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CROHN'S DISEASE EXCLUSION DIET (CDED) FOR TREATMENT OF INFLAMMATORY BOWEL DISEASE (IBD)

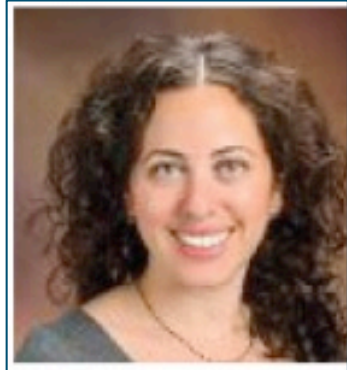


Moderator

Sandra Kim, MD

Associate Professor of Pediatrics and Director,
Inflammatory Bowel Disease Center
UPMC Children's Hospital of Pittsburgh

PRESENTING FACULTY



Lindsey Albenberg, DO

Center for Pediatric Inflammatory Bowel Disease
Assistant Professor of Pediatrics
Children's Hospital of Philadelphia



Jennifer Smith, MS, RD, CSP, LD, LMT

Clinical Dietitian
Nationwide Children's Hospital



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DISCLOSURES

- The content of this program has met the continuing education criteria of being evidence-based, fair and balanced, and non-promotional
- This educational event is supported by Abbott Nutrition Health Institute, Abbott Nutrition
- Faculty received an honorarium from Abbott Nutrition



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OBJECTIVES

- Describe the International Organization for the Study of Inflammatory Bowel Diseases' expert opinion on dietary guidance for inflammatory bowel diseases
- Identify allowed and disallowed foods from each food group and dietary components and food additives selected as the most important to address with patients
- Discuss implementation of the Crohn's Disease Exclusion Diet (CDED) with patients in clinical practice



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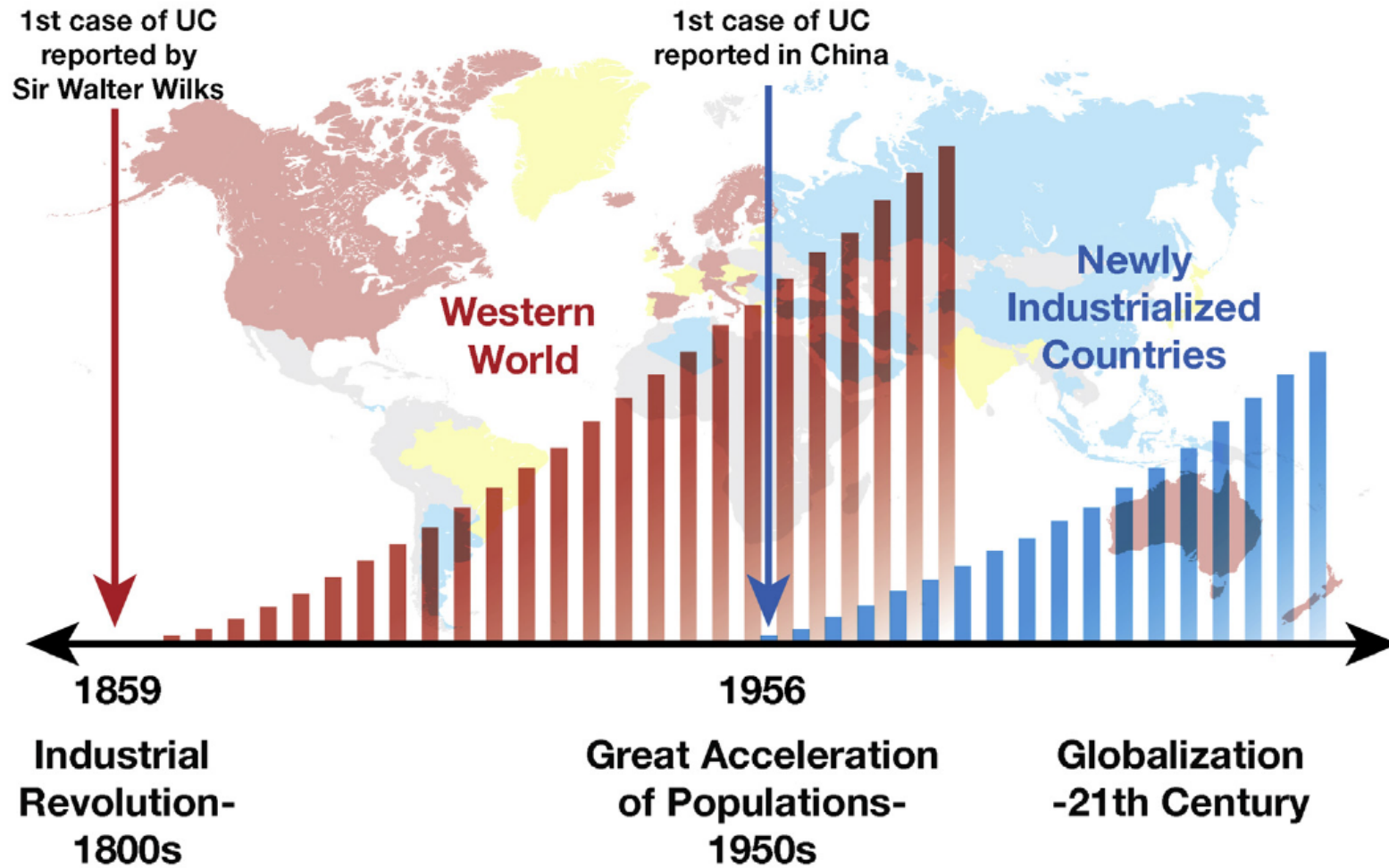


