**SDC 1: Detailed Inclusion and Exclusion Criteria**

Table adapted from Healthcare 2019: Kaplan HC, Opipari-Arrigan L, Schmid CH, Schuler CL, Saeed S, Braly KL, Burgis JC, Nguyen K, Pilley S, Stone J, Woodward G, Suskind DL. Evaluating the Comparative Effectiveness of Two Diets in Pediatric Inflammatory Bowel Disease: A Study Protocol for a Series of N-of-1 Trials. Healthcare. 2019; 7(4):129.

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| **Inclusion Criteria** | **Exclusion Criteria** |
| * Diagnosis of CD or UC or indeterminate colitis (IC)
* Age 7-18 years
* Enrolled in the ICN2 registry
* Evidence of acute inflammation and/or elevated acute phase reactant within 8 weeks of study enrollment (one of the following):
* Fecal calprotectin: 1.5X the upper limit of normal, *or*
* Lactoferrin: 1.5X the upper limit of normal, *or*
* CRP: 1.15X the upper limit of normal, *or*
* ESR: 1.15X the upper limit of normal
 | * Complex or unstable IBD
* Current or past (9 months) history of abscess, fistula, structuring CD or ostomy
* Severe disease activity
* Hospitalization or surgery planned within 3 months
* Ongoing active gastrointestinal infection
* Severe Malnutrition
* Recent Medication changes\*
 | * Other complicating medical issues
* Other serious medical conditions
* Serious psychological or psychiatric conditions
* Pregnancy
* Tobacco, alcohol, illicit drug use
* Inability to complete the protocol
* Non-English speaking
* On SCD/MSCD within 8 weeks of the study
* On a vegan diet
* Lack of smart phone and data plan
* Participating in another interventional study
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Abbreviations: CD – Crohn’s Disease, IC – Indeterminate Colitis, ICN – ImproveCareNow, MSCD – Modified Specific Carbohydrate Diet, SCD – Specific Carbohydrate Diet, UC – Ulcerative Colitis

\* The goal of ensuring that the patient is stable on medications is to ensure that any changes in symptoms or inflammation seen during the study are attributable to the diet, and not to the effects of the recent medication changes (new start of medications or increased doses of established medications or increases in dosing frequency). The protocol outlines the time period for most commonly prescribed IBD medications as follows:

* Wait 8 weeks after starting/increasing thiopurines, natalizumab, methotrexate, or anti TNF (infliximab, adalimumab).
* Wait 16 weeks after starting vedolizumab
* Wait 4 weeks after starting/increasing corticosteroids AND until the patient is on a dose of <20 mg prednisone or equivalent
* Wait 4 weeks after starting/increasing mesalamine
* Wait 8 weeks after starting Stelara (ustekinumab).
* Wait 4 weeks after starting/increasing cyproheptadine (an antihistamine to help with abdominal pain).
* Wait 4 weeks after starting/increasing budesonide (Entocort/Uceris) AND until the patient is receiving a dose of 9 mg given at a frequency of no more than every other day (average dose of 4.5 mg/day)

**The following are changes to inclusion/exclusion criteria made during the course of the study to increase the eligible patient population due to slow enrollment and/or clarify criteria based on difficulty in interpretation by study sites:**

* Modified exclusion criteria to exclude individuals participating in another interventional study because the other study’s procedures could affect the results of the individual N-of-1 study if a participant was exposed to an intervention at different times in the N-of-1 protocol
* Added the lab test lactoferrin as an option for establishing evidence of active inflammation for study inclusion
* Changed exclusion criteria from a BMI in the 10th percentile to the 5th percentile
* Changed inclusion criteria from “Past or present history of intra-abdominal abscess, fistula, stricturing CD, or ostomy” to “Currently or within the past 9 months has had an intra-abdominal abscess, fistula, stricturing CD, or ostomy”
* Added the exclusion criteria “Ever had history of full colectomy”
* Changed the inflammation criteria for the study to include evidence of acute inflammation and/or elevated acute phase reactant as measured by Fecal calprotectin 1.5 (formerly 2) times the upper limit of normal, Lactoferrin 1.5 (formerly 2) times the upper limit of normal, CRP 1,15 (formerly 1.25) times the upper limit of normal, or ESR 1.15 (formerly 1.25) times the upper limit of normal (based on local reference ranges) obtained within 8 weeks of enrollment
* Changed the inclusion/exclusion criteria to allow for including patients that are already on the SCD or modified SCD but are not compliant with the diet per the site dietitian or primary GI physician.
* Removed “Mild to moderate disease activity as measured by a short Pediatric Crohn’s Disease Activity Index (SPCDAI) score of 15-45 or Pediatric Ulcerative Colitis Activity Index (PUCAI) score of 10-60 assessed within 3 weeks of enrollment” from inclusion criteria and added “Severe disease activity as measured by a short Pediatric Crohn’s Disease Activity Index (SPCDAI) score of >45 or Pediatric Ulcerative Colitis Activity Index (PUCAI) score of >60 assessed within 3 weeks of enrollment” to the exclusion criteria.
* Changed inclusion criteria from 7-17 years to 7-18 years