeness Score^b



^aAmong participants with a large amount of or nearly complete hair loss at baseline; ^bAdjusted for using a random intercept mixed-effects model and adjusting for covariates of interest (baseline score, age, sex, education, race/ethnicity).

Assessments

- Participants completed the Body Hair Symptom and Impact Scale (BHSIS) PRO^a for nasal, genital, and beard hair loss
 - Degree of hair loss was assessed using 4 categories:
 - No hair loss
 - A limited amount of hair loss (less than half missing)
 - A large amount of hair loss (greater than half missing)
 - Complete/nearly complete hair loss
 - Participants rated the bothersomeness of hair loss from 0 to 10 (0=not bothered; 10=worst imaginable bothersomeness)
- Participants completed the Scalp Hair Assessment PRO for scalp hair loss; degree of hair loss was assessed using 4 categories:
 - “No missing hair” (0% of my scalp is missing hair; I have a full head of hair); “A limited area” (1-20% of my scalp is missing hair); “A moderate area” (21-49% of my scalp is missing hair); “A large area” (50-94% of my scalp is missing hair); “Nearly all or all” (95-100% of my scalp is missing hair)
- For each hair-bearing site, treatment response was defined as achievement of no or limited hair loss among participants with a large amount of or nearly complete hair loss at baseline

Statistical Analysis

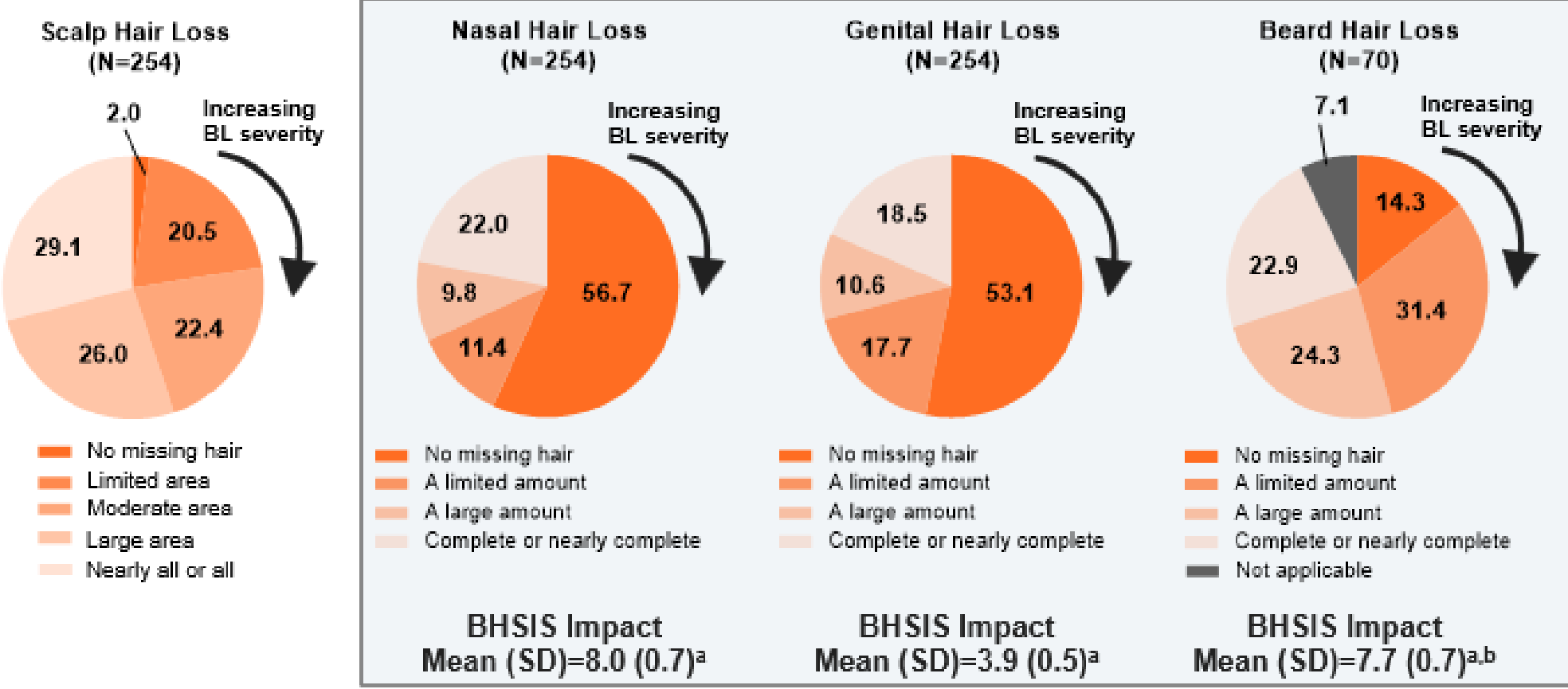
- Descriptive statistics were used to summarize data as observed cases
- Impact of body hair loss (bothersomeness) was adjusted for baseline score, age, sex, education, and race/ethnicity, and analyzed in participants with at least a little amount of hair loss at baseline

Baseline Demographics and Clinical Characteristics

Characteristic	BARI (N=254)
Age, mean (SD), years	40 (14)
Female	184 (72.4)
Race	
White	160 (63.0)
Black or African American	35 (13.8)
Asian	19 (7.5)
Age at AA diagnosis, mean (SD), years	31.4 (16.8)
Current AA episode duration	
<6 months	31 (12.2)
6 months to <1 year	44 (17.3)
1 to <2 years	35 (13.8)
2 to ≤4 years	44 (17.3)
>4 years	100 (39.4)
Hair loss pattern	
AA with single spot/patch	5 (2.0)
AA with multiple spots/patches	119 (46.9)
Ophiasis: Hair loss from behind the ears across the back of head	17 (6.7)
AT: Complete/nearly complete hair loss on scalp	51 (20.1)
AU: Complete or nearly complete hair loss of all body hair	62 (24.4)

At Month 12, 169 participants (66.5%) completed the survey

BL Scalp, Nasal, Genital, and Beard Hair Loss



^aImpact of body hair loss was assessed on participants with at least a limited amount of hair loss at baseline; ^bMale participants only, and participants who answered this question as “Not applicable” are not included.

