

ISRCTN14615267 Basic results summary

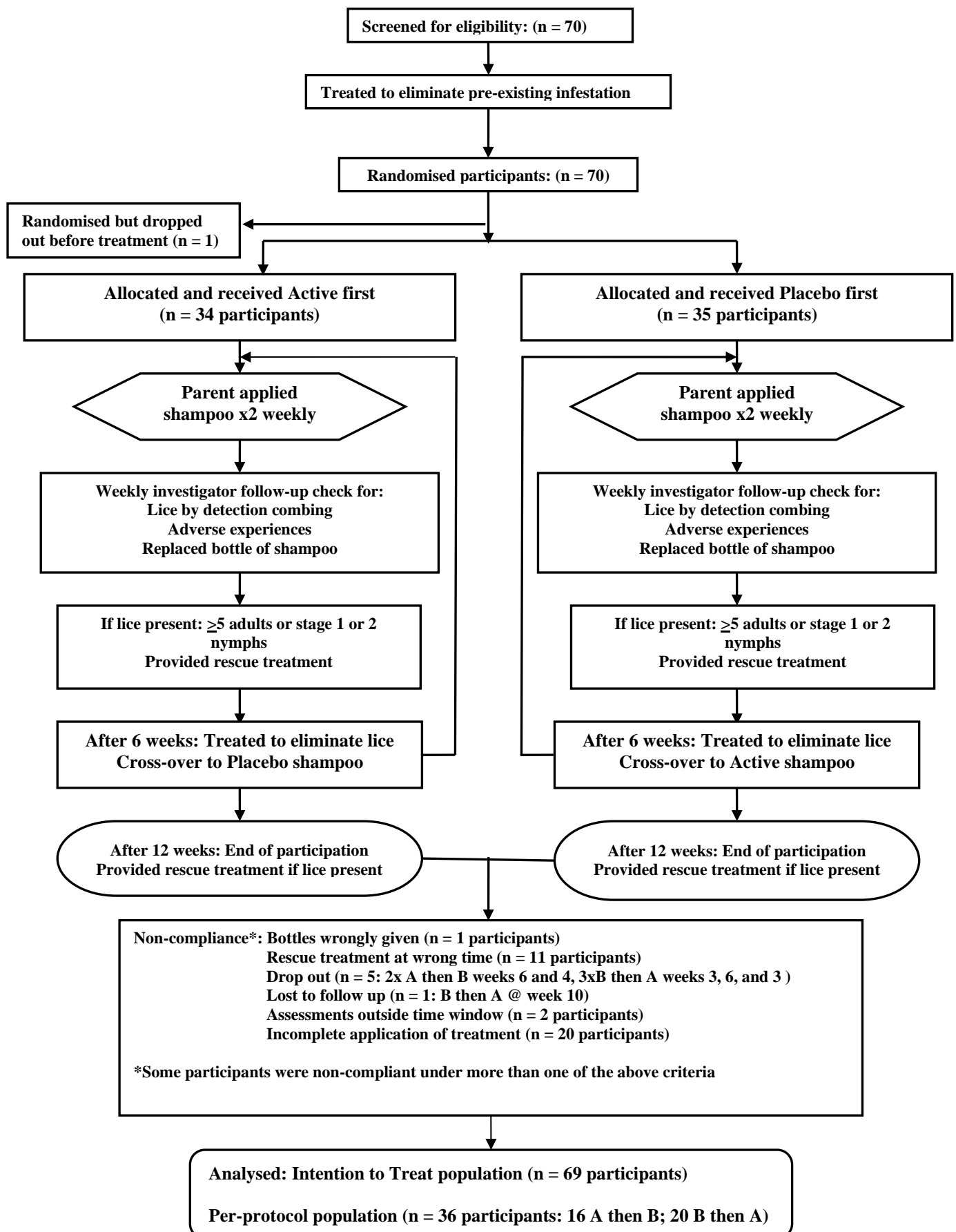


Table to show Primary outcome measure results: Mean time to first infestation of head lice in days during the six week period of treatment (Per-protocol population)

