

# Patient reported outcomes for trials of cutaneous neurofibromas

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REINS

Bethesda, MD,

December 3, 2018



Response Evaluation In Neurofibromatosis Schwannomatosis  
INTERNATIONAL COLLABORATION

# Disclosures

I have no relevant relationships with industry



# Patient reported outcome (PRO)

Any report of the status of a patient's health condition that comes directly from the patient without interpretation of the patient's response by a clinician or anyone else

# PRO tools for cNF trials

**Table 2** Patient-reported outcome (PRO) tools considered for use in clinical trials of cutaneous neurofibromas (cNF)

PRO	Use	Advantages for cNF	Drawbacks for cNF
<b>Skindex 16 or 29</b>	Assess physical and psychological effects of skin conditions	Has been used in NF1 studies	Has not been studied in NF1 interventional trials
<b>(Children's) Dermatology Quality of Life Index</b>	Widely used QoL index for children or adults with diseases affecting the skin	Validated PROs for children and for adults	Has not been used in NF1 clinical trials
<b>5D itch scale</b>	Captures intensity and time of pruritus	Symptom-specific measure	Itch is not a consistent feature in NF1
<b>Visual analog scale</b>	Widely used	Measures a specific character or symptom believed to be important in a disease (e.g., pain, itch) for its overall severity	Common uses (e.g., itch and pain) are not consistent features in cNF and may not reflect burden or severity in this manifestation
<b>Numeric rating scale</b>	Designed to rate pain	Similar to VAS in measuring patient perception of a specific symptom, but does not require a written response: it can be administered over the telephone	Pain is not a common manifestation for cNF in NF1 patients
<b>Adult PedsQL NF1 module</b>	Adult and pediatric specific QoL measures in NF1 patients	Specific to NF1	May not be sensitive to specifically capture the change in QoL from improvement in cNF as it measures multiple QoL domains in NF1

Abbreviations: NF1 = neurofibromatosis 1; QoL = quality of life; VAS = visual analog scale.






# Visual analogue scale

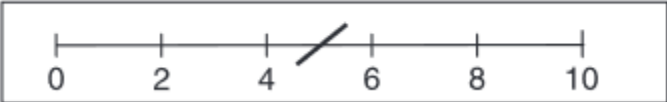
Draw a line anywhere on the scale that best represents the severity of your itching:

No itching Worst possible itching



0 2 4 6 8 10

Example:



0 2 4 6 8 10

**During the past week, how often have you been bothered by:**

Never  
Bothered  
↓

Always  
Bothered  
↓

- |   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 1. Your skin condition <b>itching</b>   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Your skin condition <b>burning</b> or <b>stinging</b>  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Your skin condition <b>hurting</b>   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Your skin condition <b>being irritated</b>   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. The <b>persistence / reoccurrence</b> of your skin condition   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. <b>Worry</b> about your skin condition (For example: that it will spread, get worse, scar, be unpredictable, etc)                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. The <b>appearance</b> of your skin condition   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. <b>Frustration</b> about your skin condition   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. <b>Embarrassment</b> about your skin condition   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. <b>Being annoyed</b> about your skin condition  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. <b>Feeling depressed</b> about your skin condition  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. The effects of your skin condition on your <b>interactions with others</b> (For example: interactions with family, friends, close relationships, etc) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 13. The effects of your skin condition on your <b>desire to be with people</b>  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 14. Your skin condition making it hard to <b>show affection</b>   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 15. The effects of your skin condition on your <b>daily activities</b>  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 16. Your skin condition making it hard to <b>work or do what you enjoy</b>  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |



# Skindex

During the past week, how often have you been bothered by:

- Your skin condition itching, burning, hurting, being irritated
- The persistence/recurrence of your skin condition
- Worry about your skin condition
- The appearance of your skin condition
- Frustration, embarrassment, being annoyed, feeling depressed about your skin condition



# Skindex cont.

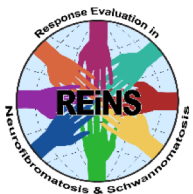
- The effects of your skin condition on your interactions with others; on your desire to be with people
- Your skin condition making it hard to show affection
- The effects of your skin condition on your daily activities
- Your skin condition making it hard to work or do what you enjoy



The aim of this questionnaire is to measure how much your skin problem has affected your life OVER THE LAST WEEK. Please tick  one box for each question.

