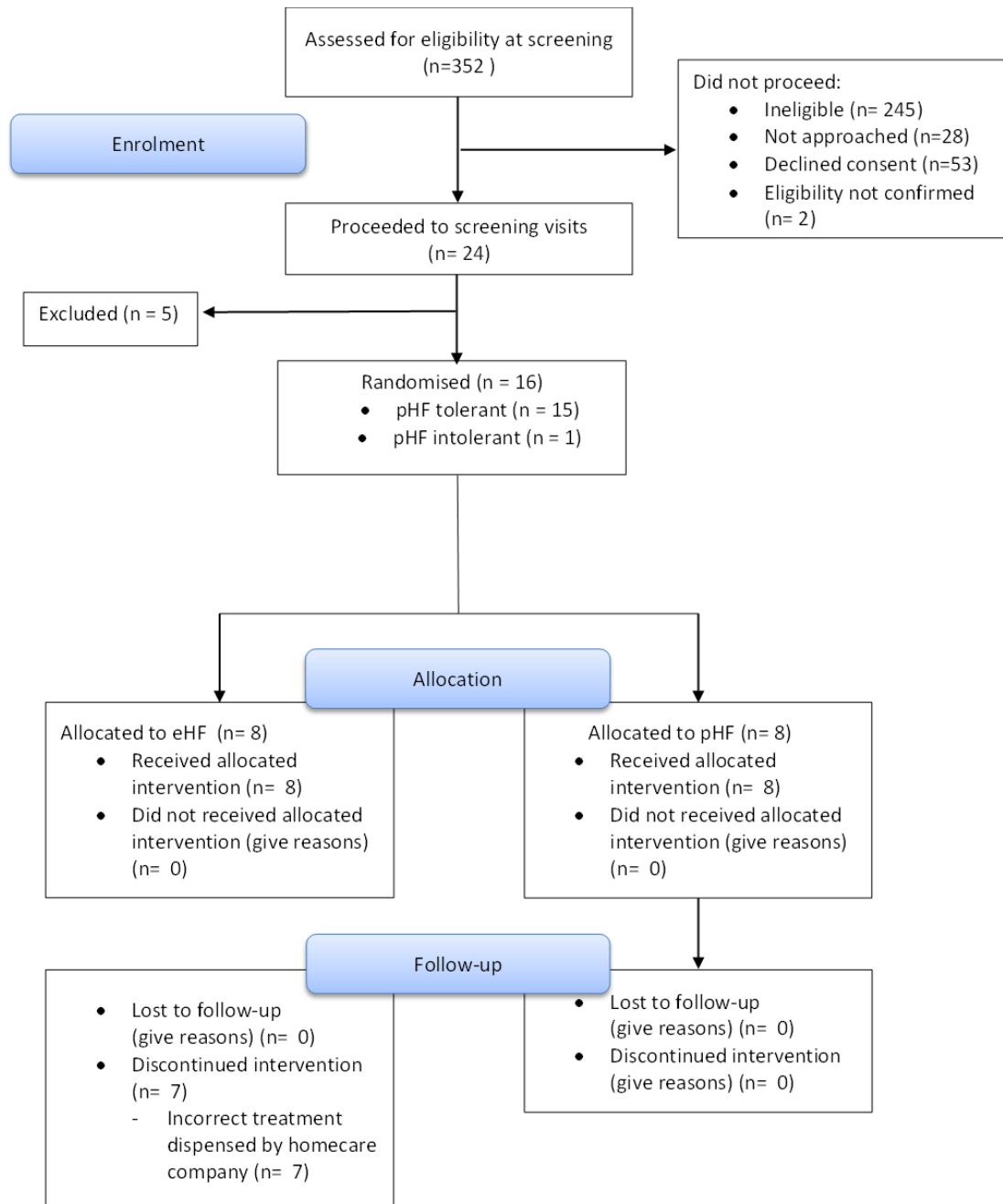# DREAM Summary Results Report

CONSORT Flow Diagram

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Baseline Characteristics

Table 7-1 Demographic details

	Randomised Patients			Patients who attended visit 1 but weren't randomised
	Intervention: pHF	**Control : eHF**	**Total**	
Age at first screening (Months)				
N	8	8	16	8
Mean (sd)	10.00 (1.51)	10.00 (1.93)	10.00 (1.67)	8.25 (3.45)
Median (IQR)	9.50 (2.50)	10.00 (2.00)	10.00 (2.50)	9.00 (3.50)
Range [Min, Max]	[8.00, 12.00]	[6.00, 12.00]	[6.00, 12.00]	[1.00, 12.00]
Missing	0	0	0	0
Gender : n(%)	(N = 8)	(N = 8)	(N = 16)	(N = 8)
Female	3 (37.5%)	2 (25%)	5 (31.3%)	3 (37.5%)
Male	5 (62.5%)	6 (75%)	11 (68.8%)	4 (50%)
Missing	0	0	0	1

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Table 7-2 Medical History

	Randomised Patients			Patients who attended visit 1 but weren't randomised
	Intervention: pHF	**Control : eHF**	**Total**	
	(N = 8)	(N = 8)	(N = 16)	(N = 8)
Asthma	0	1 (12.5%)	1 (6.3%)	1 (12.5%)
Wheeze	0	1 (12.5%)	1 (6.3%)	1 (12.5%)
Urticaria and angioedema (hives)	6 (75%)	1 (12.5%)	7 (43.8%)	6 (75%)