Endpoint	Randomisation group	n <sup>a</sup>	Under Active (A)	Under Placebo (B)	Difference (B – A)	Between treatment P <sup>b</sup>
Time to first confirmed infestation (mean score)						
	A then B	16	5.38	5.88	0.50	NS
	B then A	20	6.30	5.20	-1.10	NS
	Between group P <sup>c</sup>		NS	NS		
	Total	36	5.89	5.50	-0.39	NS
Confirmed infestation (%)						
	A then B	16	31.25	37.50		NS
	B then A	20	20.00	35.00		NS
	Between group P <sup>c</sup>		NS	NS		
	Total	36	25.00	36.11		NS
Number of confirmed infestations (mean)						
	A then B	16	0.94	0.44	-0.50	NS
	B then A	20	0.20	0.70	0.50	NS
	Between group P <sup>c</sup>		NS	NS		
	Total	36	0.53	0.58	-0.05	NS

<sup>a</sup> Number of participants.

<sup>b</sup> +++ p<0.001, ++ p< 0.01, + p<0.05, (+) p<0.1 for B greater than A, with minus signs indicating differences in the opposite direction.

<sup>c</sup> Codes as for between treatment p, but comparison is at B then A compared to A then B.

Figure 1a. Secondary outcome measures: Number of infestations and numbers of lice recovered on participants receiving Active then Placebo

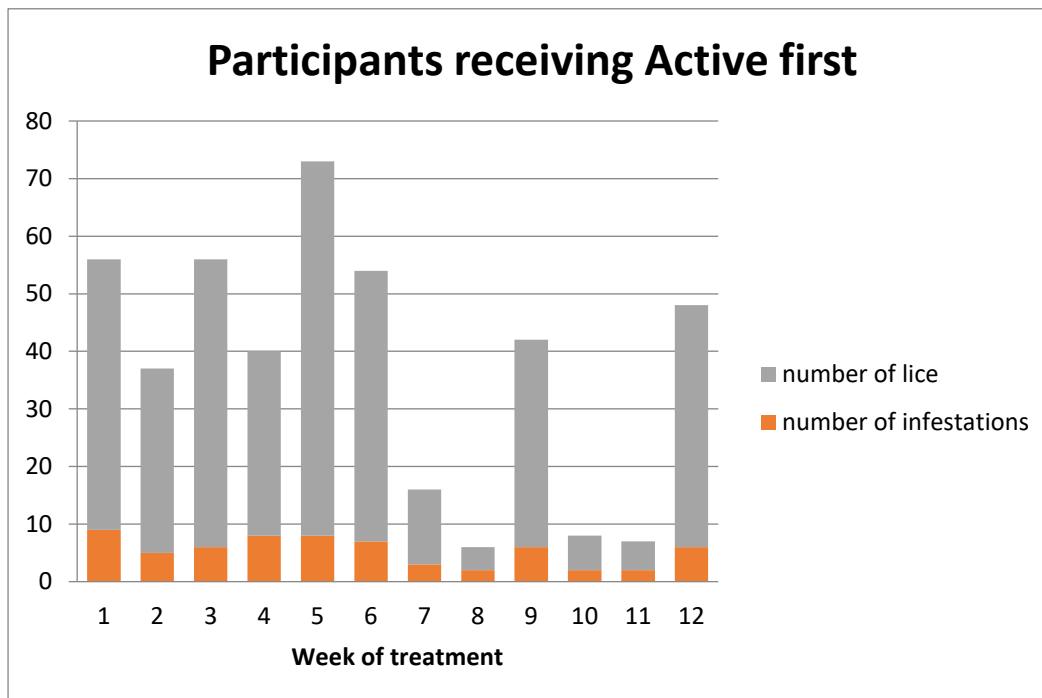
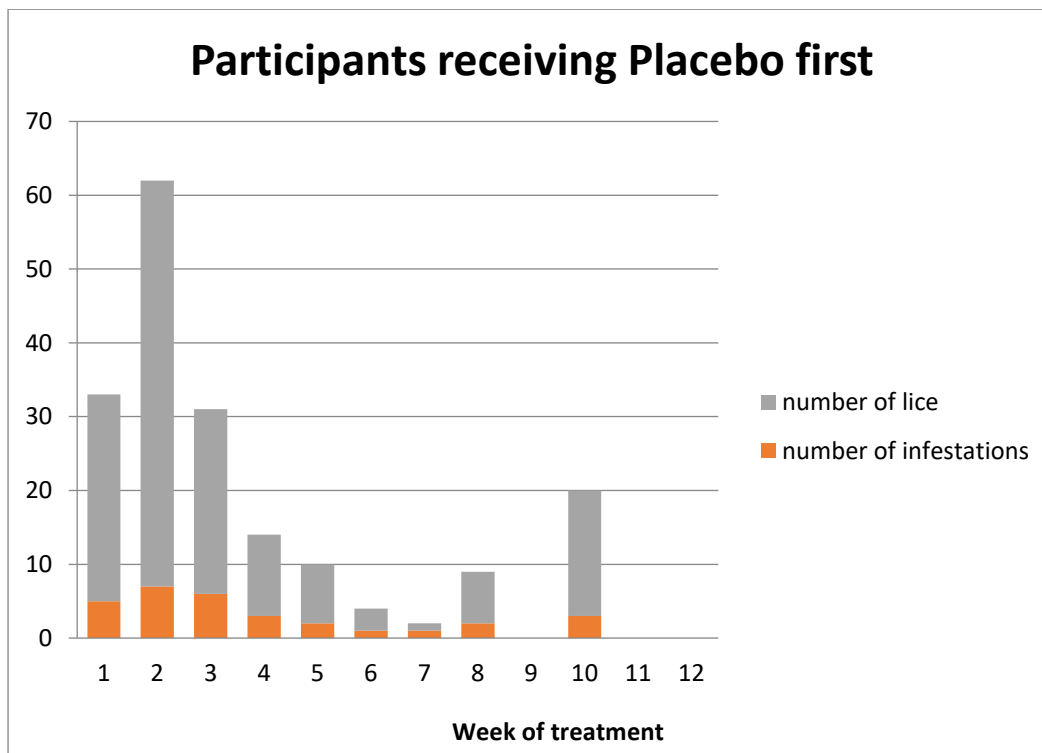