- |     |   |                                     |                                       |
|-----|---|-------------------------------------|---------------------------------------|
| 1.  | Over the last week, how <b>itchy, sore, painful or stinging</b> has your skin been?   | Very much <input type="checkbox"/>  |                                       |
|     |   | A lot <input type="checkbox"/>      |                                       |
|     |   | A little <input type="checkbox"/>   |                                       |
|     |   | Not at all <input type="checkbox"/> |                                       |
| 2.  | Over the last week, how <b>embarrassed or self conscious</b> have you been because of your skin?  | Very much <input type="checkbox"/>  |                                       |
|     |   | A lot <input type="checkbox"/>      |                                       |
|     |   | A little <input type="checkbox"/>   |                                       |
|     |   | Not at all <input type="checkbox"/> |                                       |
| 3.  | Over the last week, how much has your skin interfered with you going <b>shopping</b> or looking after your <b>home or garden</b> ?                  | Very much <input type="checkbox"/>  |                                       |
|     |   | A lot <input type="checkbox"/>      |                                       |
|     |   | A little <input type="checkbox"/>   |                                       |
|     |   | Not at all <input type="checkbox"/> | Not relevant <input type="checkbox"/> |
| 4.  | Over the last week, how much has your skin influenced the <b>clothes</b> you wear?  | Very much <input type="checkbox"/>  |                                       |
|     |   | A lot <input type="checkbox"/>      |                                       |
|     |   | A little <input type="checkbox"/>   |                                       |
|     |   | Not at all <input type="checkbox"/> | Not relevant <input type="checkbox"/> |
| 5.  | Over the last week, how much has your skin affected any <b>social or leisure</b> activities?  | Very much <input type="checkbox"/>  |                                       |
|     |   | A lot <input type="checkbox"/>      |                                       |
|     |   | A little <input type="checkbox"/>   |                                       |
|     |   | Not at all <input type="checkbox"/> | Not relevant <input type="checkbox"/> |
| 6.  | Over the last week, how much has your skin made it difficult for you to do any <b>sport</b> ?   | Very much <input type="checkbox"/>  |                                       |
|     |   | A lot <input type="checkbox"/>      |                                       |
|     |   | A little <input type="checkbox"/>   |                                       |
|     |   | Not at all <input type="checkbox"/> | Not relevant <input type="checkbox"/> |
| 7.  | Over the last week, has your skin prevented you from <b>working or studying</b> ?   | Yes <input type="checkbox"/>        |                                       |
|     |   | No <input type="checkbox"/>         | Not relevant <input type="checkbox"/> |
|     | If "No", over the last week how much has your skin been a problem at <b>work or studying</b> ?  | A lot <input type="checkbox"/>      |                                       |
|     |   | A little <input type="checkbox"/>   |                                       |
|     |   | Not at all <input type="checkbox"/> |                                       |
| 8.  | Over the last week, how much has your skin created problems with your <b>partner</b> or any of your <b>close friends or relatives</b> ?             | Very much <input type="checkbox"/>  |                                       |
|     |   | A lot <input type="checkbox"/>      |                                       |
|     |   | A little <input type="checkbox"/>   |                                       |
|     |   | Not at all <input type="checkbox"/> | Not relevant <input type="checkbox"/> |
| 9.  | Over the last week, how much has your skin caused any <b>sexual difficulties</b> ?  | Very much <input type="checkbox"/>  |                                       |
|     |   | A lot <input type="checkbox"/>      |                                       |
|     |   | A little <input type="checkbox"/>   |                                       |
|     |   | Not at all <input type="checkbox"/> | Not relevant <input type="checkbox"/> |
| 10. | Over the last week, how much of a problem has the <b>treatment</b> for your skin been, for example by making your home messy, or by taking up time? | Very much <input type="checkbox"/>  |                                       |
|     |   | A lot <input type="checkbox"/>      |                                       |
|     |   | A little <input type="checkbox"/>   |                                       |
|     |   | Not at all <input type="checkbox"/> | Not relevant <input type="checkbox"/> |

Please check you have answered EVERY question. Thank you.