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THE IBD EPIDEMIC



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Kaplan GG, et al. *Gastroenterology*. 2017;152(2):313-321.e2.



GLOBAL BURDEN OF IBD: PREDICTION IN 2025

- IBD is a global disease
- ~5 million affected worldwide
- Prevalence in the Western World 0.5%
- Rate in the rise of incidence is steep in ***newly industrialized countries and in adolescents in industrialized countries***
- The number of patients with IBD in newly industrialized countries might approximate that in the Western world by 2025 owing to rising prevalence and rapidly growing populations



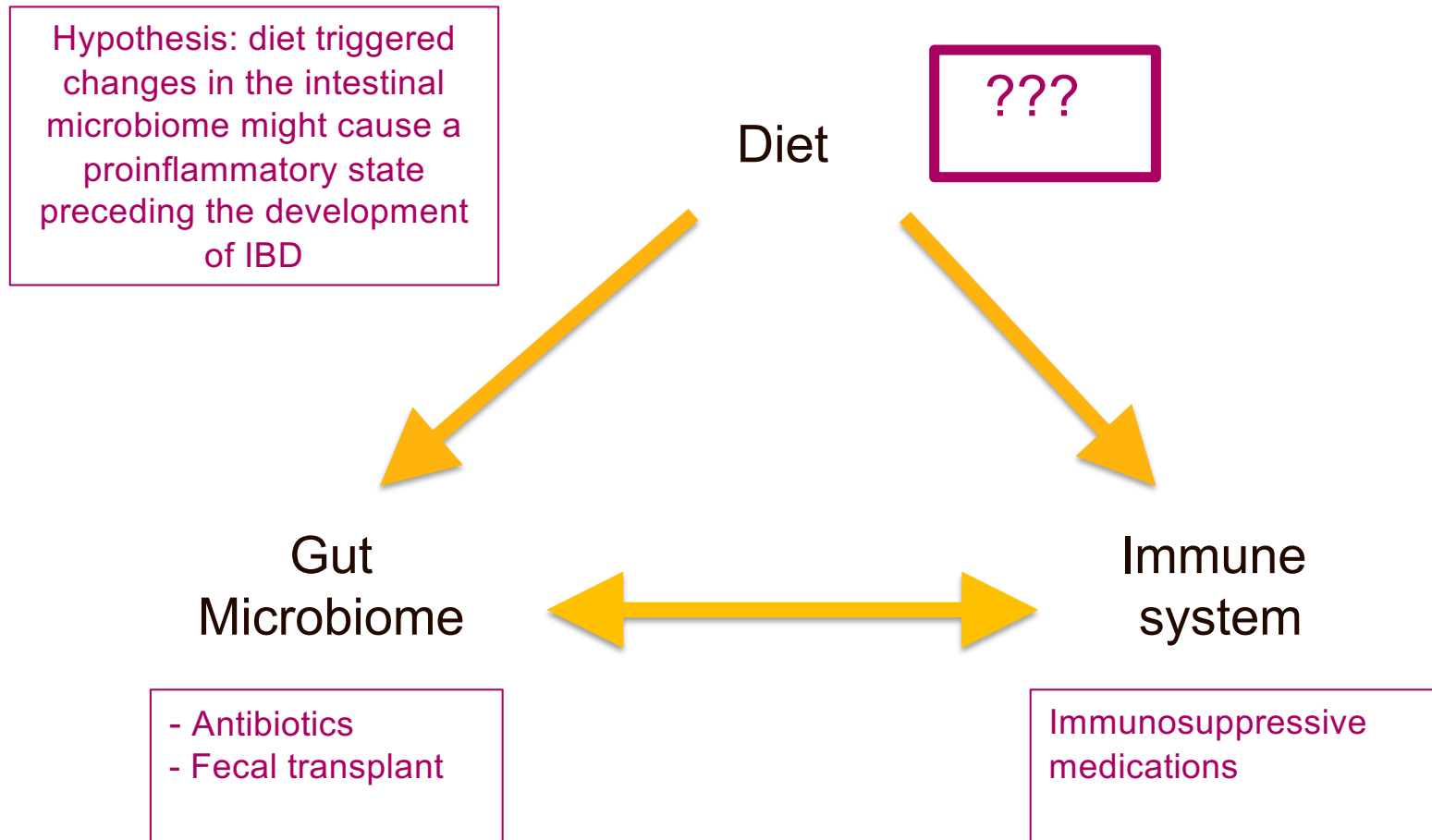
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Kaplan GG. *Nat Rev Gastroenterol Hepatol.* 2015;12(12):720-727.



