Title

Meaningful Changes in What Matters to Individuals with Vitiligo: Content Validity and Meaningful Change Thresholds of the Vitiligo Area Scoring Index (VASI)

Authors/Affiliations

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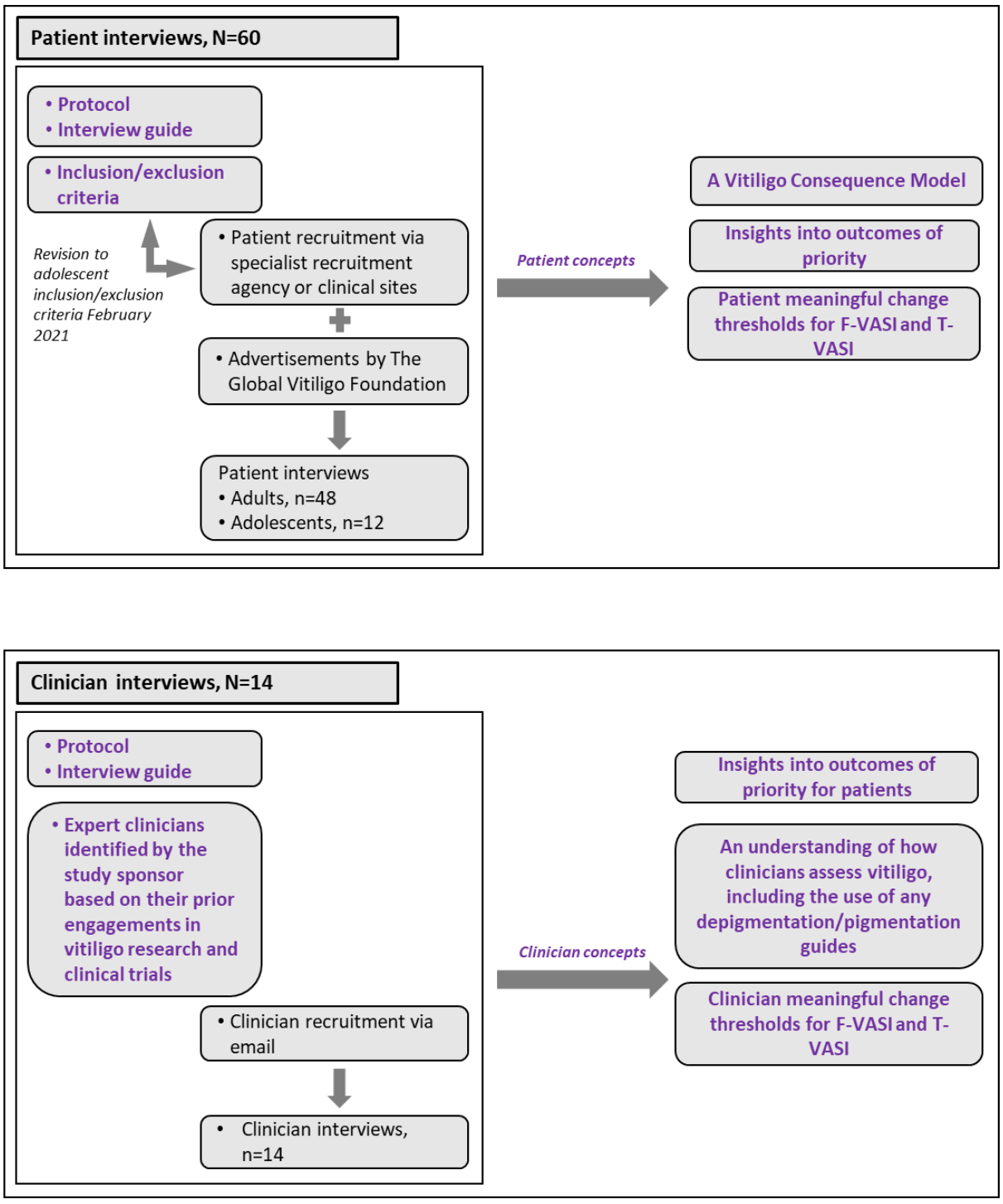
Supplementary material

Supplementary material 1. Schematic of Research Process



Abbreviations: F-VASI, Facial Vitiligo Area Scoring Index; T-VASI, Total body Vitiligo Area Scoring Index

Key: Purple font reflects outputs from the research process; black font reflects the methodological steps undertaken to achieve the outputs.