Figure 1b. Secondary outcome measures: Number of infestations and numbers of lice recovered on participants receiving Placebo then Active



### Adverse events listed by treatment group

**A then B**

Participant	AE no	Participant age	Adverse event	Week reported	Severity	Action taken	Relationship to study product	Duration	Outcome
001	1	5	Itchy scalp	Week 0	Moderate	None	Probable	12 days	Resolved
	2		Cut on head	Week 1	Mild	None	None	1 day	Resolved
	3		Joint injury	Week 3	Moderate	None	None	1 day	Resolved
003	1	11	Toothache	Week 3	Mild	Medication	None	1 day	Resolved
	2		Abdominal pain	Week 4	Mild	Medication	Unlikely	1 day	Resolved
	3		Muscle strain	Week 5	Mild	Medication	None	1 day	Resolved
	4		Aches from exercise	Week 8	Moderate	Medication	None	1 day	Resolved
	5		Headache	Week 12	Moderate	Medication	Unlikely	1 day	Resolved
005	1	10	Chipped tooth	Week 2	Moderate	Medication	None	1 day	Resolved
	2		Hay fever	Week 5	Moderate	Medication	None		Persists
	3		Pyrexia	Week 9	Mild	Medication	None	1 day	Resolved
	4		Cut hand	Week 10	Moderate	Medication	None	1 day	Resolved
006	1	6	Abdominal pain	Week 8	Moderate	Medication	None	1 day	Resolved
	2			Week 9	Moderate	Medication	None	1 day	Resolved
	3			Week 10	Moderate	Medication	None	1 day	Resolved
011	1	7	Joint injury	Week 6	Severe	Medication	None	45 days	Resolved
017	1	7	Diarrhoea	Week 9	Moderate	None	None	3 days	Resolved
027	1	7	Hair brittle - breaking	Week 3	Mild	None	Possible	44 days	Resolved
029	1	9	Skin infection	Week 8	Moderate	Medication	None	12 days	Resolved
034	1	8	Tonsillitis	Week 6	Moderate	Medication	None	7 days	Resolved