TARGETS IN IBD PATHOGENESIS



WHY DO WE NEED DIETARY THERAPIES FOR IBD?

- Science tells us that something in the lumen of the gut is driving inflammation
- Our patients want to know what they should eat and the information on the internet is not consistent and not evidence based
 - Our patients are already changing their diets
- Even our best therapies are not effective in all patients and they are associated with risks

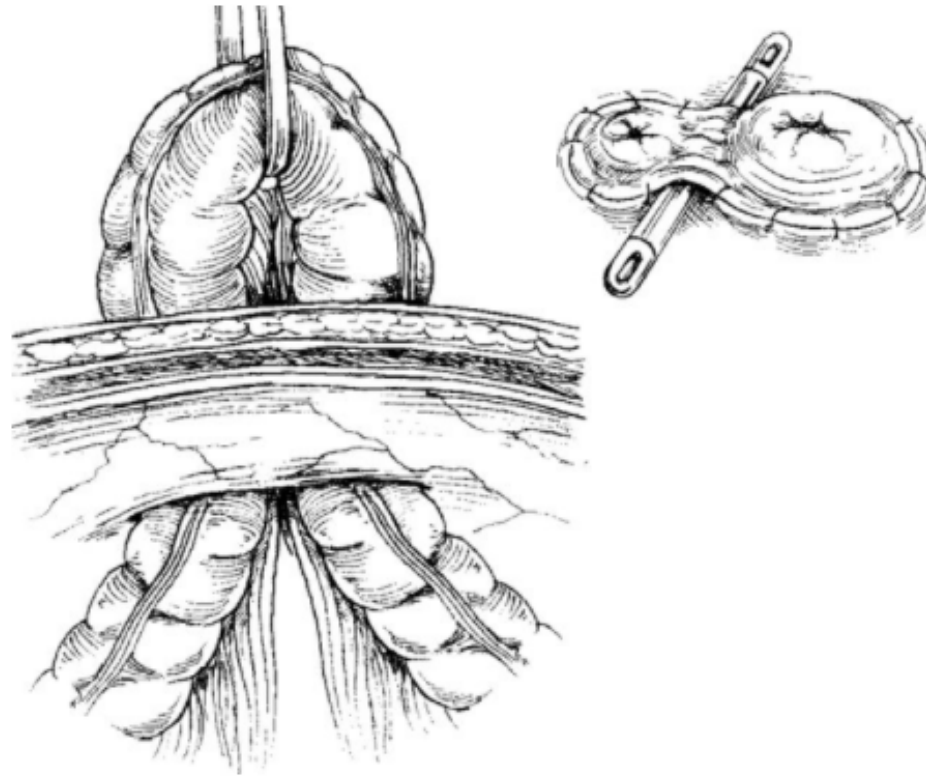


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CROHN'S DISEASE SURGERY: AN EXPERIMENTAL MODEL

- We have known for 20 years that diversion of the fecal stream is a treatment for some patients with Crohn's Disease



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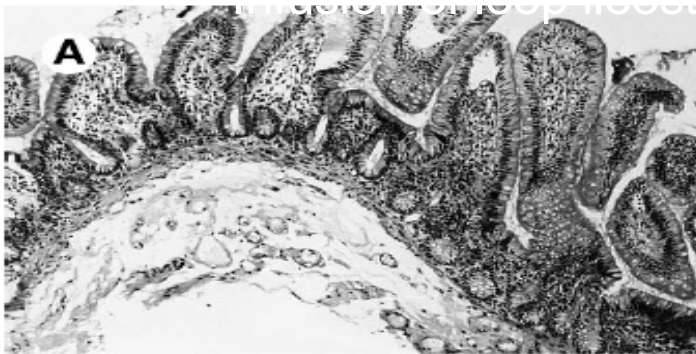


D'Haens GR, et al. *Gastroenterology*. 1998;114(2):262-267.
Brand MI, Dujovny N. *Clin Colon Rectal Surg*. 2008;21(1):5-16.