Abbreviations: AA=alopecia areata; AT=alopecia totalis; AU=alopecia universalis; BARI=baricitinib; BHSIS=Body Hair Symptom and Impact Scale; BL=baseline; JAK=Janus kinase; LSM=least squares mean; n=number of participants who responded to treatment; Nx=number of participants with non-missing values; PRO=patient-reported outcome; SD=standard deviation

Disclosures: J. Ko has served as an investigator or consultant for: AbbVie, Eli Lilly and Company, Pfizer, Regeneron, and Sanofi; K. Lal has served as a speaker for: AbbVie, Aerolase, Boehringer Ingelheim, Eli Lilly and Company, Galderma, Incyte Corporation, Pfizer, and Sanofi; M. Tarbox has served as an investigator for: Castle Biosciences and Sanofi-Regeneron; an advisor for: Boehringer Ingelheim, Celldex Therapeutics, Dermeleve, Eli Lilly and Company, Novartis, Sanofi, and UCB Pharma; and a speaker for: Galderma, Novartis, and UCB Pharma; S. Ball, A. Sontag, and N. Somani are current employees and shareholders of: Eli Lilly and Company; F. Dabbous, M. K. Ladd, and K. Kornalska are, or were at the time this research was conducted, employees of: PPD Evidera, clinical research business of Thermo Fisher Scientific, and received funding from: Eli Lilly and Company to conduct this study; J. Shapiro is an investigator or consultant for: AbbVie, Eirion Therapeutics, Eli Lilly and Company, Pfizer, and Thirty Madison

Medical writing assistance was provided by Tomo Sawado, PhD, of Envision Catalyst, an Envision Medical Communications agency, a part of Envision Pharma Group, and was funded by Eli Lilly and Company

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BACKGROUND AND OBJECTIVE

Background

- Alopecia areata (AA) causes hair loss across hair-bearing sites, including nasal, genital, and beard hair, which is often under-recognized
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^aMean BHSIS scores were adjusted for baseline score, age, sex, education, and race/ethnicity.