Atopic dermatitis	7 (87.5%)	7 (87.5%)	14 (87.5%)	3 (37.5%)
Doctor diagnosed food allergies	7 (87.5%)	7 (87.5%)	14 (87.5%)	5 (62.5%)
Drug allergies	0	1 (12.5%)	1 (6.3%)	1 (12.5%)
Other diseases	4 (50%)	1 (12.5%)	5 (31.3%)	2 (25%)
None	0	0	0	0
Not Known	0	0	0	0

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Table 7-3 Physical Exam

	Randomised Patients			Patients who attended visit 1 but weren't randomised
	Intervention: pHF	**Control : eHF**	**Total**	
Weight (kg)				
N	8	8	16	8
Mean (sd)	8.65 (0.74)	8.27 (0.54)	8.46 (0.66)	7.59 (3.20)
Median (IQR)	8.75 (1.20)	8.30 (0.73)	8.45 (1.00)	8.90 (1.80)
Range [Min, Max]	[7.50, 9.60]	[7.50, 9.10]	[7.50, 9.60]	[0.00, 9.90]
Missing	0	0	0	0
Height (cm)				
N	8	8	16	8
Mean (sd)	71.13 (2.47)	71.50 (1.20)	71.31 (1.89)	61.63 (25.04)
Median (IQR)	71.50 (3.50)	71.00 (1.00)	71.00 (1.50)	70.00 (5.50)
Range [Min, Max]	[67.00, 74.00]	[70.00, 74.00]	[67.00, 74.00]	[0.00, 74.00]
Missing	0	0	0	0
EASI Score				
N	8	7	15	3
Mean (sd)	9.75 (14.29)	1.87 (1.68)	6.07 (10.95)	1.43 (1.91)
Median (IQR)	2.95 (16.80)	1.80 (3.40)	1.80 (5.00)	0.70 (3.60)
Range [Min, Max]	[0.00, 37.10]	[0.00, 4.40]	[0.00, 37.10]	[0.00, 3.60]
Missing	0	1	1	5