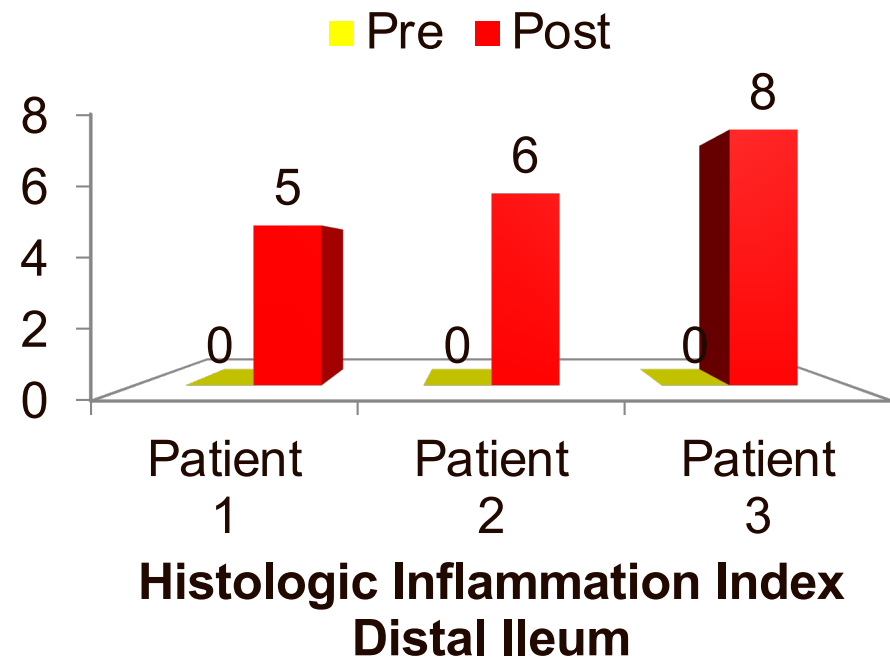


FECAL DIVERSION HEALS ILEAL MUCOSA EXPOSURE TO ILEAL CONTENTS LEAD TO INFLAMMATION

Prior to
infusion
of ileal
contents



Following
infusion
of ileal
contents



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D'Haens GR, et al. *Gastroenterology*. 1998;114(2):262-267.



DIET IS ASSOCIATED WITH NEW ONSET IBD

- High dietary intakes of total fats, PUFAs, omega-6 and meat were associated with an increased risk of CD and UC
- High fiber and fruit intakes were associated with decreased CD risk
- High vegetable intake was associated with decreased UC risk



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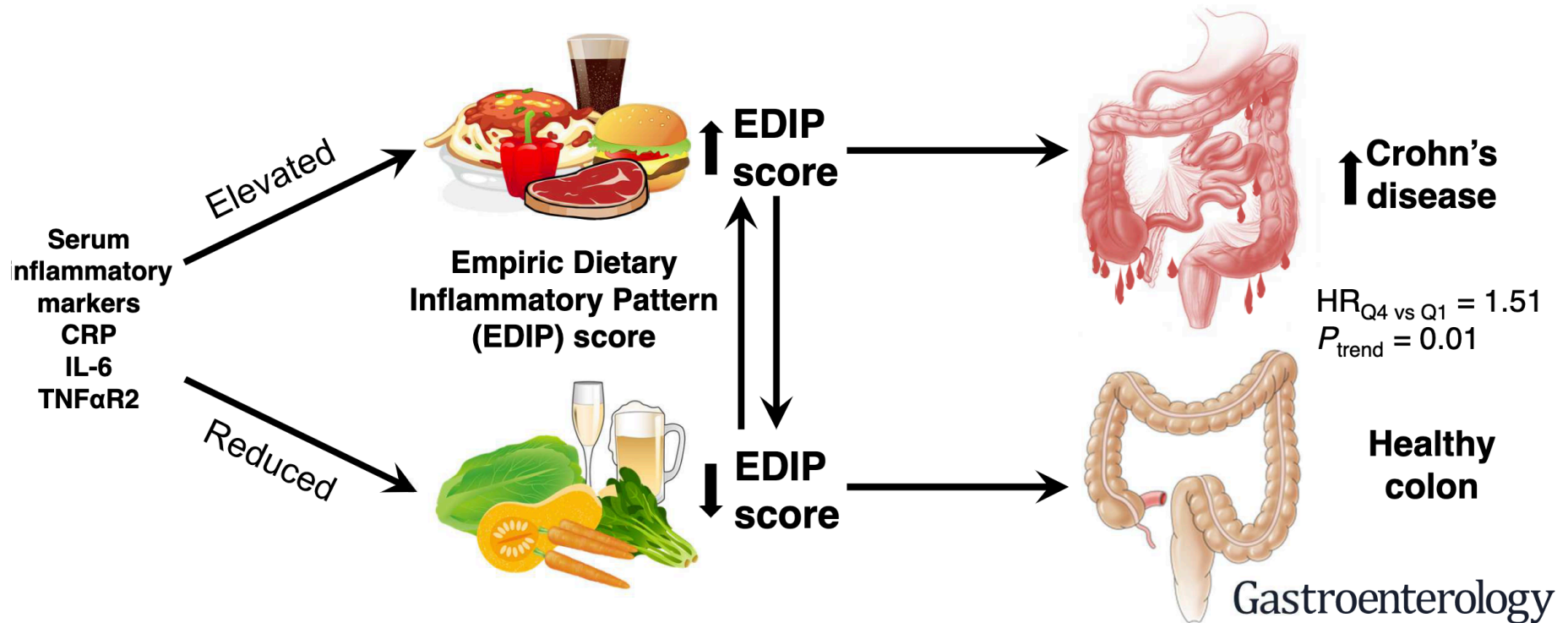