PRO=patient-reported outcomes

Baseline Demographics and Clinical Characteristics

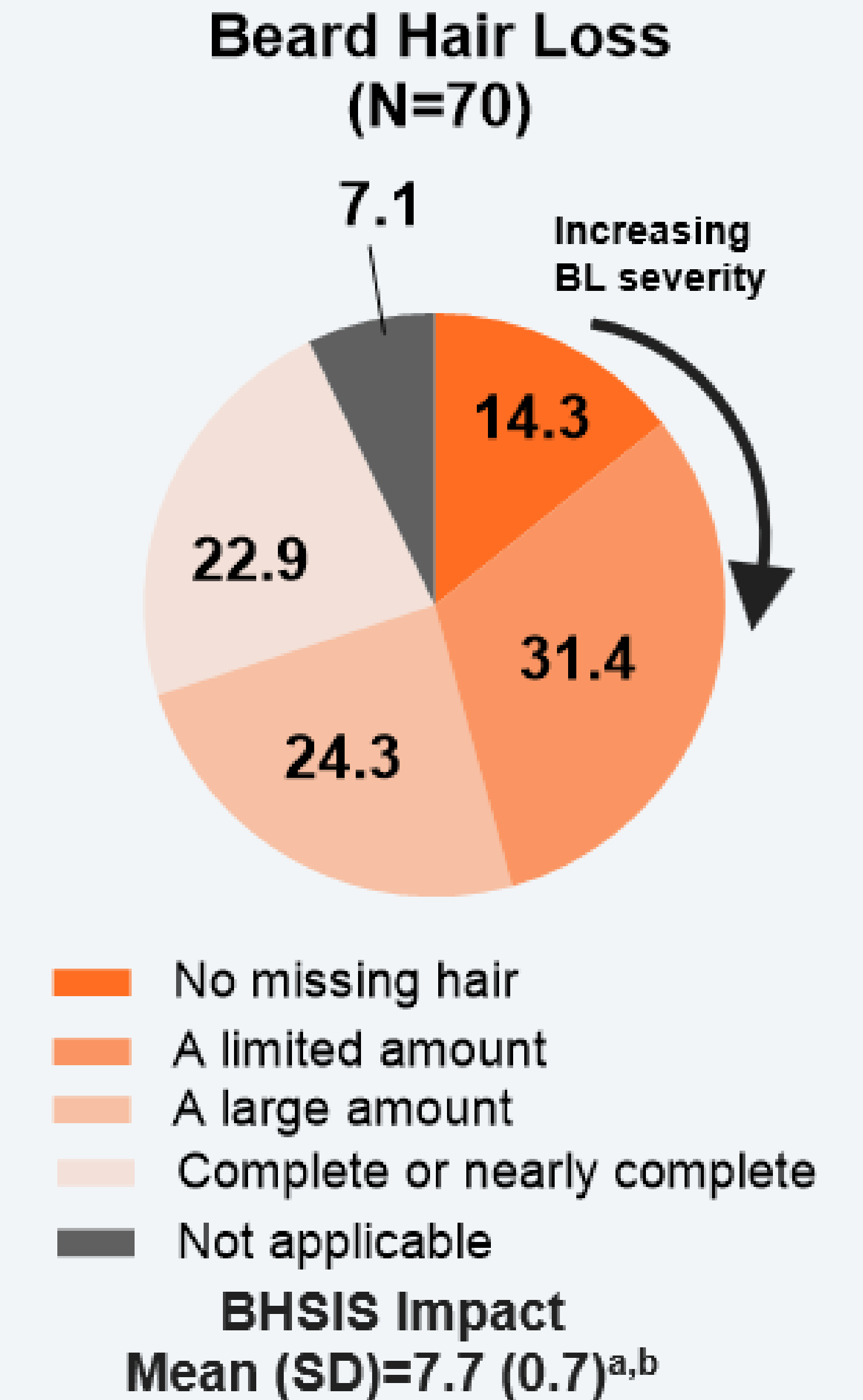
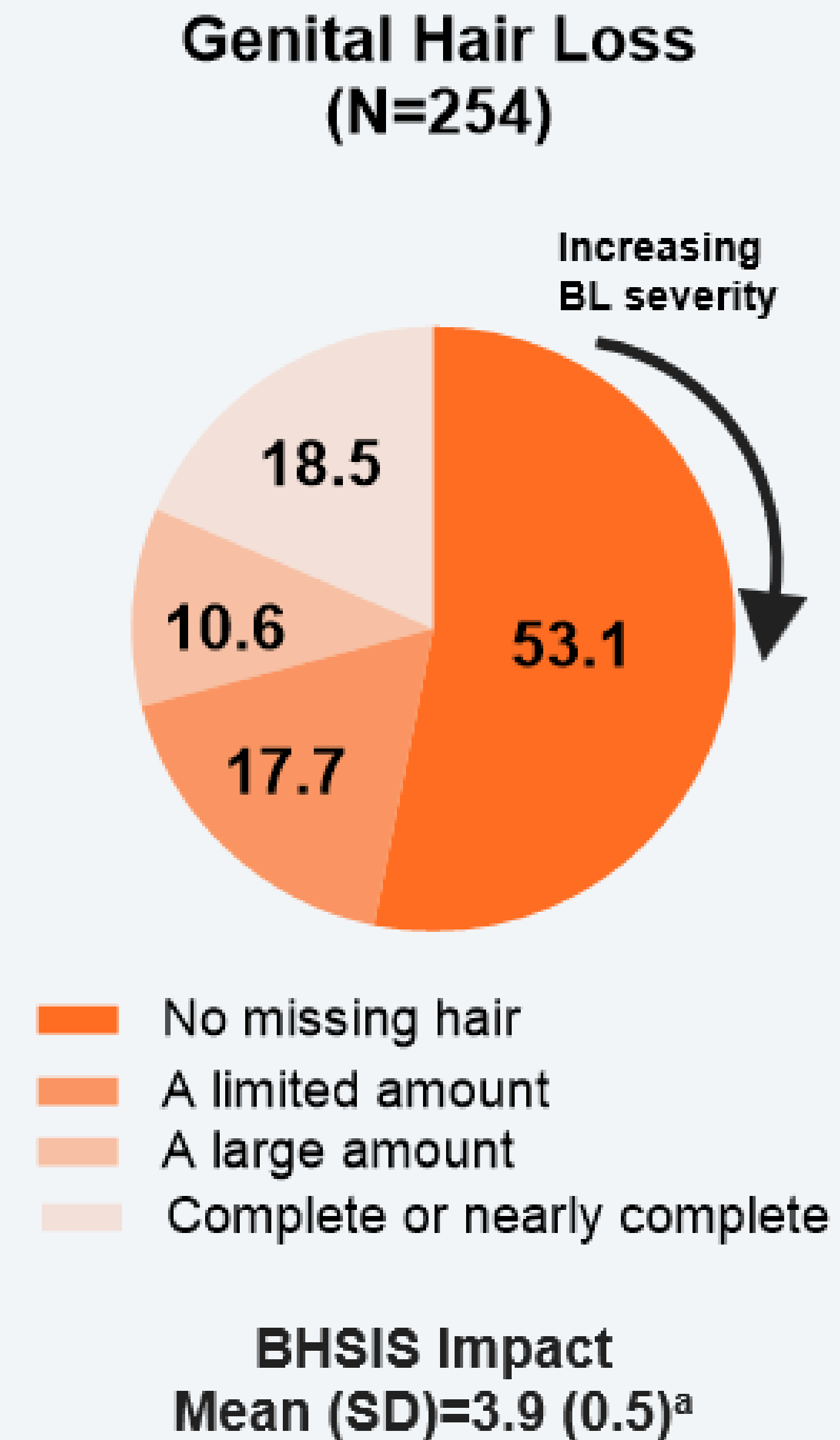