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Table 7-4 Skin Prick Tests

	Randomised Patients			Patients who attended visit 1 but weren't randomised
	Intervention: pHF	Control : eHF	Total	
Cow's milk wheal diameter using whole fresh milk (mm)				
N	8	8	16	7
Mean (sd)	8.63 (2.88)	10.75 (4.43)	9.69 (3.77)	6.29 (4.82)
Median (IQR)	7.50 (2.50)	11.50 (7.00)	8.50 (5.50)	6.00 (10.00)
Range [Min, Max]	[6.00, 15.00]	[4.00, 17.00]	[4.00, 17.00]	[0.00, 12.00]
Missing	0	0	0	1
Commercial milk extracts wheal diameter (mm)				
N	8	8	16	7
Mean (sd)	7.38 (2.83)	8.13 (4.09)	7.75 (3.42)	4.86 (4.85)
Median (IQR)	7.00 (4.50)	8.00 (5.00)	7.50 (4.50)	5.00 (10.00)
Range [Min, Max]	[3.00, 11.00]	[2.00, 15.00]	[2.00, 15.00]	[0.00, 10.00]
Missing	0	0	0	1
Egg wheal diameter (mm)				
N	6	6	12	7
Mean (sd)	4.00 (3.41)	4.83 (3.31)	4.42 (3.23)	1.14 (2.27)
Median (IQR)	4.50 (7.00)	4.50 (5.00)	4.50 (6.00)	0.00 (2.00)
Range [Min, Max]	[0.00, 8.00]	[0.00, 9.00]	[0.00, 9.00]	[0.00, 6.00]
Missing	2	2	4	1
House dust mite mix wheal diameter (mm)				
N	8	8	16	7
Mean (sd)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
Median (IQR)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
Range [Min, Max]	[0.00, 0.00]	[0.00, 0.00]	[0.00, 0.00]	[0.00, 0.00]
Missing	0	0	0	1
Cat dander wheal diameter (mm)				
N	8	8	16	7
Mean (sd)	1.00 (1.93)	2.13 (2.53)	1.56 (2.25)	0.57 (0.98)
Median (IQR)	0.00 (1.50)	1.00 (4.50)	0.00 (3.50)	0.00 (2.00)
Range [Min, Max]	[0.00, 5.00]	[0.00, 6.00]	[0.00, 6.00]	[0.00, 2.00]
Missing	0	0	0	1

	Randomised Patients			Patients who attended visit 1 but weren't randomised
	Intervention: pHF	Control : eHF	Total	
6 grass pollen wheal diameter (mm)				
N	8	8	16	7
Mean (sd)	0.38 (1.06)	0.00 (0.00)	0.19 (0.75)	0.00 (0.00)
Median (IQR)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
Range [Min, Max]	[0.00, 3.00]	[0.00, 0.00]	[0.00, 3.00]	[0.00, 0.00]
Missing	0	0	0	1

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Table 7-5 Antigen specific IgE test

	Randomised Patients			Patients who attended visit 1 but weren't randomised
	Intervention: pHF	Control : eHF	Total	
Cows milk (CM-IgE) (kU/L)				
N	8	7	15	6
Mean (sd)	19.98 (33.49)	12.29 (22.37)	16.39 (28.12)	5.09 (8.21)
Median (IQR)	4.60 (19.59)	3.56 (4.82)	4.39 (17.24)	1.72 (5.08)
Range [Min, Max]	[1.62, 100.00]	[0.93, 62.80]	[0.93, 100.00]	[0.00, 21.30]
Missing	0	1	1	2
Alpha Lactalumin (ALA-IgE) (kU/L)				
N	7	6	13	6
Mean (sd)	3.19 (5.13)	1.38 (1.62)	2.35 (3.89)	0.77 (1.10)
Median (IQR)	1.34 (4.20)	0.86 (1.24)	1.06 (1.24)	0.41 (0.12)
Range [Min, Max]	[0.11, 14.30]	[0.10, 4.50]	[0.10, 14.30]	[0.00, 3.00]
Missing	1	2	3	2
Beta Lactoglobulin (BLA-IgE) (kU/L)				
N	7	6	13	5
Mean (sd)	3.94 (6.12)	3.31 (2.88)	3.65 (4.72)	2.26 (4.17)
Median (IQR)	0.61 (9.41)	3.00 (6.03)	0.62 (6.03)	0.58 (0.31)
Range [Min, Max]	[0.35, 15.40]	[0.10, 6.87]	[0.10, 15.40]	[0.00, 9.71]
Missing	1	2	3	3