Hou JK, et al. *Am J Gastroenterol.* 2011;106(4):563-573.

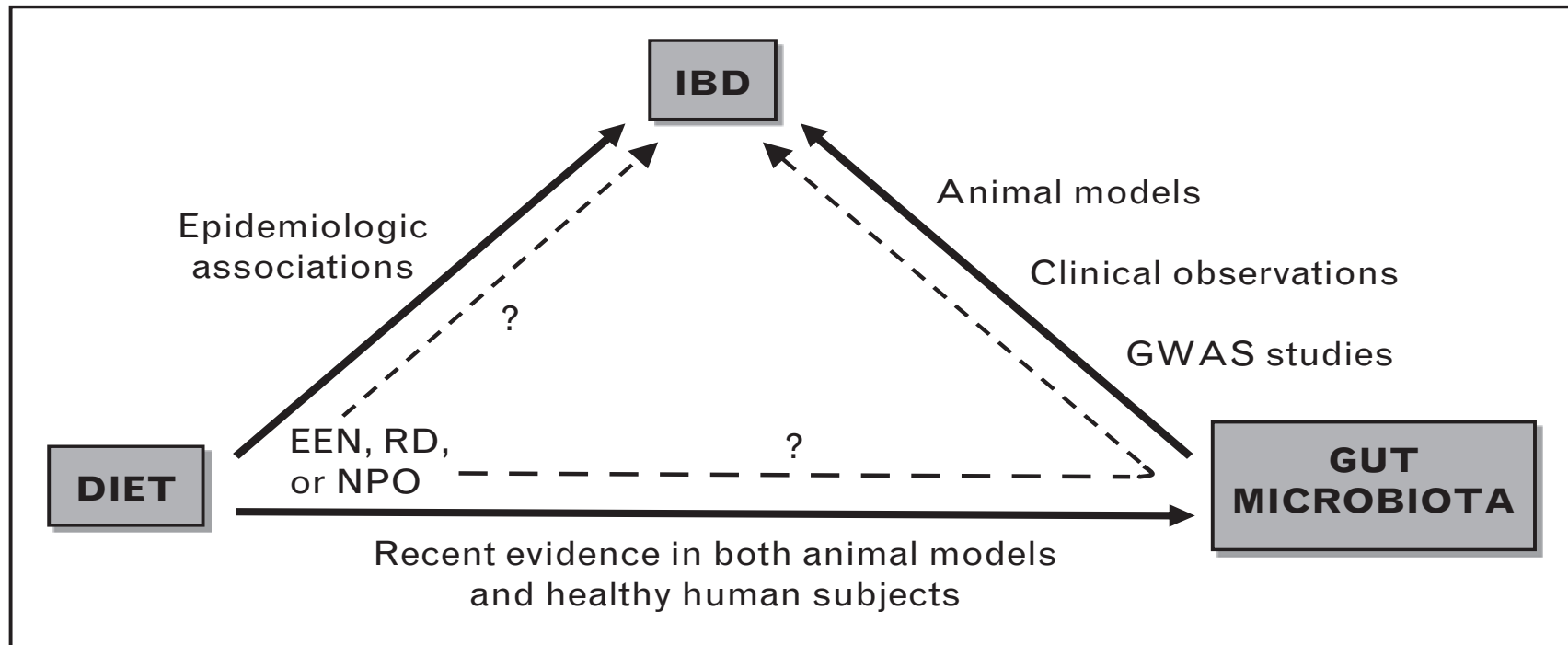
PUFAs- Polyunsaturated Fatty Acids
CD- Crohn's Disease
UC- Ulcerative Colitis



DIETARY INFLAMMATORY POTENTIAL ASSOCIATED WITH INCREASED RISK OF CD



IS THERE A RELATIONSHIP BETWEEN DIET, THE GUT MICROBIOTA, AND IBD?