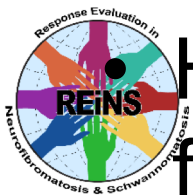
# DLQI

Over the last week:

- How itchy, sore, painful, or stinging has your skin been?
- How embarrassed or self conscious have you been because of your skin
- How much has your skin interfered with you going shopping or looking after your home or garden
- How much has your skin influenced the clothes you wear



- How much has your skin affected any social or leisure activities?
- How much has your skin made it difficult for you to do any sport?
- Has your skin prevented you from working or studying?
- How much has your skin created problems with your partner or any of your close friends or relatives?
- Has your skin caused any sexual difficulties



How much of a problem has a treatment for your skin been?





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Health  
Northern Sydney  
Local Health District



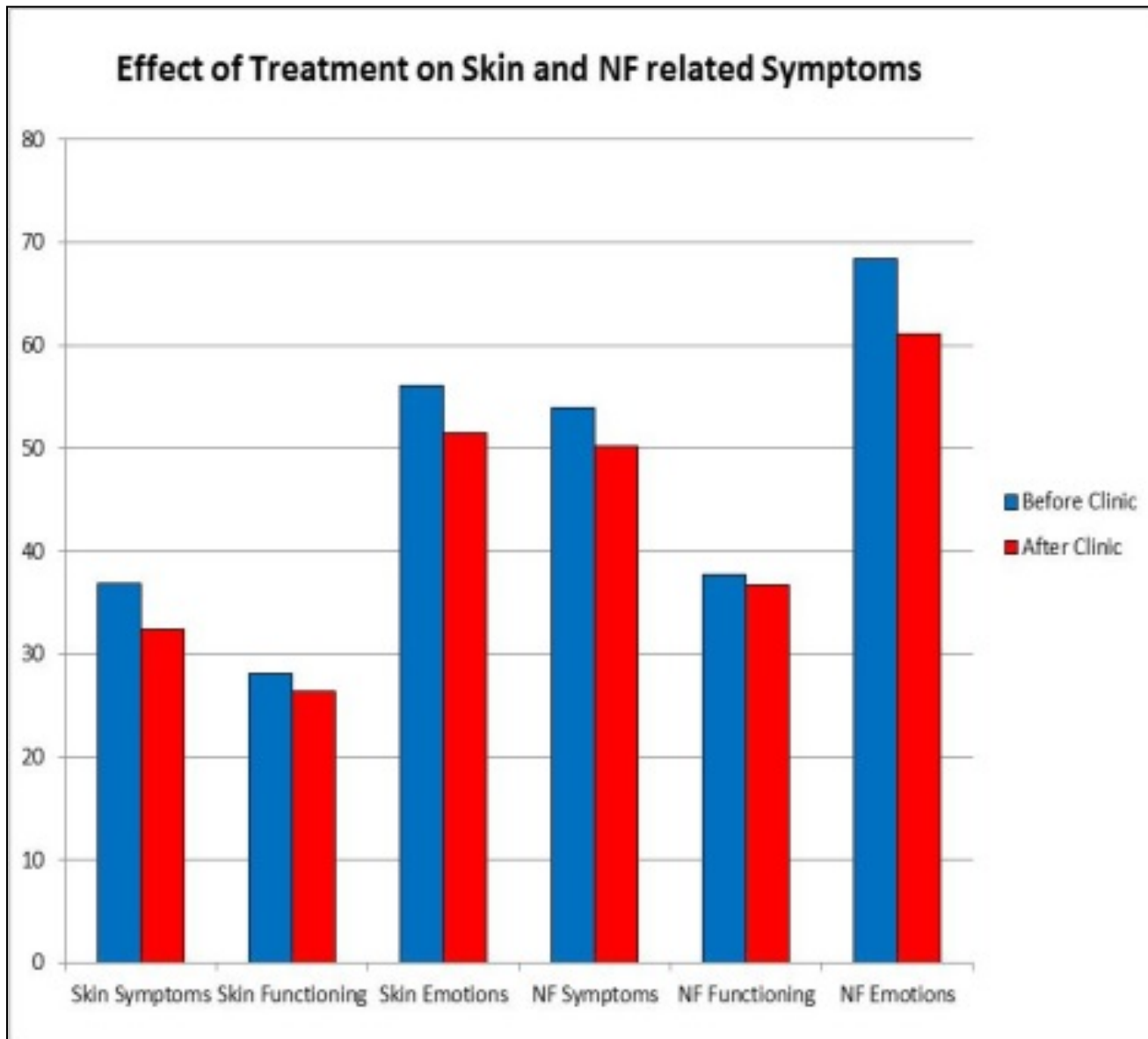


# Evaluate the patient view on their cutaneous disease

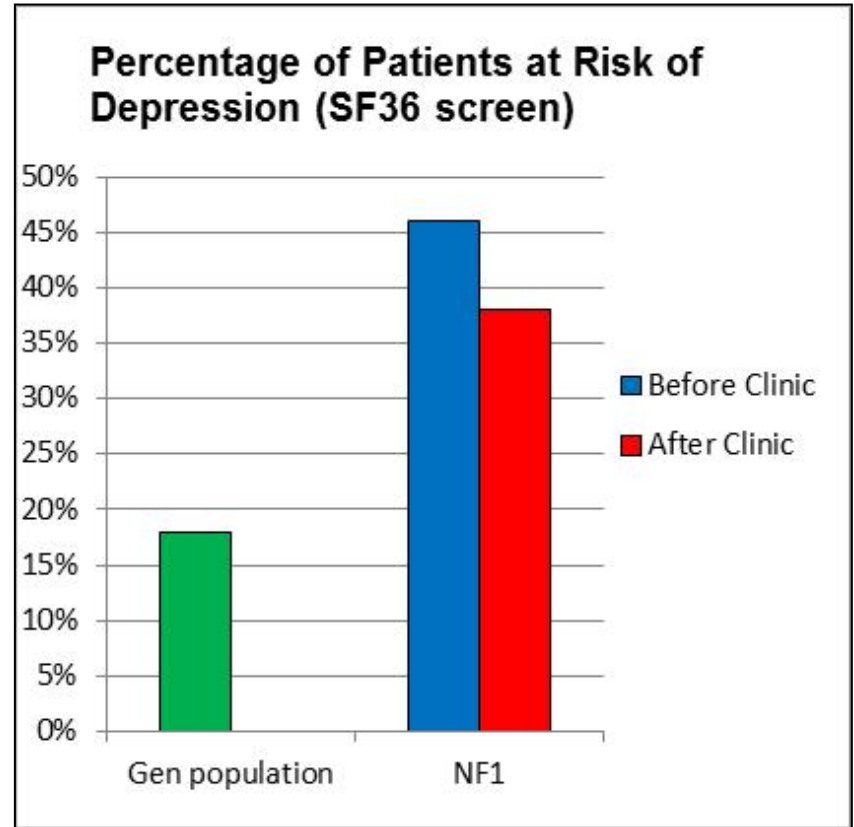
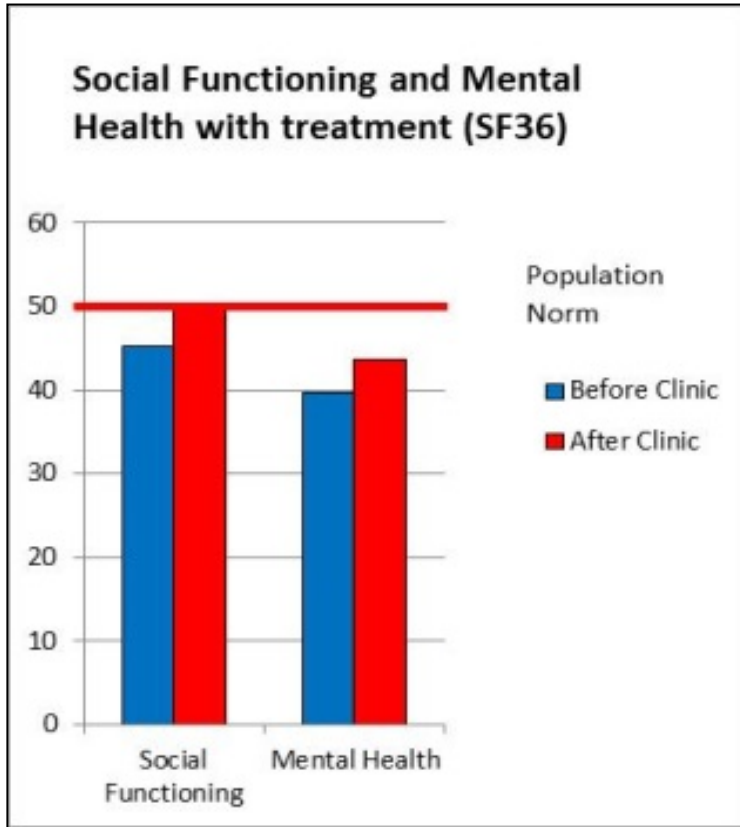
- 2015 started an NF skin clinic
- Dermatology and Genetics
  - Excisions and shaving
  - RF ablation
  - LASER funded by CTF/donation- preferred treatment modality
  - Topical rapamycin/ ketotifen
- Hilda Crawford administered several PROs simultaneously
  - Skindex, the adjusted NF QOL, DLQI, K10, SF36, 5d itch scale