	Randomised Patients			
	Intervention: pHF	**Control : eHF**	**Total**	**Patients who attended visit 1 but weren't randomised**
Casein (Cas-IgE) (kU/L)				
N	7	6	13	6
Mean (sd)	19.63 (36.70)	2.77 (3.92)	11.85 (27.50)	4.92 (8.73)
Median (IQR)	1.99 (26.59)	1.52 (2.64)	1.99 (4.99)	1.05 (4.92)
Range [Min, Max]	[0.50, 100.00]	[0.10, 10.40]	[0.10, 100.00]	[0.00, 22.30]
Missing	1	2	3	2

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Table 7-6 Demographics

	Randomised Patients		
	Intervention: pHF	Control : eHF	Total
Ethnicity	(N = 8)	(N = 8)	(N = 16)
White	5 (62.5%)	4 (50%)	9 (56.3%)
Mixed/Multiple Ethnic groups	0	1 (12.5%)	1 (6.3%)
Asian/Asian British	2 (25%)	3 (37.5%)	5 (31.3%)
Black, African, Caribbean or Black British	0	0	0
Other ethnic group	1 (12.5%)	0	1 (6.3%)
Missing	0	0	0
Birth Weight (kg)			
N	7	8	15
Mean (sd)	3.33 (0.37)	3.27 (0.24)	3.30 (0.30)
Median (IQR)	3.40 (0.60)	3.18 (0.34)	3.30 (0.40)
Range [Min, Max]	[2.70, 3.80]	[3.02, 3.70]	[2.70, 3.80]
Missing	1	0	1
Gestation time (weeks)			
N	8	7	15
Mean (sd)	39.25 (1.16)	38.86 (1.35)	39.07 (1.22)
Median (IQR)	39.50 (2.00)	39.00 (2.00)	39.00 (2.00)
Range [Min, Max]	[38.00, 41.00]	[37.00, 41.00]	[37.00, 41.00]
Missing	0	1	1
Parity			
N	7	8	15
Mean (sd)	1.71 (1.50)	1.25 (0.46)	1.47 (1.06)
Median (IQR)	2.00 (3.00)	1.00 (0.50)	1.00 (1.00)
Range [Min, Max]	[0.00, 4.00]	[1.00, 2.00]	[0.00, 4.00]
Missing	1	0	1
Number of siblings living at same house			
N	8	8	16
Mean (sd)	1.00 (1.07)	0.38 (0.52)	0.69 (0.87)
Median (IQR)	1.00 (1.50)	0.00 (1.00)	0.50 (1.00)
Range [Min, Max]	[0.00, 3.00]	[0.00, 1.00]	[0.00, 3.00]
Missing	0	0	0

Table 7-7 Family history

	Randomised Patients		
	Intervention: pHF	**Control : eHF**	**Total**
	(N = 8)	(N = 8)	(N = 16)
Eczema-atopic dermatitis	6 (75%)	4 (50%)	10 (62.5%)
Allergic rhinoconjunctivitis (hay fever)	6 (75%)	6 (75%)	12 (75%)
Asthma	5 (62.5%)	3 (37.5%)	8 (50%)
Food allergy	1 (12.5%)	3 (37.5%)	4 (25%)
None	0	1 (12.5%)	1 (6.3%)
Not Known	0	0	0

Outcome Measures

No analysis of primary or secondary outcomes undertaken due to trial stopping prematurely.