PATIENT-REPORTED FOODS THAT IMPROVE/ WORSEEN SYMPTOMS

Food Items	CD (n=1121)	UC (n=597)	CD-O (n=405)	UC-P (n=206)
	(B, W)	(B, W)	(B, W)	(B, W)
Improved Symptoms				
Yogurt	108, 7*	54, 3*	26, 0*	19, 0*
Rice	59, 3*	30, 3*	20, 3†	16, 0*
Bananas	NR	NR	NR	14, 0*
Worsened Symptoms				
Non-Leafy Vegetables	28, 221*	29, 81*	7, 90*	3, 36*
Spicy Foods	1, 145*	3, 79*	0, 46*	0, 33*
Fruit	50, 136*	40, 63	22, 51†	15, 24
Nuts	3, 120*	1, 33*	0, 52*	0, 21*
Leafy Vegetables	6, 115*	2, 50*	2, 29*	1, 14†
Fried Foods	0, 105*	0, 53*	0, 22*	0, 11†
Milk	6, 105*	0, 49*	5, 28*	2, 14†
Red Meat	6, 103*	7, 47*	2, 24*	NR
Soda	11, 99*	0, 46*	0, 33*	0, 28*
Popcorn	2, 97*	NR	0, 27*	0, 18*
Dairy	3, 94*	1, 56*	NR	0, 12†
Alcohol	0, 90*	0, 54*	NR	0, 23*
High Fiber	19, 87*	19, 35†	7, 46*	NR
Corn	0, 77*	0, 31*	0, 29*	NR
Fatty Foods	0, 62*	NR	NR	NR
Seeds	NR	NR	0, 22*	NR
Coffee	NR	4, 37*	NR	NR
Beans	NR	5, 30*	NR	NR

P values from the sign test. Bonferroni method $p < 0.00039$ (i.e., $0.05/127$) identified with an asterisk (*).



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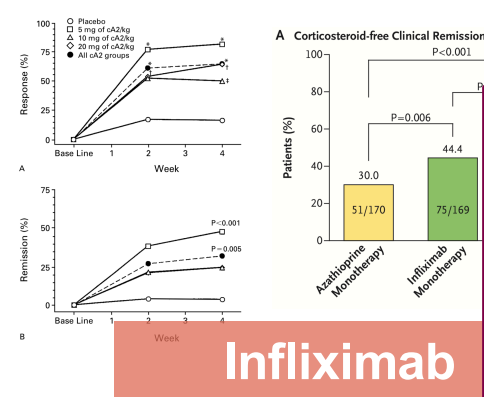


Cohen AB, et al. *Dig Dis Sci.*
2013;58(5):1322-1328.

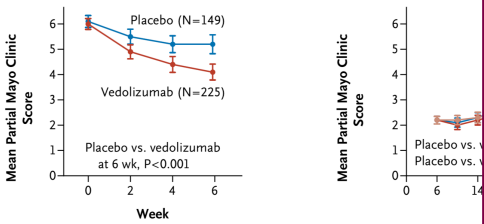
O- Ostomy
P- Pouch



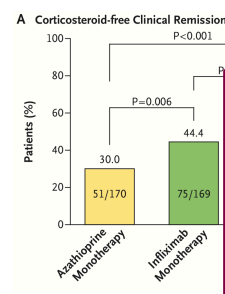
BIOLOGIC AND SMALL MOLECULE THERAPIES IN THE LAST 2 DECADES



SONIC
Targan et al, NEJM 1997 Colombel et al, NE



GEMINI
Feagan et al, NEJM 2013



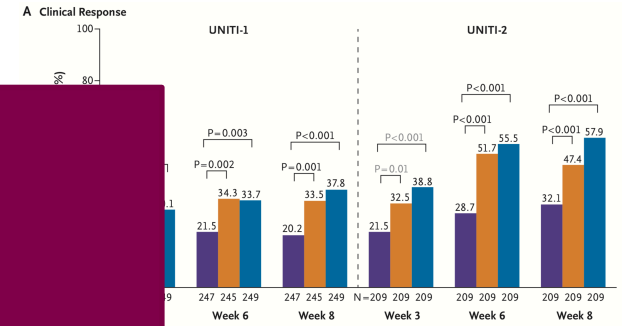
50-60% clinical responders to induction treatment

