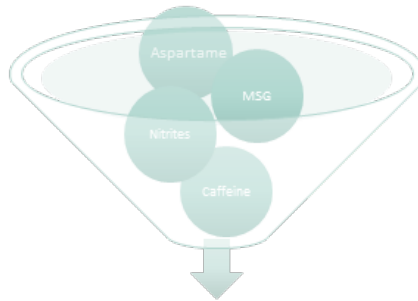


## BACKGROUND

- Chronic recurrent headache (HA) is a significant cause of morbidity in children, with a prevalence of 10% being recorded in 3-14 year olds and evidence of global increase in incidence.
- Dietary factors are considered to play a significant role in the etiology of recurrent HA in adults; however, good data to confirm this statement in the paediatric population is lacking.
- Some food triggers have direct mechanism of provoking a HA, such as caffeine, nitrites and monosodium glutamate (MSG).
- Evidence in adults demonstrates that HAs and other conditions may be secondary to an immunological mechanism mediated by immunoglobulin G (IgG) against certain foods.(1)
- Exclusion of foods based on high serum IgG levels has led to significant reduction of symptoms in adults; however, this has yet to be studied in children.



**Figure 1: Common dietary HA triggers.**  
Previous research has demonstrated certain non-IgG mediated dietary components to be probable triggers for HAs in children and adults.

## STUDY DESIGN AND METHODOLOGY

- DESIGN:** Randomized, controlled, single-centre trial.
- SETTING:** Outpatient tertiary paediatric HA clinic, Children's Hospital, London, Ontario.
- PARTICIPANTS:** 50 children aged 7-15 referred to the HA clinic.
- EXCLUSION CRITERIA:** 1) Children less than 7 years of age. 2) Secondary HA. 3) Concomitant use of complementary and alternative medication. 4) Elective surgery planned for within 24 weeks of the start of the study. 5) Diagnosis of failure-to-thrive. 6) Children with body weight plotting lower than 5<sup>th</sup> centile on a growth chart. 7) Medical conditions that in the opinion of the PI would be unsafe for trial participation. 8) Lack of follow-up or failure to comply with study procedures.
- METHODOLOGY:**
  - Patients are randomized to either conventional or dietary intervention group in the ratio of 1:1.
  - Conventional group receive standard treatment for HA. Dietary intervention group receive targeted dietary elimination advice based on serum IgG positivity and/or non-IgG foods, based on frequency of consumption from their food diary.
  - Only 1 IgG- positive food is eliminated in each 6-week visit. Handouts are given to provide alternative recipe ideas. In non-reactive patients, non-IgG foods (e.g. caffeine, MSG) are eliminated.
  - Patients are followed up at 6-weekly intervals for a total of 5 study visits (24 weeks). Non-responders in each group are crossed over to the other arm of the study. Food and HA diaries are reviewed.
  - IgG levels are measured at start and end of study using Food IgG Screen Kits (120 foods) provided by **Cambridge Nutritional Sciences**, and are analyzed using the ELISA technique (2,3).

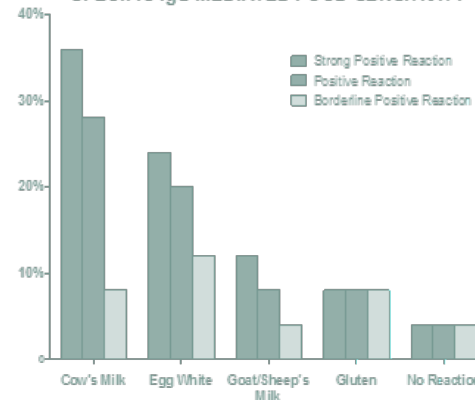
## INTERIM RESULTS

	Conventional Treatment	Dietary Intervention
Recruited	8 (includes 1 crossover patient)	17 (includes 10 crossover patients)
In Progress	4	4
Withdrawn	2	1
Completed	2	12

### Of the 14 completed participants:

- 11 patients in diet group resolved (HA reduction >90%)
- 2 patients in diet group improved (HA reduction by 50-90%)
- 7 patients crossed study arms (6 patients from conventional to dietary and 1 from dietary to conventional due to non-response)
- 1 patient had no food triggers identified and remained in conventional group

## SPECIFIC IgG MEDIATED FOOD SENSITIVITY



**Figure 2: Common IgG mediated food sensitivities.**  
This figure displays centile data on the most common IgG mediated food sensitivities from all patients in the study. Patients often present with several food sensitivities.

## INTERIM RESULTS

Dietary Intervention	IgG Level (%)		Δ
	Before	After	
Cow's Milk	190	106	-84%
Egg White	121	97	-25%
Goat/Sheep Milk	116	54	-62%
Gluten	103	88	-16%

**Table 1: Result of dietary intervention on IgG levels..**  
This table displays the average relative change in IgG levels after eliminating a certain food for the period of the study. Values are represented as a percentage relative to the minimum IgG threshold required to indicate a strong positive reaction.

## DISCUSSION

- Elimination of 1 or 2 foods, based on IgG positivity, has resulted in significant reduction in HA frequency and severity in children.
- This correlates well with a demonstrated reduction in serum IgG levels at the end versus beginning of the study.
- Further investigation is required to clarify the correlation between IgG-mediated food sensitivity and primary HA in children.
- We await the conclusion of this study to publish our final results.

## REFERENCES

- Baykal B, Alpay KEM, Orhan EK. Diet restriction in migraine based on IgG antibodies against food antigens: A clinical double-blind, randomized crossover trial. Neurology. 2009 Abstract no: P04.070;72(11 Suppl 3):A182.
- The enzyme-linked immunosorbent assay (ELISA). (1976). Bulletin of the World Health Organization, 54(2), 129-139.
- We acknowledge Dr Nigel Abraham of **Cambridge Nutritional Sciences** for providing the IgG kits and for his valuable advice