# Effect of Treatment on Skin and NF Related Symptoms (Skindex, NFQoL)



# QoL Outcomes SF36



Power: need 100 patients - aim for end 2019 and more definitive treatments in 2019



# Management of Itch in Neurofibromatosis Type 1 (NF1): A Single-centre Experience

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## Background

- Previous studies have reported a high frequency of itch (19-70%) amongst individuals with Neurofibromatosis Type 1 (NF1)<sup>1,2,3</sup>.
- Chronic itch can be an independent factor for altered QoL, disrupting sleep and daily living<sup>2</sup>.
- NF1-associated itch has been postulated to be of neuropathic origin, resulting from neuronal or glial damage<sup>4</sup>.
- We selected a tricyclic antidepressant as our preferred treatment option based on its effectiveness on neuropathic itch<sup>5</sup>.
- Here we report on the characteristics and management of itch in NF1 from a single-centre experience.

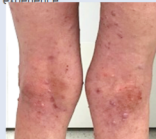


Figure 1. Skin lacerations from chronic itch in NF1.

- This study aims to characterise chronic itch in NF1 and evaluate the effectiveness of a tricyclic antidepressant for the management of NF1-associated itch.

## Method

- Adults (N=32) attending an NF1 clinical genetics dermatological service (skin clinic) in Sydney, Australia (Table 1).

- Median age 39y, range 26-69y.

Table 1. Patient characteristics (N=32)

Gender	Female	19
	Male	13
Age	25-34	9
	35-44	12
	45-54	5
	55-64	2
	>65	4

- As part of routine clinical care since 2017, patients attending the skin clinic are questioned regarding their experience of itch and previous treatments.
- Patients who reported itch were offered treatment, and outcomes were recorded and analysed.

## Results

### Clinical Characteristics

- 78% (25/32) of patients described itchiness of the skin (Figure 1).
- 76% (16/21) moderate to severe.
- Half of patients (7/13) reported daily or almost daily symptoms.
- A further two patients reported severe and daily itch during the warmer months only.
- Distribution was reported to be generalised (7/16) or localised at particular regions of the body (8/16) or to cutaneous neurofibromas (1/16).
- Most patients (12/16) reported trialling treatments with little to no effect.

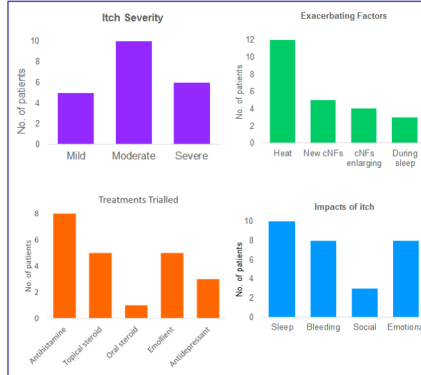


Figure 2. Frequency bar charts summarising clinical characteristics of itch in NF1.