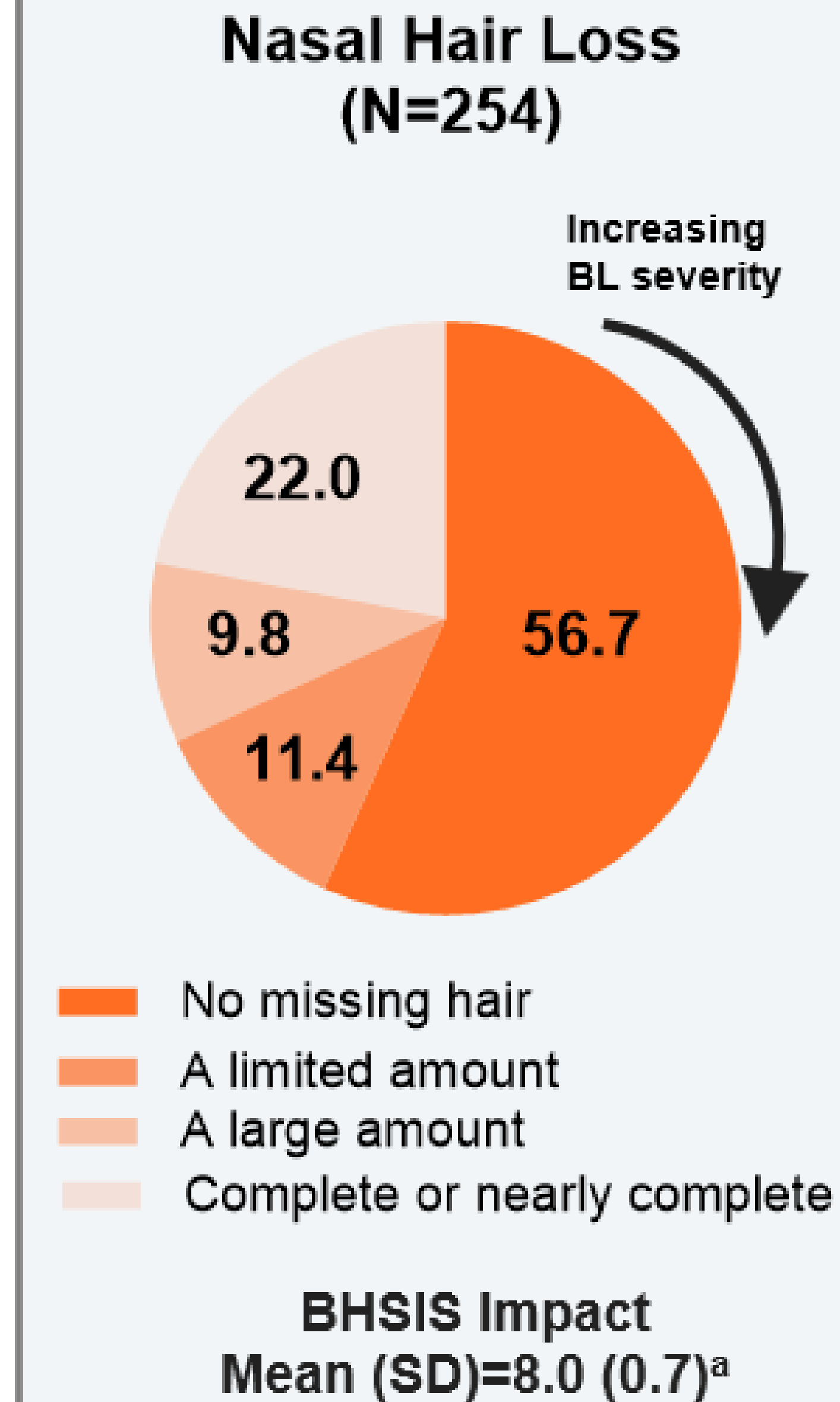
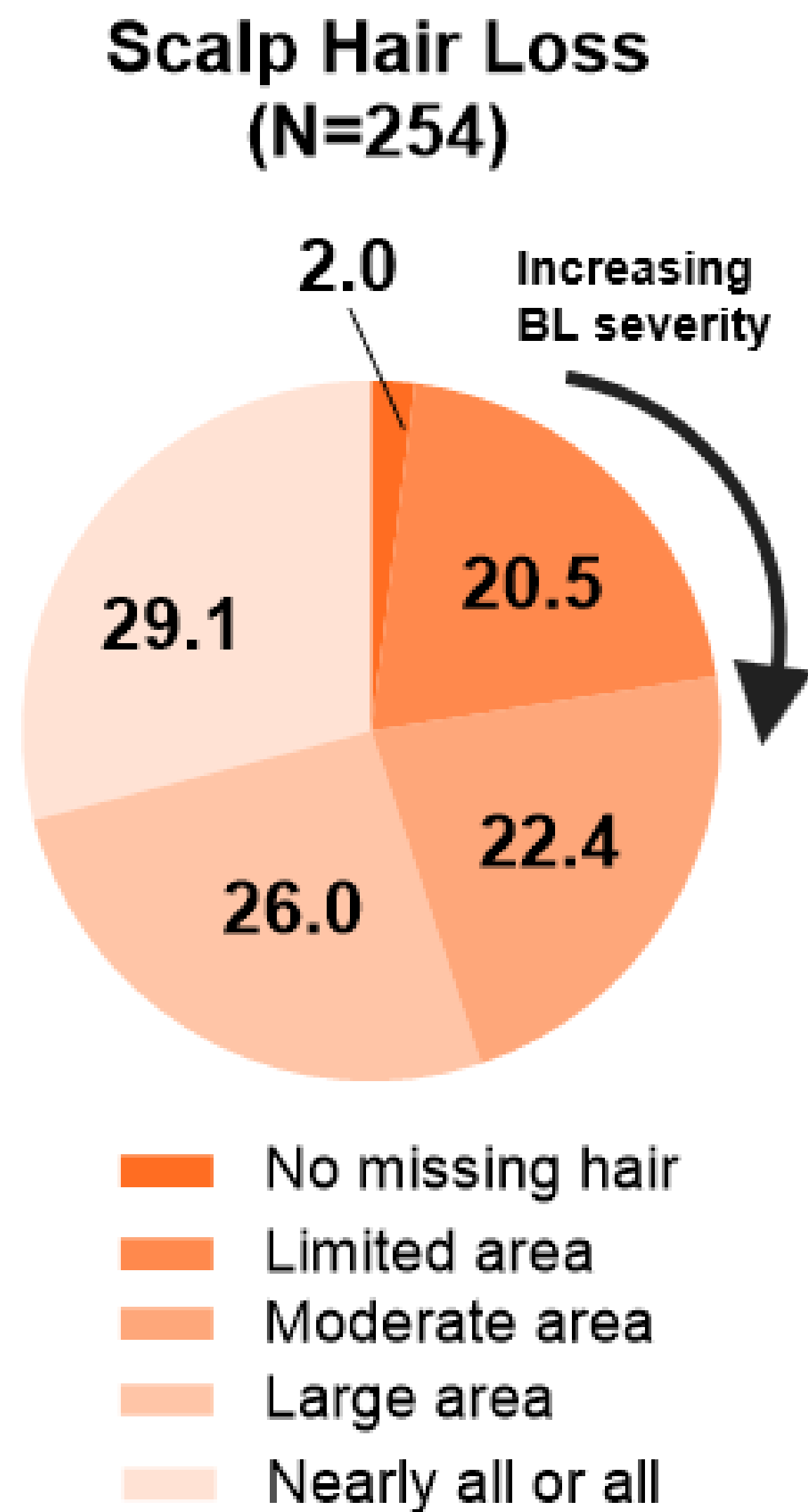
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Note: Data are n (%) unless otherwise stated.