Supplementary material 2. Sampling quotas

Representation of FST 1-6
Sex (>25% male; >25% female)
Education level (~35% high school only, with or without diploma)
1st or 2nd generation living in the US from the Middle East (e.g. Egypt, Iran, Israel, Iraq, Qatar, Syria), Asia (e.g. China, India, Pakistan, Thailand, Indonesia) or Africa (e.g. Nigeria, Ethiopia) (~15% of total sample
Low level of facial vitiligo (n≤10 patients with 0.25-0.50 BSA)
Improved vitiligo within 12 months (n≥10)

Supplementary material 3. Additional demographic and clinical sample characteristics

Demographic characteristic	Adults (N=48) n (%)	Adolescents (N=12) n (%)	TOTAL (N=60) n (%)
Self-reported demographic characteristics (N=60)			
Work status			
Working paid	34 (71%)	1 (8%)	35 (58%)
Student	3 (6%)	12 (100%)	15 (25%)
Homemaker	4 (8%)	-	4 (7%)
Other	6 (13%)	-	6 (10%)
Retired	1 (2%)	-	1 (2%)
Self-reported improvement in vitiligo in past 12 months			
No	40 (83%)	7 (58%)	47 (78%)
Yes	8 (17%)	4 (33%)	12 (20%)
Don't know	-	1 (8%)	1 (2%)
Clinician-reported clinical characteristics (N=60)			
Disease activity (Face)			
New/extending lesion(s) in the past 3 months	29 (60%)	9 (75%)	38 (63%)
Confetti-like lesion(s)	8 (17%)	-	8 (13%)
Trichrome lesion(s)	7 (15%)	-	7 (12%)
Koebner phenomenon/ phenomena	2 (4%)	-	2 (3%)
Coexistence of halo nevus/nevi	1 (2%)	-	1 (2%)
Unable to say based on patient's clinic records[†]	10 (21%)	2 (17%)	12 (20%)
Disease activity (Body)			
New/extending lesion(s) in the past 3 months	31 (65%)	8 (67%)	39 (65%)
Confetti-like lesion(s)	7 (15%)	-	7 (12%)
Trichrome lesion(s)	7 (15%)	-	7 (12%)
Koebner phenomenon/ phenomena	1 (2%)	-	1 (2%)
Coexistence of halo nevus/nevi	2 (4%)	-	2 (3%)
Unable to say based on patient's clinic records[†]	7 (15%)	3 (25%)	10 (17%)
Comorbidities (selected from a pre-defined list)			
Anxiety	16 (33%)	6 (50%)	22 (37%)
Thyroid disease	9 (19%)	2 (17%)	11 (18%)
Depression	8 (17%)	1 (8%)	9 (15%)
ADHD	1 (2%)	4 (33%)	5 (8%)
Diabetes – Type 1	4 (8%)	1 (8%)	5 (8%)
Arthritis	5 (10%)	-	5 (8%)
Asthma	2 (4%)	2 (17%)	4 (7%)
Alopecia areata	3 (6%)	1 (8%)	4 (7%)
Rheumatoid arthritis	3 (6%)	-	3 (5%)
IBD	3 (6%)	-	3 (5%)
Cardiovascular disease	3 (6%)	-	3 (5%)
Cancer (excluding skin cancers)	2 (4%)	-	2 (3%)
Other [‡]	4 (8%)		4 (7%)