### Treatment

- Of the 16 patients offered, 7 commenced treatment with a low dose tricyclic antidepressant (Table 2).
- Barriers for uptake include minimal concerns, unacceptable side effects, medication stigma and non-compliance.
- Six patients reported improvements and one ceased treatment due to unrelated health complications.
- Adverse effects included weight gain, sedation and a wearing-off effect.
- Two patients with weight gain reported a significant improvement to itch and daily living, preferring to continue treatment despite adverse effects.

Table 2. Patient characteristics and outcomes of treatment of itch with tricyclic antidepressant.

Patient	Gender	Itch Severity	Improvement to Itch	Other Outcomes	Dose Changes
1	Female	Moderate	Some	Sedation	Reduced
2	Male	Moderate	Some	Sedation	Treatment ceased
3	Male	Moderate	Some	Improved sleep	Unchanged
4	Female	Moderate	Great	Weight gain Unrelated health complications	Unchanged
5	Female	Moderate	N/A	None	Treatment ceased
6	Male	Severe	Great	None	Unchanged
7	Female	Severe	Great	Improved sleep, Wearing-off effect, Weight gain	Increased

## Conclusions

- Consistent with other reports, chronic itch in NF1 is common in our skin clinic cohort and can impact on quality of life.
- NF1-associated itch is amenable to effective treatment with low dose tricyclic antidepressant.
- When seeking treatment outside of a specialist NF service, many patients received treatment that was ineffective and potentially harmful.
- We hope these findings will increase awareness of NF1 as a manifestation of NF1 and facilitate development of best practices for clinical management of this potentially debilitating symptom.
- Findings were used to guide the development of patient-reported outcome measures for standardised long-term evaluation of treatment efficacy.

## References

1. Khosrotharani K, et al. Am J Med Gen. 2005; 132(1): 49-53.
2. Brenaut E, et al. Acta Derm Venereol. 2015; 95(3): 398-399.
3. Fjermestad KOV, et al. J Genet Couns. 2018; 27(5): 1102-1110.
4. Mitaliy L, et al. Nat Rev Neurol. 2014; 10: 408-416.
5. Weisshaar E, et al. Acta Derm Venereol. 2012; 92(5): 563-586.

## Acknowledgement

This project was generously supported by Children's Tumour Foundation (CTF) of Australia.



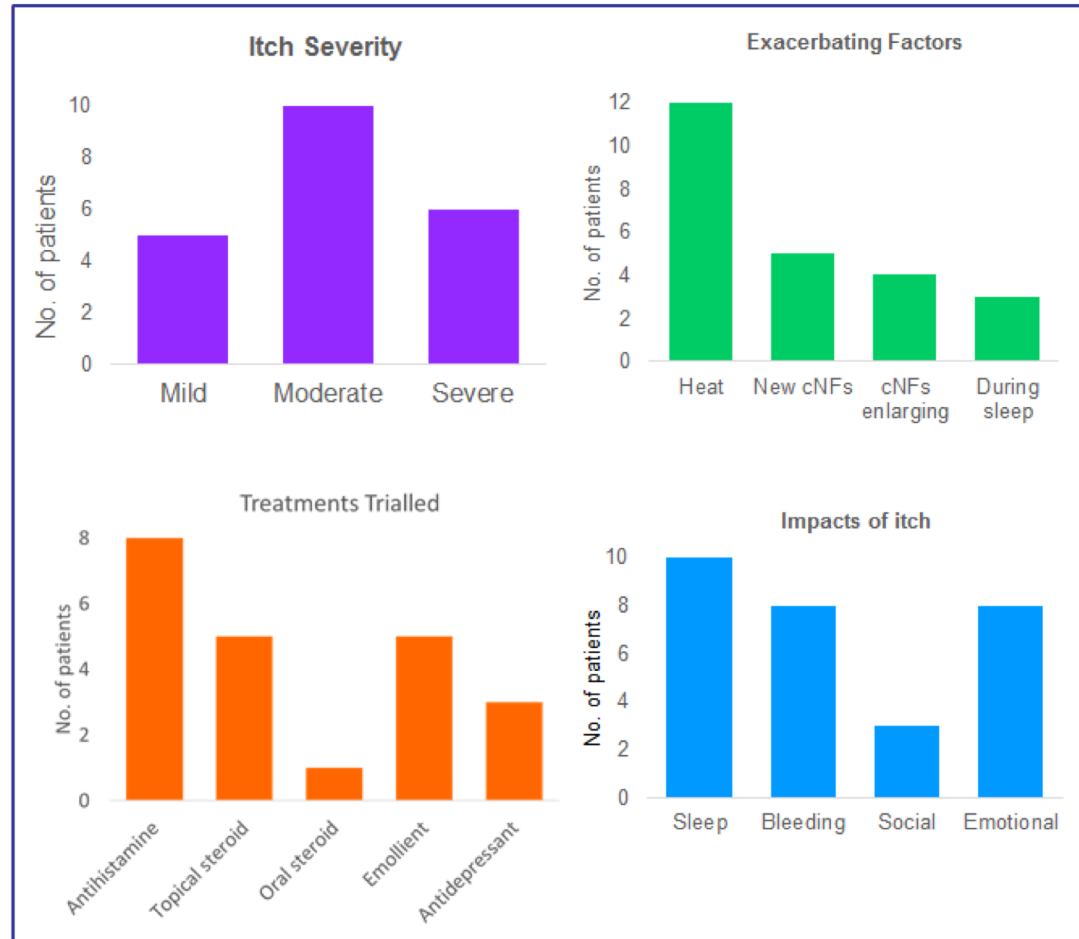
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# Results