15% endoscopic & histologic remission

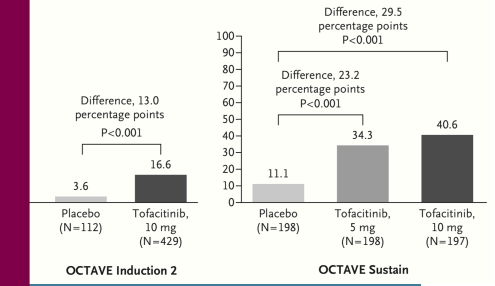
Loss of response 15% per year

100% recurrence of disease sometime after treatment stop

GEMINI
Sandborn et al, NEJM 2013



UNITI
Feagan et al, NEJM 2016



Tofacitinib

OCTAVE
Sandborn et al, NEJM 2017



1) Targan SR, et al. *N Engl J Med.* 1997;337(15):1029-1035; 2) Colombel JF, et al. *N Engl J Med.* 2010;362(15):1383-1395; 3) Colombel JF, et al. *Lancet.* 2018;390(10114):2779-2789; 4) Sandborn WJ, et al. *Gastroenterology.* 2014;146(1):85-e15; 5) Feagan BG, et al. *N Engl J Med.* 2016;375(20):1946-1960; 6) Feagan BG, et al. *N Engl J Med.* 2013;369(8):699-710; 7) Sandborn WJ, et al. *N Engl J Med.* 2013;369(8):711-721; 8) Sandborn WJ, et al. *N Engl J Med.* 2017;376(18):1723-1736.



SAFETY CONCERNS...

Table 3. Absolute Risk of Cancer in Patients With IBD, and Adjusted Ratio of Cancer in Patients With IBD Exposed to Thiopurines and/or Anti-TNF Agents, Compared With Patients Not Exposed to Immunosuppressive Drugs

	Incidence rate (cases per 1000 person-years) in total IBD population	Adjusted RR (95% CI), HR (95% CI), or OR (95% CI) in patients with IBD exposed to immunosuppressive therapy versus those not exposed to immunosuppressive therapy		
		Thiopurines alone	Anti-TNF agents alone	Thiopurines in combination with anti-TNF agents
All cancers, excluding nonmelanocytic skin cancers	7.3 ^a	RR, 1.4 (1.2–1.7) ^b	RR, 1.1 (0.9–1.4) ^a	ND
Hematologic malignancies				
All	0.5 ^a	ND	RR, 0.9 (0.4–1.9) ^a	ND
Lymphoma ^b	0.3 ^c	HR, 2.6 (2.0–3.4) ^c	HR, 2.4 (1.6–3.6) ^c	HR, 6.1 (1.3–4.2) ^c
Skin cancers				
Nonmelanocytic Skin cancer	9.1 ^d	OR, 1.9 (1.7–2.1) ^d	OR, 1.1 (0.9–1.4) ^d	ND
Melanoma	0.4 ^a	OR, 1.1 (0.7–1.7) ^d	OR, 1.9 (1.1–3.3) ^d	ND
Urinary tract cancer ^e	0.3 ^a	HR, 2.8 (1.0–7.7) ^e	RR, 1.6 (0.6–4.2) ^a	ND



SAFETY CONCERNS...

Table 3. Absolute Risk of Cancer in Patients with IBD Exposed to Thiopurines

Cancer Type	Relative Risk (95% CI)
All cancers, excluding nonmelanocytic skin cancers	1.4 (1.1-1.8)
Hematologic malignancies	1.8 (1.2-2.8)
All	1.8 (1.2-2.8)
Lymphoma ^b	2.1 (1.2-3.7)
Skin cancers	1.1 (0.8-1.5)
Nonmelanocytic	1.1 (0.8-1.5)
Melanoma	1.1 (0.8-1.5)
Urinary tract cancers	1.1 (0.8-1.5)

^aAdjusted for age, sex, and duration of IBD. ^bIncludes both Hodgkin and non-Hodgkin lymphomas. ^cAdjusted for age, sex, and duration of IBD.

- Patients with IBD exposed to thiopurines exhibit an increased risk of cancers
 - Young patients, particularly males, are at risk of postmononucleosis lymphomas and hepatosplenic T-cell lymphomas
- Patients with IBD exposed to thiopurines exhibit an increased risk of nonmelanocytic skin cancers
- Patients exposed to anti-TNF agents are at increased risk of melanoma
- Whether patients treated with anti-TNF agents alone exhibit an excess risk of lymphoma remains controversial.

WHY DO WE NEED NUTRITION THERAPY IN IBD?

- Because it makes sense!
- Medications have limited efficacy
- Medications are not a cure!
- Safety concerns
- Children with IBD have a lifetime of treatment ahead of them