Adverse Events

Non-serious adverse events

Table 0-8 Non-serious adverse events

	Control : eHF		Intervetion:pHF		Total	
Non-Serious adverse event	**Events n**	**Patients n(%)**	**Events n**	**Patients n(%)**	**Events n**	**Patients n(%)**
Allergic Reaction	0	0	6	5 (33.3%)	6	5 (31.3%)
Bronchial Infection	1	1 (12.5%)	1	1 (6.7%)	2	2 (12.5%)
Chest Infection	0	0	2	1 (6.7%)	2	1 (6.3%)
Conjunctivitis	0	0	2	1 (6.7%)	2	1 (6.3%)
Cough	0	0	1	1 (6.7%)	1	1 (6.3%)
Croup	0	0	2	2 (13.3%)	2	2 (12.5%)
Diarrhoea	0	0	3	2 (13.3%)	3	2 (12.5%)
Eczema flare	0	0	8	2 (13.3%)	8	2 (12.5%)
Eye Angioedema	0	0	1	1 (6.7%)	1	1 (6.3%)
Fall	0	0	2	1 (6.7%)	2	1 (6.3%)
Fever	2	2 (25%)	7	3 (20%)	9	5 (31.3%)
Flu symptoms	0	0	1	1 (6.7%)	1	1 (6.3%)

Non-Serious adverse event	Control : eHF		Intervetion:pHF		Total	
	Events n	Patients n(%)	Events n	Patients n(%)	Events n	Patients n(%)
Gastric Reflux	0	0	1	1 (6.7%)	1	1 (6.3%)
Hand, Foot & mouth disease	0	0	1	1 (6.7%)	1	1 (6.3%)
Hayfever	0	0	1	1 (6.7%)	1	1 (6.3%)
Heat Stroke	0	0	1	1 (6.7%)	1	1 (6.3%)
Infected bite (animal)	1	1 (12.5%)	0	0	1	1 (6.3%)
Loose Stool	0	0	1	1 (6.7%)	1	1 (6.3%)
Post vaccination symptoms	0	0	1	1 (6.7%)	1	1 (6.3%)
Rash	0	0	2	1 (6.7%)	2	1 (6.3%)
Red swollen eye	1	1 (12.5%)	0	0	1	1 (6.3%)
Skin Infection	0	0	3	1 (6.7%)	3	1 (6.3%)
Sore throat	0	0	1	1 (6.7%)	1	1 (6.3%)
Teething	2	1 (12.5%)	5	1 (6.7%)	7	2 (12.5%)
Tonsillitis	1	1 (12.5%)	1	1 (6.7%)	2	2 (12.5%)
Toothache	1	1 (12.5%)	1	1 (6.7%)	2	1 (6.3%)
Upper Respiratory Infection	2	2 (25%)	5	4 (26.7%)	7	6 (37.5%)
Urticaria	2	1 (12.5%)	7	2 (13.3%)	9	3 (18.8%)
Viral illness	2	2 (25%)	1	1 (6.7%)	3	3 (18.8%)
Vomiting	0	0	7	3 (20%)	7	3 (18.8%)
Vomiting and diarrhoea	1	1 (12.5%)	0	0	1	1 (6.3%)
Total	**16**	**6 (75%)**	**75**	**9 (60%)**	**91**	**11 (68.8%)**

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Table 0-9 Non-serious adverse events by severity