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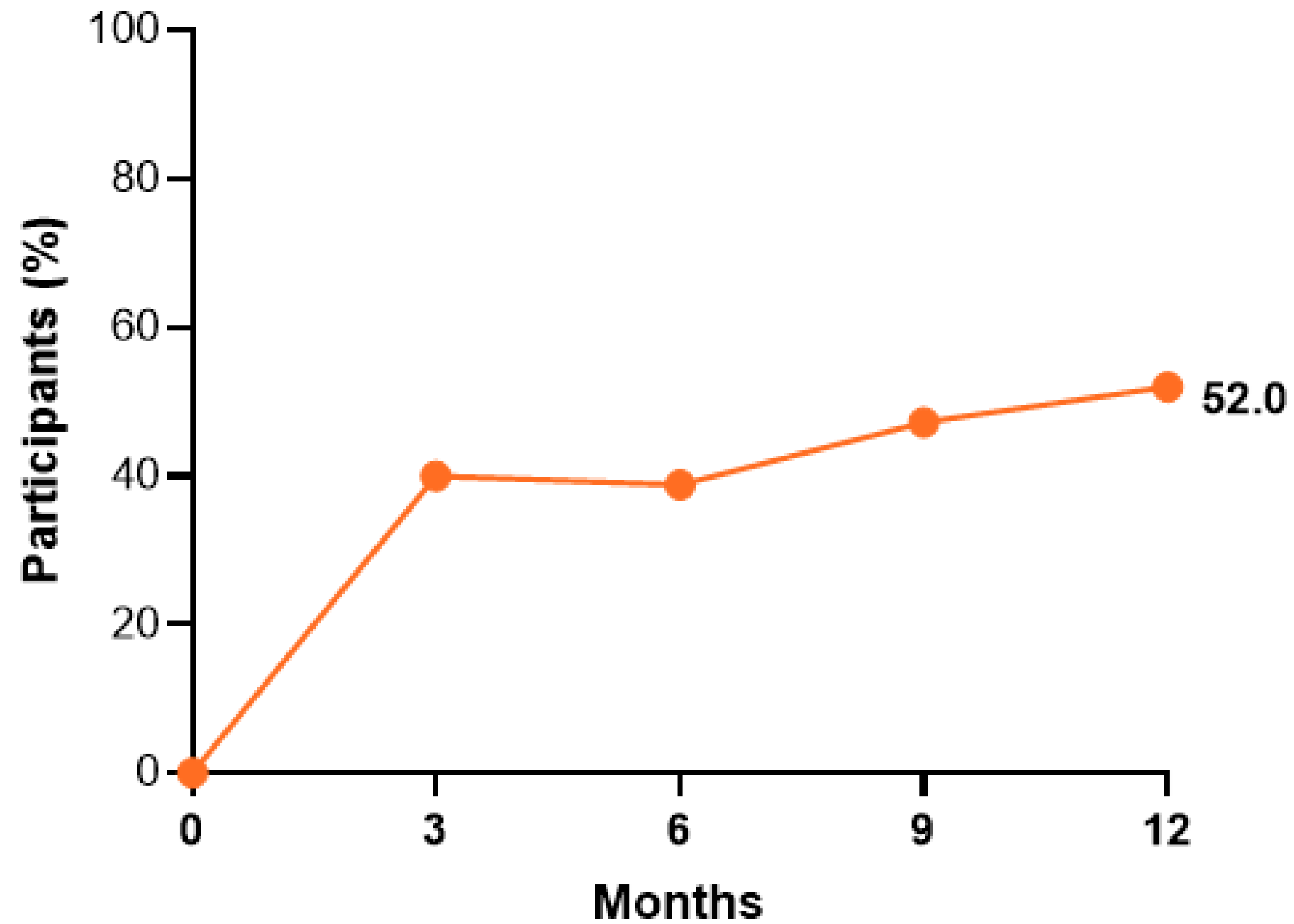