Demographic characteristic	Adults (N=48) n (%)	Adolescents (N=12) n (%)	TOTAL (N=60) n (%)
Current treatment(s)*			
Tacrolimus	5 (10%)	3 (25%)	8 (13%)
Phototherapy/NBUVB	3 (6%)	2 (17%)	5 (8%)
Sunscreen	2 (4%)	1 (8%)	3 (5%)
Pimecrolimus	2 (4%)		2 (3%)
Meclizine	2 (4%)	-	2 (3%)
Other[§]	5 (10%)	1 (8%)	6 (10%)
No current treatment(s) reported	*32 (67%)*	*6 (50%)*	*38 (63%)*
Previous treatment (s)*			
Steroids/topical creams	8 (17%)	6 (50%)	14 (23%)
Phototherapy/NBUVB	9 (19%)	2 (17%)	11 (18%)
Pimecrolimis	3 (4%)	3 (25%)	6 (10%)
Laser therapy	4 (8%)	1 (8%)	5 (8%)
Clobetasol	4 (8%)	-	4 (7%)
Tacrolimus	4 (8%)	-	4 (7%)
Other[¶]	4 (8%)	1 (8%)	5 (8%)
No previous treatments reported	*19 (40%)*	*2 (17%)*	*21 (35%)*
Discontinuation reason*	**n=24**	**n=7**	**n=31**
Ineffective	19 (79%)	6 (86%)	25 (81%)
Cost	2 (8%)	-	2 (6%)
Switched to alternative	2 (8%)	-	2 (6%)
Other[††]	3 (13%)	1 (14%)	4 (13%)

[†]Clinicians could select this option in instances where they could not see the individual in-person due to the COVID-19 pandemic; * Multiple treatments (and reasons for discontinuation) may have been reported for each patient.

[‡] Other comorbidities included type 2 diabetes, skin cancer, chronic kidney disease, epilepsy, multiple sclerosis, Sjogren syndrome and chronic obstructive pulmonary disease (each reported by N=1; multiple comorbidities may have been reported for each patient).

[§] Other current treatments included triamcinolone (n=2), clobetasol, desonide, hydrocortisone, tofacitinib, crisaborole, an unspecified topical steroid and Excimer laser treatment (each reported by N=1; multiple treatments may have been reported for each patient).

[¶] Other previous treatments included liquid nitrogen, triamcinolone, Medclizine, supplements (including vitamins C, B12 and folic acid), pUVA and "tanning" (each reported by N=1; multiple treatments may have been reported for each patient).

[††] Other reasons for treatment discontinuation included the result being achieved, the treatment being too strong for the face, Covid and "location" (each reported by N=1).

Supplementary material 4. Patient sub-group comparisons of F-VASI and T-VASI thresholds

Threshold	Subgroup (Number of patients asked)	Treatment success	Somewhat successful	Not a success	Other response/ Not asked
F-VASI					
F-VASI 50	Adults (n=48)	28 (58%)	2 (4%)	12 (25%)	6 (13%)
	Adolescents (n=11)	11 (100%)	-	-	-
F-VASI 75	Adults (n=48)	39 (81%)	6 (13%)	3 (6%)	-
	Adolescents (n=11)	11 (100%)	-	-	-
F-VASI 90	Adults (n=48)	47 (98%)	-	1 (2%)	-
	Adolescents (n=11)	11 (100%)	-	-	-
T-VASI					
T-VASI 33	Adults (n=40)	21 (53%)	5 (13%)	10 (25%)	4 (10%)
	Adolescents (n=10)	9 (90%)	-	1 (10%)	-
T-VASI 50	Adults (n=38)	30 (79%)	2 (5%)	5 (13%)	1 (3%)
	Adolescents (n=10)	10 (100%)	-	-	-
T-VASI 75	Adults (n=38)	35 (92%)	1 (3%)	2 (5%)	-
	Adolescents (n=10)	10 (100%)	-	-	-