

Clinical Summary: HALT Study of the Nit Happens Complete Lice Treatment Kit

An open-label, single-arm, IRB-approved study of a pesticide-free head lice treatment kit in 26 children and adults with active infestations. Investigators: Maria Elena Villar and Susan Rubio Rivera. Homestead, Florida, October 2020. The study was commissioned by Arbor Development (Mike Hatten), developer and licensor of the formulation, and reported on December 3, 2020. This summary, version 2 (October 2026), was prepared by Cartwheel (FreezeNit, Inc.), the licensee that manufactures and sells the kit as Nit Happens. The full report is archived with this summary at the DOI below.

Key results at a glance

Outcome	Result	Count
Lice free at Day 8 after a single application	54%	14 of 26
Lice free at Day 15, intent to treat (all enrolled participants)	89%	23 of 26
Lice free at Day 15, per protocol (two participants with likely re-infestation between visits excluded)	95.8%	23 of 24
Adverse events reported	None	0 of 26
Participants who needed a second application on Day 8	46%	12 of 26
Mean time for the first application, including comb-out	About 47.5 minutes	

The intent to treat figure (89%) counts every participant who enrolled and is the primary result. The per protocol figure (95.8%) excludes two participants judged by the investigators to have been re-exposed to lice between visits. Both figures are reported so that readers can weigh them.

Study design

- **Type:** open-label, single-arm, real-world effectiveness and tolerability study. No comparator or placebo arm.
- **Ethics:** protocol approved by IntegReview IRB (Austin, Texas), an independent institutional review board. Written informed consent was obtained from adult participants and from parents or guardians of children.
- **Site and dates:** a community center in Homestead, Florida. Day 1 on October 10 and 11, 2020; Day 8 on October 17; Day 15 on October 24. Participants were recruited by word of mouth through MUJER, a local community organization.
- **Participants:** 26 people with at least three live lice at enrollment and no pediculicide use in the prior two weeks; eligible ages 3 to 70. 23 were children aged 3 to 17 (88%); 3 were adults. At baseline 82% had mild live lice counts (1 to 5) and 63% had moderate or severe nit loads.

- **Intervention:** the kit tested under the study name H.A.L.T. Lice Treatment Kit (treatment gel, removal gel, applicator brush, metal lice comb), the formulation now sold as the Nit Happens Complete Lice Treatment Kit, applied by study staff per label: gel on wet hair, 10 minute wait, sectioned brushing for 15 to 30 minutes depending on hair length, 10 minute wait, removal wash, neutral shampoo and comb out. One application on Day 1; the 12 participants with live lice on Day 8 received a second application. Mean application time 47.5 minutes (range 33 to 56) for the first treatment and 50.0 minutes for the second.
- **Visits:** Day 1 (enrollment and first treatment), Day 8 (assessment, optional second treatment), Day 15 (final assessment).
- **Primary outcome:** absence of live lice on examination at Day 8 and Day 15.
- **Safety:** adverse events recorded at each visit.

How the kit works

Nit Happens is an FDA Class I medical device kit. The treatment gel contains coconut oil, trihydroxystearin, limonene, hydrogenated methyl abietate, walnut shells, jojoba oil, diatomaceous earth, tea tree oil, argan oil, tocopherol and glycerin. It acts physically rather than chemically: the mild abrasives in the gel, worked gently through sectioned hair with the applicator brush, damage the outer shell of lice and loosen the glue that holds nits to the hair shaft. The gel is washed out with the removal shampoo and remaining lice and nits are combed out with the metal comb. Because no insecticide is involved, the pyrethroid resistance now found in most US head lice populations does not apply.

The kit contains no pesticides and no parabens. It is labeled for ages 3 and up; the label states it is not for children under 3 years. Full directions, warnings and ingredient lists are in the printed Instructions for Use and at gocartwheel.com/pages/nit-happens-instructions-for-use.

Skin tolerance

In a separate dermatologist-controlled 48-hour patch test conducted by Evalulab (study 20H-0224-34), the treatment gel was applied to the skin of 27 healthy adult volunteers. No reactions were recorded and the gel was classified as non-irritant. This test evaluates skin tolerance only and is not a measure of effectiveness against lice.

Limitations

- Small sample (26 participants) at a single site.
- Open-label and single-arm: no randomization, blinding or comparison product, so results cannot be used to claim superiority over other treatments.
- Commissioned by the formulation's developer and licensor (Arbor Development), and this summary was prepared by the licensee and manufacturer (Cartwheel). The investigators' report also contains a small internal inconsistency: the text says 14 participants were treated a second time while its treatment-time table and the conclusions give 12; this summary uses 12.
- The study was not registered on a clinical trial registry at the time it was run and has not been peer reviewed. Registration and publication are in progress as of October 2026.

- The per protocol analysis depends on the investigators' judgment that two participants were re-infested rather than treatment failures.

What this summary does not claim

This study shows that, used as directed, the kit cleared lice in most participants within 15 days with no adverse events. It does not show that the kit is more effective than permethrin, ivermectin, spinosad, dimethicone, heated air or wet combing, none of which were tested alongside it. Earlier versions of this summary rounded the per protocol result to 96%; the exact figure is 95.8% (23 of 24).

Suggested citation

Villar ME, Rubio Rivera S. HALT study: open-label evaluation of the Nit Happens Complete Lice Treatment Kit in 26 participants with active head lice infestation. Final clinical report prepared for Arbor Development, December 3, 2020; Homestead, FL. Clinical summary v2, October 2026. DOI: 10.5281/zenodo.23510395 (<https://doi.org/10.5281/zenodo.23510395>). Also available at <https://gocartwheel.com/pages/clinical-evidence> and <https://licetreatments.org/assets/nit-happens-halt-clinical-summary-2026.pdf>

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This document is a plain-language summary prepared by the manufacturer for consumers, clinicians and health publishers. It is not medical advice. Head lice infestation should be confirmed by finding a live louse before any treatment is used.