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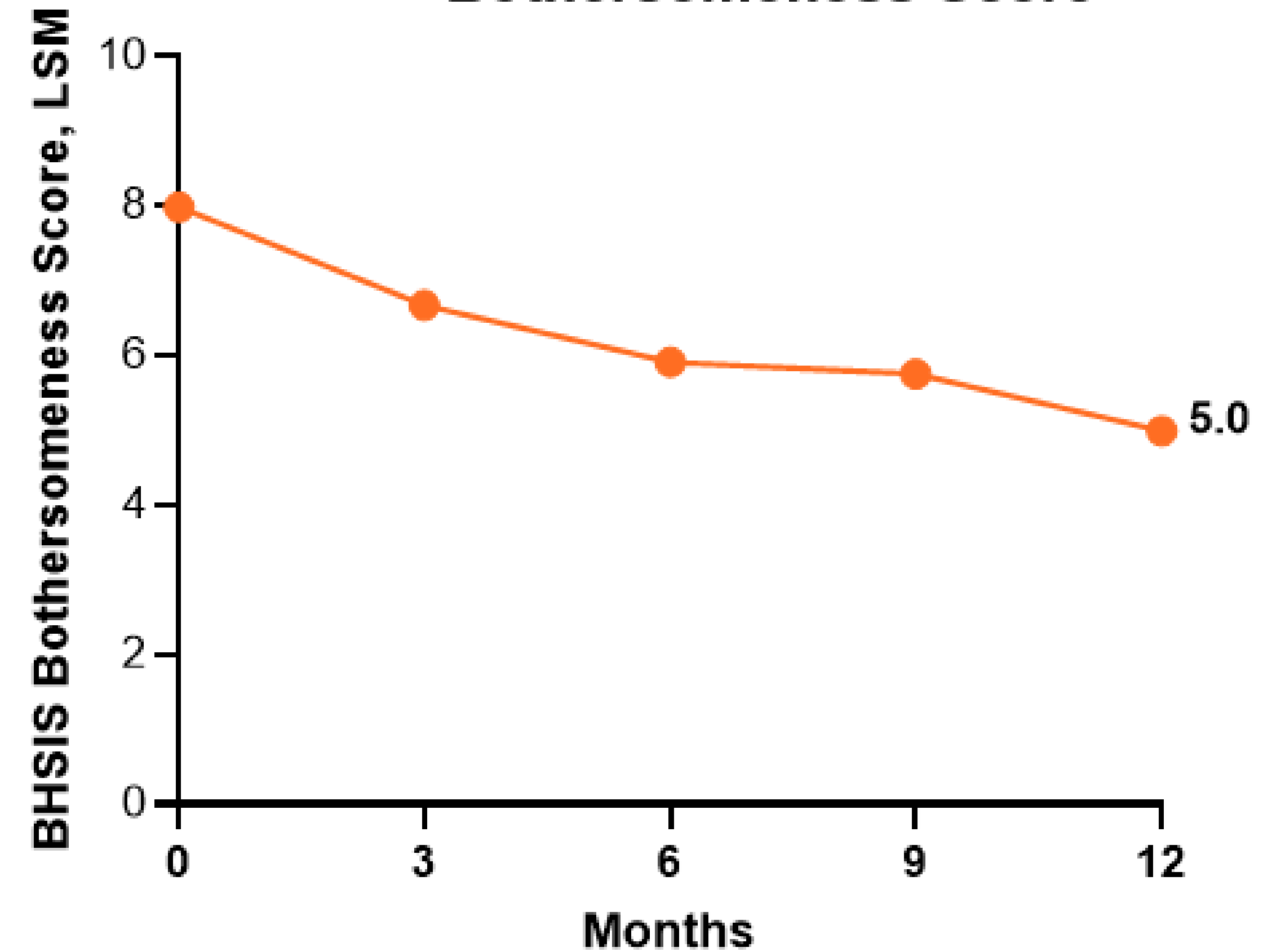
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Proportion of Participants Who Achieved Limited/No Nasal Hair Loss^a



