

Bare® Air-free Feeding System Mitigates Gas & Acid Reflux Symptoms in Infants

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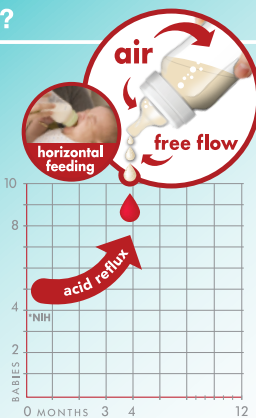
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PEDIATRIC FEEDING DISORDERS

- Feeding disorders are defined as a persistent disturbance of eating or eating-related behaviors, which prevents the appropriate consumption or absorption of food, in turn, significantly impairing physical health and psychosocial functioning¹
- Recent studies demonstrate pediatric feeding disorders affect 20-50% of normally developing children and up to 70-89% of children with developmental disorders²
- When considering the overwhelming evidence suggesting a robust relationship between prolonged feeding difficulties and long-term deficits in cognition, emotional functioning, growth delays, malnutrition, low energy, susceptibility to disease, and death, there is still a major need for the science, technology and the medical field to address the needs of children with feeding difficulties³
- One common feeding discomfort for babies is **acid reflux**.

WHAT IS GER?

- Acid reflux, also known as gastroesophageal reflux (GER), describes the abnormal ascension of hydrochloric acid from the stomach to the esophagus
- GER causes inflammation of the esophageal lining, pyrosis, extreme pain when eating and inconsolable crying in infants
- Research indicates 2/3 of 4-month olds have symptoms of gastroesophageal reflux disease (GERD), which can lead to an acidic taste at the back of the mouth, chest pain, breathing difficulties, speech impediments, tooth decay, esophageal stricture, and Barrett syndrome.⁴
- However, despite overwhelming evidence suggesting a robust relationship between GER and negative health outcomes, there is still a major void in the literature, and the technological market to address the feeding needs of children with acid reflux
- While different groups have developed variations of disposable liners and vented technology to relieve feeding discomfort for infants, clinical observations indicated the persistence of air infiltration into the bottle, leading to gas build-up, pain, and worsening acid reflux upon ingestion.

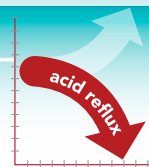


RESEARCH QUESTION

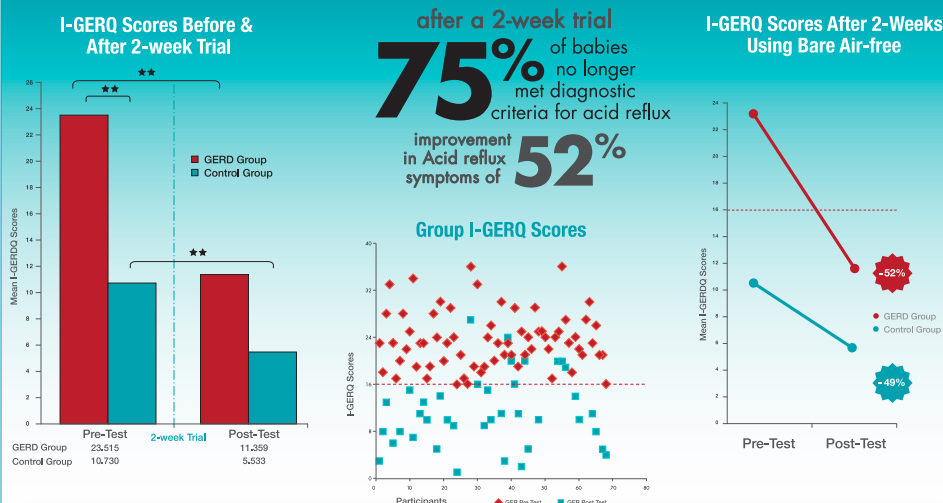
Can new air-free feeding technology such as Bare Air-Free help attenuate GER symptoms in infants with GER symptomology ages 0-18 months?

HYPOTHESIS

We hypothesize that Bare Air-Free will reduce GER symptoms in infants exhibiting GER symptomology ages 0-18 months.

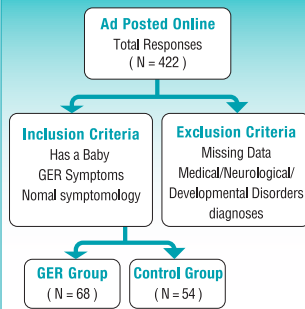


MAIN FINDINGS & CONCLUSION

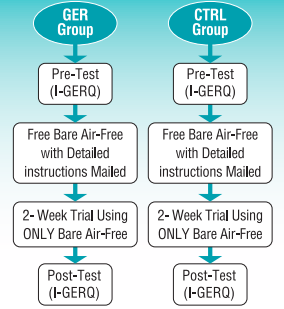


- The use of Bare Air-Free for 2-weeks had a statistically significant effect on GER symptoms in infants
- After two-weeks of using Bare Air-Free **75%** of GER babies scored below the clinical cut off for GER
- Control participants experienced a 49% decrease in GI discomfort after utilizing Bare Air-Free for 2-weeks

PARTICIPANT: RECRUITMENT



CLINICAL STUDY TIMELINE



CLINICAL TABLE

Number of Participants Screened	422
Number of Participants Completed Enrolled	122
Female Babies	56
Male Babies	66
Median Age	0-3 m (75%)
Number of Participants With High Ger Symptoms	68
Number of Healthy Controls	54
Main Caregiver	Mothers (99%)

WHAT IS BARE?



Dispenses **AIR-FREE** milk to prevent gas build up

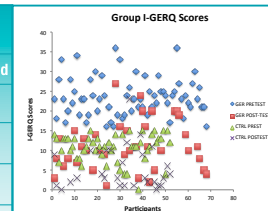
Feeds in **UPRIGHT** position to reduce regurgitation of stomach acids into the mouth



Baby **CONTROLS** the **FLOW/PACE** of feeding to discourage over-feeding behaviors.

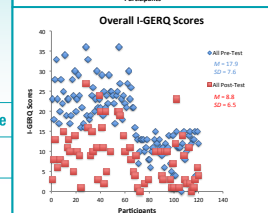
ATTRITION RATE

	Pre-Test	Post-Test	% Retained
GER	68	39	57%
CTRL	54	30	56%
SUM	122	69	57%



SHIFT IN NUMBER OF BABIES MEETING CLINICAL CRITERIA

	Pre-Test	Post-Test	% Change
GER	56%	16%	-40%
CTRL	44%	86%	+42%



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