Adverse events listed by treatment group									
A then B continued									
Participant	AE no	Participant age	Adverse event	Week reported	Severity	Action taken	Relationship to study product	Duration	Outcome
036	1	5	Vomiting	Week 10	Mild	None	None	4 days	Resolved
045	1	7	Vomiting	Week 3	Mild	None	Unlikely	1 day	Resolved
	2		Cough	Week 4	Mild	None	Unlikely	4 days	Resolved
046	1	6	Rash on neck	Week 0	Mild	None	Possible	2 days	Resolved
050	1	7	Joint injury	Week 8	Moderate	Outpatient referral	None	24 days	Resolved
053	1	10	Bruising when hit in orbit by a stick	Week 7	Mild	None	None	8 days	Resolved
054	1	5	Nasopharyngitis with sticky eyes	Week 3	Mild	Medication	None	2 days	Resolved
	2		Joint injury	Week 7	Mild	Medication	None	2 days	Resolved
062	1	5	Diarrhoea and vomiting	Week 0	Severe	None	None	5 days	Resolved
	2		Blister on heel	Week 4	Moderate	None	None	13 days	Resolved
069	1	5	Pyrexia	Week 4	Moderate	Medication	None	1 day	Resolved
B then A									
004	1	4	Insect bites	Week 9	Moderate	Medication	None	1 day	Resolved
009	1	9	Hay fever affecting eyes	Week 2	Mild	Medication	None		Persists
	2		Headache	Week 7	Mild	Medication	None	1 day	Resolved
	3		Nasopharyngitis	Week 10	Mild	Medication	None	1 day	Resolved
014	1	10	Cut on abdomen	Week 6	Mild	Medication	None	2 days	Resolved

<b>Adverse events listed by treatment group</b>									
<b>B then A continued</b>									
Participant	AE no	Participant age	Adverse event	Week reported	Severity	Action taken	Relationship to study product	Duration	Outcome
019	1	15	Rash on abdomen	Week 1	Mild	Study product stopped	Unlikely	2 days	Resolved
023	1	7	Itchy scalp	Week 1	Mild	None	Possible	1 day	Resolved
	2		Joint injury	Week 5	Severe	None	None	6 days	Resolved
028	1	6	Pyrexia	Week 7	Moderate	None	None	1 day	Resolved
	2		Tonsillitis	Week 9	Moderate	Medication	None	11 days	Resolved
031	1	9	Joint injury	Week 8	Severe	None	None	7 days	Resolved
033	1	10	Bruising from punch in face	Week 7	Mild	None	None	8 days	Resolved
035	1	5	Migraine and vomiting	Week 1	Severe	Medication	None	3 days	Resolved
	2		Abdominal pain	Week 7	Moderate	Medication	None	4 days	Resolved
039	1	6	Vomiting	Week 4	Severe	None	None	1 day	Resolved
	2		Blisters on heels	Week 10	Mild	None	None	7 days	Resolved
041	1	9	Ear discomfort	Week 1	Mild	None	Possible	3 days	Resolved
	2		Rash around hairline	Week 1	Mild	None	Possible	5 days	Resolved
	3		Ear discomfort	Week 5	Mild	None	Possible	2 days	Resolved
042	1	8	Nausea and vomiting	Week 6	Severe	None	None	1 day	Resolved
	2		Flaky scalp	Week6/7	Mild	None	Probable	4 days	Resolved
047	1	11	Constipation	Week 1	Severe	None	None	2 days	Resolved
	2		Nasopharyngitis	Week 2	Severe	Medication	Unlikely	5 days	Resolved

Adverse events listed by treatment group									
B then A continued									
Participant	AE no	Participant age	Adverse event	Week reported	Severity	Action taken	Relationship to study product	Duration	Outcome
052	1	5	Pyrexia and nausea	Week 6	Severe	Medication	Unlikely	3 days	Resolved
058	1	7	Itch and rash on neck	Week 0	Mild	None	Possible	1 day	Resolved
063	1	6	Nasopharyngitis	Week 9	Mild	Medication	None	4 days	Resolved
065	1	8	Vomiting	Week 10	Severe	None	None	2 days	Resolved
066	1	5	Pyrexia	Week 1	Mild	None	None	1 day	Resolved
	2		Fell of chair	Week 10	Mild	None	None	1 minute	Resolved
068	1	6	Motion sickness	Week 1	Mild	Medication	Unlikely	1 day	Resolved
	2		Swollen eyes and neck after shampooing	Week 2	Severe	Medication	Possible	1 day	Resolved
070	1	7	Rash on face, arms, legs, back	Week 5	Moderate	Study product stopped	Possible	10 days	Persists