## Clinical Characteristics

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- Most patients (12/16) reported trialling treatments with little to no effect.



**Figure 2.** Frequency bar charts summarising clinical characteristics of itch in NF1.

# 5D itch scale

**5-D Pruritus Scale**

1. **Duration** : During the last 2 weeks, how many hours a day have you been itching?

Less than 6hrs/day	6-12 hrs/day	12-18 hrs/day	18-23 hrs/day	All day
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

2. **Degree** : Please rate the intensity of your itching over the past 2 weeks

Not present	Mild	Moderate	Severe	Unbearable
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

3. **Direction** : Over the past 2 weeks has your itching gotten better or worse compared to the previous month?

Completely resolved	Much better, but still present	Little bit better, but still present	Unchanged	Getting worse
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

4. **Disability**: Rate the impact of your itching on the following activities over the last 2 weeks

	Never affects sleep	Occasionally delays falling asleep	Frequently delays falling asleep	Delays falling asleep and occasionally wakes me up at night	Delays falling asleep and frequently wakes me up at night	
<b>Sleep</b>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
	N/A	Never affects this activity	Rarely affects this activity	Occasionally affects this activity	Frequently affects this activity	Always affects this activity
<b>Leisure/Social</b>	<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
<b>Housework/Errands</b>	<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
<b>Work/School</b>	<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

5. **Distribution**: Mark whether itching has been present in the following parts of your body over the last 2 weeks. If a body part is not listed, choose the one that is closest anatomically.

	Present		Present
Head/Scalp	<input type="checkbox"/>	Soles	<input type="checkbox"/>
Face	<input type="checkbox"/>	Palms	<input type="checkbox"/>
Chest	<input type="checkbox"/>	Tops of Hands/Fingers	<input type="checkbox"/>
Abdomen	<input type="checkbox"/>	Forearms	<input type="checkbox"/>
Back	<input type="checkbox"/>	Upper Arms	<input type="checkbox"/>
Buttocks	<input type="checkbox"/>	Points of Contact w/ Clothing (e.g waistband, undergarment)	<input type="checkbox"/>
Thighs	<input type="checkbox"/>	Groin	<input type="checkbox"/>
Lower legs	<input type="checkbox"/>		<input type="checkbox"/>
Tops of Feet/Toes	<input type="checkbox"/>		<input type="checkbox"/>







# **Sydney and Minneapolis Come Together to Help Solve NF1 Skin**







**Health**  
Northern Sydney  
Local Health District



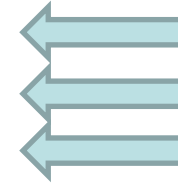
 **HEALTH**<sup>SM</sup>  
University of Minnesota  
Masonic Children's Hospital