n/Nx, Nasal 0/81 24/50 19/49 25/53 26/50

Mean Change in Nasal Bothersomeness Score^b



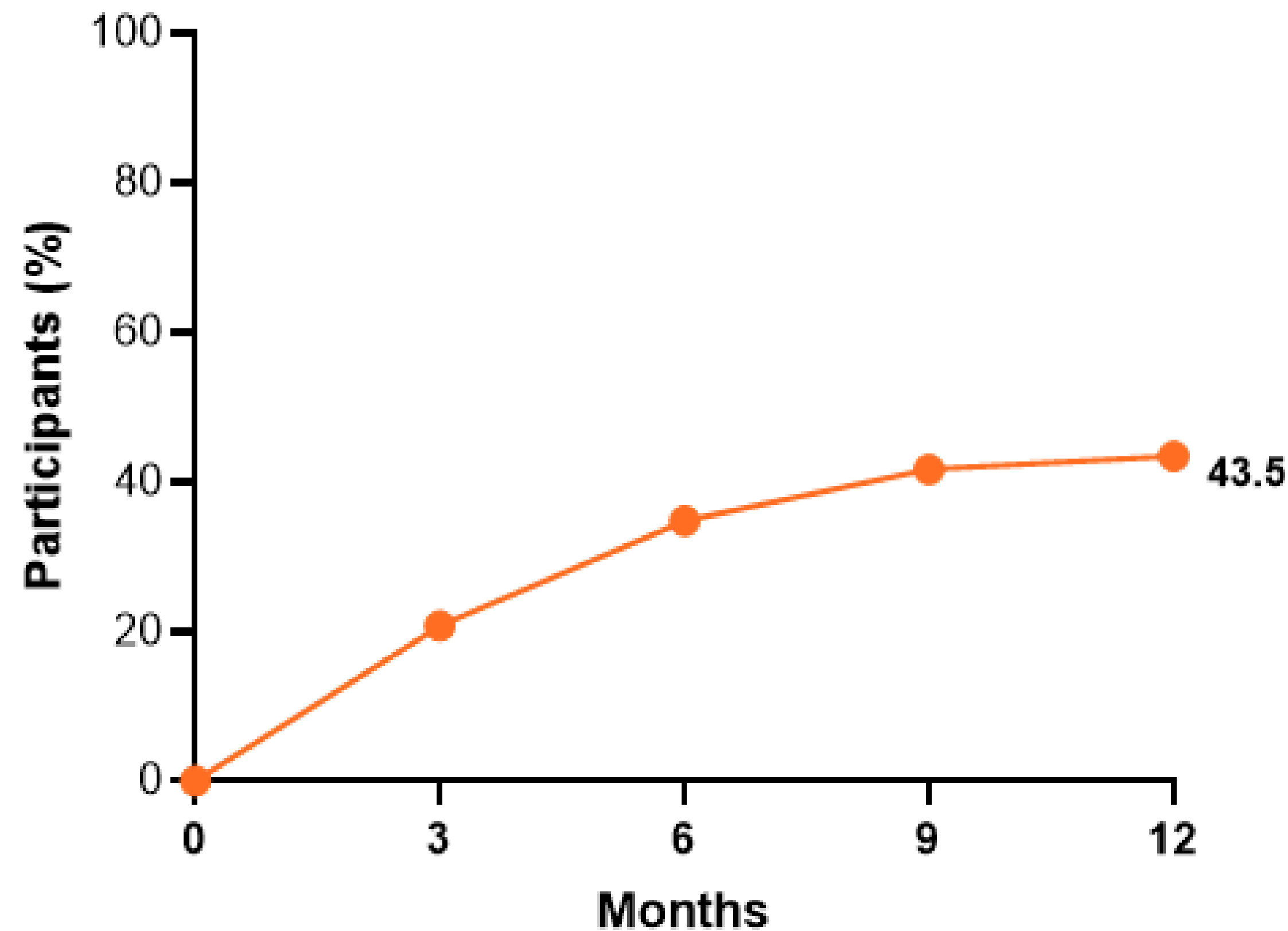
n, Nasal 110 68 66 69 65

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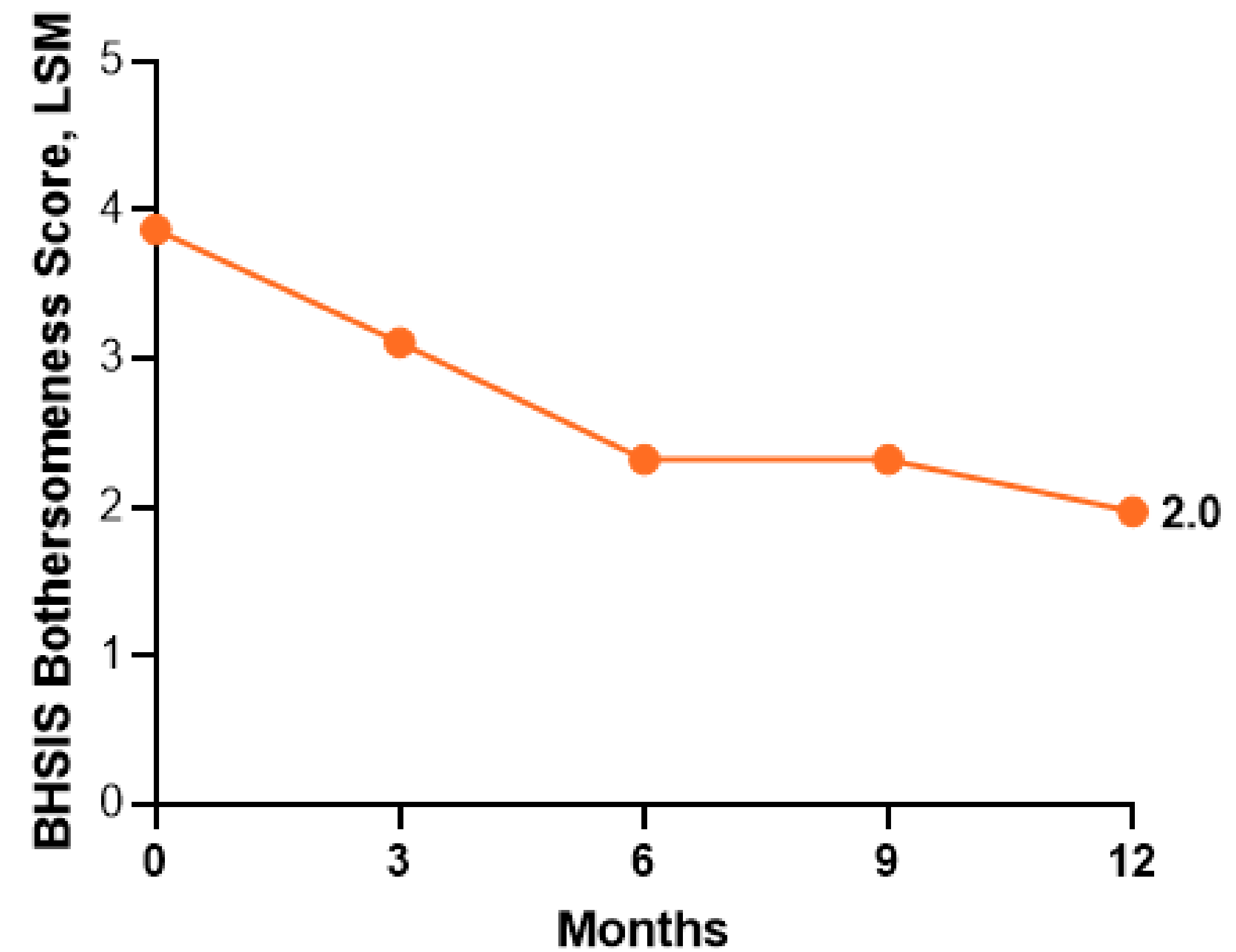
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Proportion of Participants Who Achieved Limited/No Genital Hair Loss^a



