

Telephone screen for eligibility expected (n = 200)

Ineligible: expect to exclude (n = 80)
Headache characteristics
Other medical exclusions
No physician
Scheduling difficulties

First confirmation of eligibility (n = 120)

Baseline study visit with neurologist (PI)
Consent for study, begin baseline diary collection
Baseline instruments (HIT-6, SF-12, BSI-18)

Expect to exclude (n = 30)
Headache characteristics
Unstable co-morbid conditions

Second confirmation of eligibility (n = 90)

Baseline diaries reviewed

Expect to exclude (n = 20)
Failure to keep diaries
Headache characteristics
Other intervening problems

Random allocation to one of two diets

Expect to randomize (n = 70)

Baseline blood fatty acid acids and metabolic biomarkers
Pre-intervention Instruments (HIT-6, SF-12, MIDAS, BSI-18)
Baseline dietary intake assessment

Low n-6 diet

Dietary counseling Q2 wks
Study foods supplied Q2 wks
Daily Headache Diary
Dietary adherence assessments

Week 4 blood collection

Week 8 blood collection

Post-intervention assessment

Week 12 blood collection
Dietary assessment; HIT-6, MIDAS, SF-12, BSI-18
Nutritional/metabolic biomarker analyses
Expected withdrawal = 3

ITT analysis of data

Expected n = 32

Low n-6, high n-3 diet

Dietary counseling Q2 wks
Study foods supplied Q2 wks
Daily Headache Diary
Dietary adherence assessments

Week 4 blood collection

Week 8 blood collection

Post-intervention assessment

Week 12 blood collection
Dietary assessment; HIT-6, MIDAS, SF-12, BSI-18
Nutritional/metabolic biomarker analyses
Expected withdrawal = 3

ITT analysis of data

Expected n = 32