# Question 1: Do the RNS and UMN patient populations differ for the various clinical factors?

Variable	Overall (n = 79)	RNS (n = 40)	UMN (n = 39)	p-value
Skindex (total avg)	30.7 (25.9)	38.8 (25.6)	22.4 (23.9)	0.004
Skindex (physical avg)	31.1 (24.0)	37.1 (24.6)	24.9 (21.9)	0.022
Skindex (emotions avg)	39.7 (32.6)	51.6 (32.2)	27.4 (28.4)	<0.001
Skindex (fuctional avg)	21.5 (25.0)	26.7 (25.0)	16.2 (24.1)	0.060
Skindex (Itch Q)	53.2 (32.9)	57.5 (33.6)	48.7 (31.9)	0.237
Age	38.7 (12.7)	40.7 (12.4)	36.7 (12.8)	0.159
Gender, M (%)	32 (40.5%)	15 (37.5%)	17 (43.6%)	0.650
# of cut. NFS				
0	6 (7.6%)	0 (0%)	6 (15.4%)	0.012
1-19	15 (19.0%)	6 (15%)	9 (23.1%)	
20-99	17 (21.5%)	11 (27.5%)	6 (15.4%)	
100-500	11 (13.9%)	2 (5.0%)	9 (23.1%)	
>500	29 (36.7%)	20 (50.0%)	9 (23.1%)	
Missing	1 (1.3%)	1 (2.5%)	0 (0%)	
Face, Yes (%)	41 (52%)	18 (45%)	23 (59%)	0.365
Riccardi				
Minimal	2 (2.5%)	1 (2.5%)	1 (2.6%)	0.010
Mild	16 (20.3%)	14 (35%)	1 (5.1%)	
Moderate	41 (52%)	18 (45%)	23 (59.0%)	
Severe	18 (22.8%)	7 (17.5%)	11 (28.2%)	
Missing	2 (2.5%)	0 (0%)	2 (5.1%)	



## Question 2: What is the relationship between each of the factors, both overall, and within each site?

The correlation between each of the Skindex domains are very strong (all correlations ( $r$ ) are above 0.67).

Age doesn't correlate very strongly with the Skindex scores (all  $r < 0.25$ ).

It seems that females have higher Skindex scores on all domains.

As # of cutaneous NFs increase, the Skindex scores also increase. The # of cNFs also increases with age, and females and those with facial cNFs also tend to have more # cNFs.

Those with facial cNFs have higher Skindex scores.

Riccardi severity doesn't seem to change much for the total skindex or the physical average. The more severe Riccardi categories may have small emotional and functional averages.



### Question 3: Does the relationship between the total avg skindex score and each of the factors differ by site?

Clinical Factor	Interaction size	p-value
Age	0.35	0.435
Gender (M)	7.5	0.490
# of cut NFs	3.2	0.426
Face	11.4	0.281
Riccardi	5.2	0.530



None of the interactions were significant, so we cannot say that the relationship between the total avg Skindex score different on any of the clinical factors differed by site. This provides some evidence that the data can be combined.



## Questions 4: Do the Skindex scores differ between sites, after adjusting for the differences in the various clinical factors?

Response variable	Unadjusted diff (UMN – RNS)	Unadjusted p-value	Adjusted diff (UMN – RNS)	Adjusted p-value
Skindex avg total	-16.4	0.004	-11.6	0.081
Physical avg	-12.2	0.022	-8.0	0.230
Emotions avg	-24.2	<0.001	-16.8	0.036
Functional avg	-10.5	0.060	-7.2	0.292
Itch question	-8.8	0.237	-2.8	0.776



# Conclusion

- Overall, the Skindex domain scores at the RNS site were higher than the UMN site. However, the sites also differed among many clinical factors. After adjusting for these differences, the Skindex differences were now smaller, and mostly non-significant.



# Acknowledgements

- A/Prof Gayle Fischer
- Dr Rebecca Sanderson
- Dr Hilda Crawford
- Dr Lavvina Thiyangarajan
- Claire Wong
- Dr Mathilda Wilding
- Ashley Crook
- Dr Rebecca Sanderson
- Katie Nelson
- A/Prof Kristine Barlow-Stewart
- Rosie O'Shea



# Acknowledgements - Minnesota

- Sheilagh Maguiness, MD – Dermatology
- Melissa Dodds, MD - Interviewer
- Nathan Rubin, MS – Statistics