n/Nx, Genital 0/74 10/48 16/46 20/48 20/46

Mean Change in Genital Bothersomeness Score^b



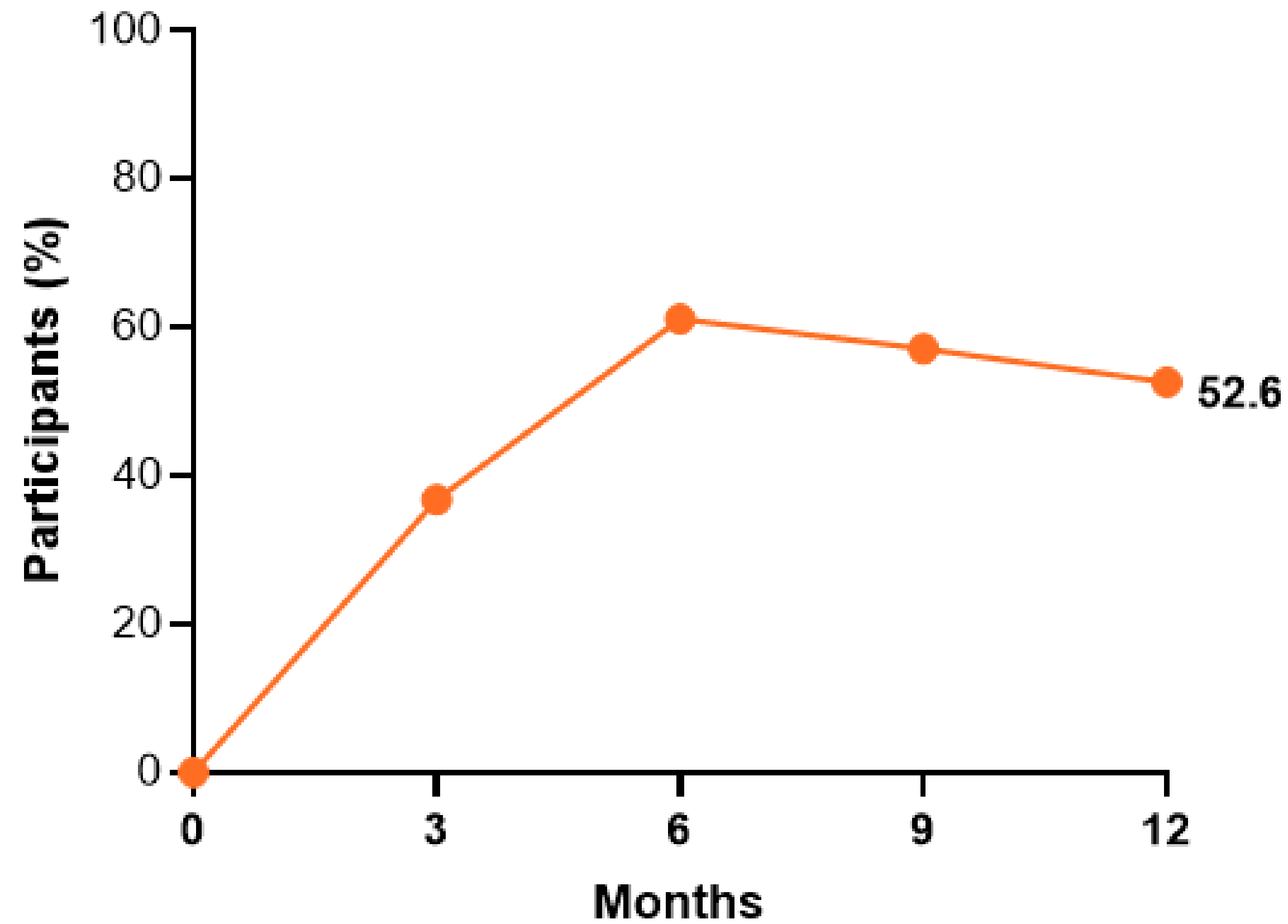
n, Genital 119 76 77 79 75

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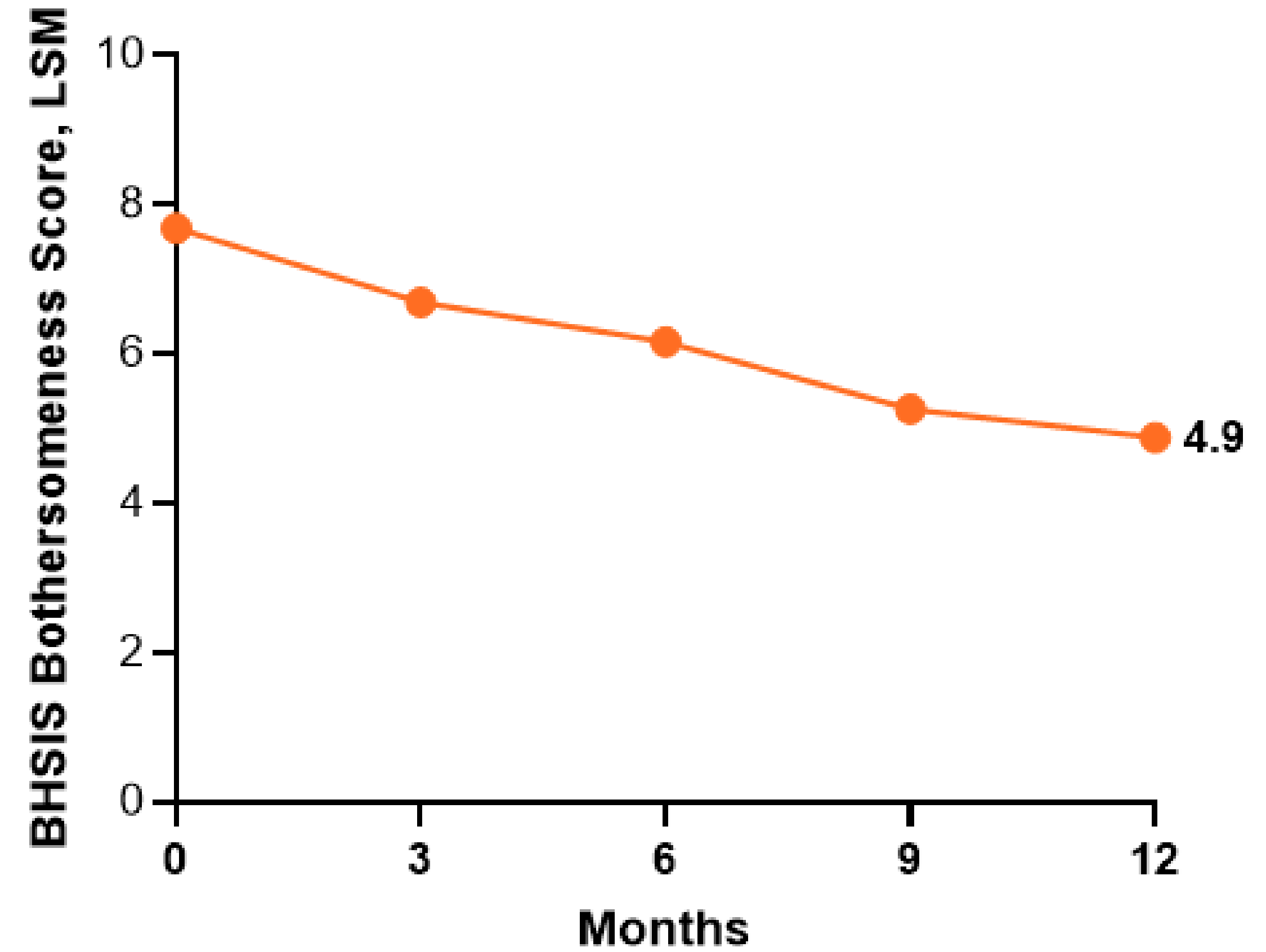
53% of Participants Achieved Beard Hair Regrowth After Baricitinib Treatment With Accompanying Improvement in Bothersomeness Score

Proportion of Participants Who Achieved Limited/No Beard Hair Loss^a



n/Nx, Beard 0/33 7/19 11/18 12/21 10/19

Mean Change in Beard Bothersomeness Score^b



n, Beard 55 33 34 33 34

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CONCLUSIONS

- Among adults with severe AA, high baseline bothersomeness from nasal and beard hair loss was reported (scores of 8 out of 10, with 10 being the worst imaginable bothersomeness), indicating that these hair-bearing sites should be assessed alongside scalp, eyebrow, and eyelash hair when evaluating AA
- Overall, baricitinib therapy was associated with clinically meaningful regrowth in nasal (52% of participants), genital (44% of participants), and beard hair (53% of participants) as well as reduced bothersomeness from hair loss at these sites
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