Non-Serious adverse event	Severity	Control : eHF		Intervetion:pHF		Total	
		Events n	Patients n(%)	Events n	Patients n(%)	Events n	Patients n(%)
Allergic Reaction	Mild	0	0	5	4 (26.7%)	5	4 (25%)
	Severe	0	0	1	1 (6.7%)	1	1 (6.3%)
Bronchial Infection	Mild	1	1 (12.5%)	1	1 (6.7%)	2	2 (12.5%)
Chest Infection	Mild	0	0	2	1 (6.7%)	2	1 (6.3%)
Conjunctivitis	Mild	0	0	2	1 (6.7%)	2	1 (6.3%)
Cough	Mild	0	0	1	1 (6.7%)	1	1 (6.3%)
Croup	Mild	0	0	1	1 (6.7%)	1	1 (6.3%)
	Moderate	0	0	1	1 (6.7%)	1	1 (6.3%)
Diarrhoea	Mild	0	0	2	2 (13.3%)	2	2 (12.5%)
	Moderate	0	0	1	1 (6.7%)	1	1 (6.3%)
Eczema flare	Mild	0	0	8	2 (13.3%)	8	2 (12.5%)
Eye Angioedema	Mild	0	0	1	1 (6.7%)	1	1 (6.3%)
Fall	Mild	0	0	2	1 (6.7%)	2	1 (6.3%)
Fever	Mild	2	2 (25%)	7	3 (20%)	9	5 (31.3%)
Flu symptoms	Mild	0	0	1	1 (6.7%)	1	1 (6.3%)
Gastric Reflux	Mild	0	0	1	1 (6.7%)	1	1 (6.3%)
Hand, Foot & mouth disease	Mild	0	0	1	1 (6.7%)	1	1 (6.3%)
Hayfever	Mild	0	0	1	1 (6.7%)	1	1 (6.3%)
Heat Stroke	Mild	0	0	1	1 (6.7%)	1	1 (6.3%)
Infected bite (animal)	Mild	1	1 (12.5%)	0	0	1	1 (6.3%)
Loose Stool	Mild	0	0	1	1 (6.7%)	1	1 (6.3%)
Post vaccination symptoms	Mild	0	0	1	1 (6.7%)	1	1 (6.3%)
Rash	Mild	0	0	2	1 (6.7%)	2	1 (6.3%)

Non-Serious adverse event	Severity	Control : eHF		Intervetion:pHF		Total	
		Events n	Patients n(%)	Events n	Patients n(%)	Events n	Patients n(%)
Red swollen eye	Mild	1	1 (12.5%)	0	0	1	1 (6.3%)
Skin Infection	Mild	0	0	3	1 (6.7%)	3	1 (6.3%)
Sore throat	Mild	0	0	1	1 (6.7%)	1	1 (6.3%)
Teething	Mild	2	1 (12.5%)	5	1 (6.7%)	7	2 (12.5%)
Tonsillitis	Mild	1	1 (12.5%)	1	1 (6.7%)	2	2 (12.5%)
Toothache	Mild	1	1 (12.5%)	1	1 (6.7%)	2	1 (6.3%)
Upper Respiratory Infection	Mild	2	2 (25%)	5	4 (26.7%)	7	6 (37.5%)
Urticaria	Mild	2	1 (12.5%)	7	2 (13.3%)	9	3 (18.8%)
Viral illness	Mild	2	2 (25%)	1	1 (6.7%)	3	3 (18.8%)
Vomiting	Mild	0	0	7	3 (20%)	7	3 (18.8%)
Vomiting and diarrhoea	Mild	1	1 (12.5%)	0	0	1	1 (6.3%)
Total	**Mild**	**16**	**6 (75%)**	**72**	**6 (40%)**	**88**	**8 (50%)**
Total	**Moderate**	**0**	**0**	**2**	**2 (13.3%)**	**2**	**2 (12.5%)**
Total	**Severe**	**0**	**0**	**1**	**1 (6.7%)**	**1**	**1 (6.3%)**

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Note: Where patients have experienced more than one adverse event and more than one severity, they have been reported in the most severe category

Serious adverse events

Table 0-10 Line listing of serious adverse events

SAE number	Treatment Allocation	Diagnosis	Onset date	Serious Criteria	Severity	eHF			pHF			Most likely cause, if unrelated (PI assessment)	Outcome
						Relatedness			Relatedness				
						Site assessment	MR assessment	Expectedness	Site assessment	MR assessment	Expectedness		
1	pHF	chest infection	26/06/2023	Required Hospitalisation	Moderate	Unrelated	Unrelated	Not Expected	Unrelated	Unrelated	Not Expected	viral infection	Resolved
2	pHF	anaphylaxis to cows milk exposure	21/08/2023	Required Hospitalisation	Severe	Unrelated	Unrelated	Expected	Unrelated	Unrelated	Expected	Patient's original condition	Resolved
3	pHF	infected chickenpox	15/10/2023	Required Hospitalisation	Severe	Unlikely	Unrelated	Not Expected	Unlikely	Unrelated	Not Expected	infection- chickenpox	Resolved

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