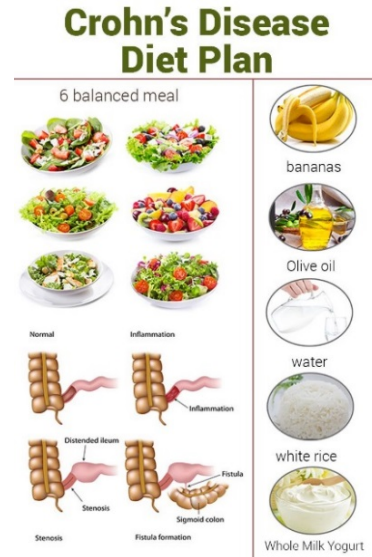
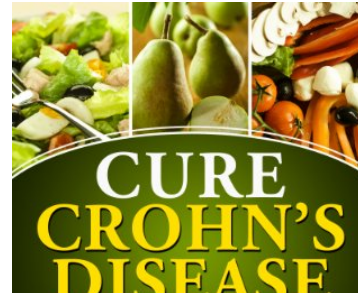
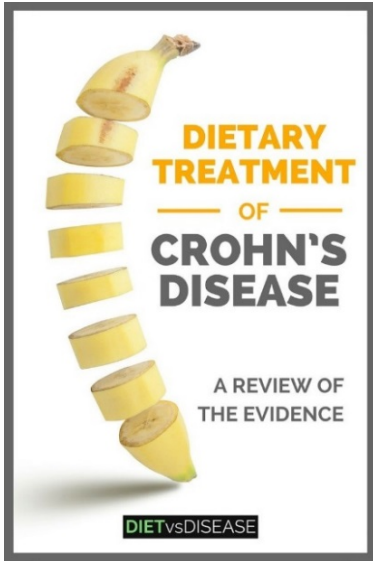
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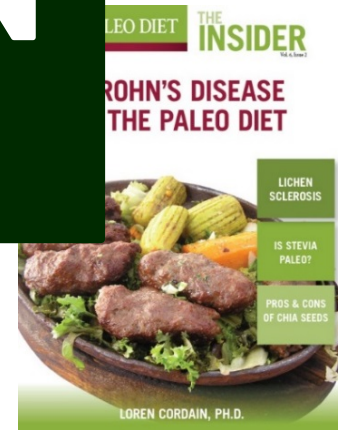
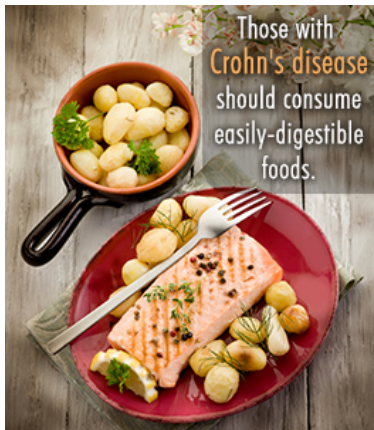
Levine A, et al. *Gastroenterology*. 2019;157(2):440-450.e8.



DIET AND CROHN'S DISEASE: WHAT'S OUT THERE?



#1
QUESTION
WE GET

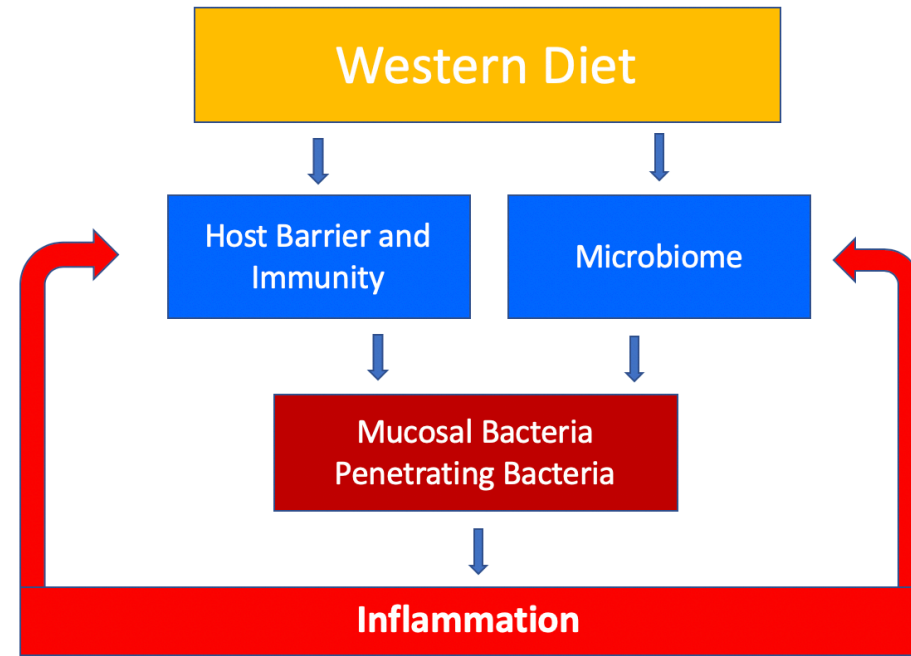


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SOMETHING “BAD” IN DIET AND THE MICROBIOME?

Nutrient	Effect on permeability	Proposed mechanisms
SCFAs	↓	↑ATP, Treg regulation, cytokine production, HIF-1 regulation, relocation of ZO-1& occludin
Vitamin D	↓	Regulation of innate& adaptive immunity, ↑Ezrin, altered villous morphology
Vitamin A	↓	↑ Mucus and defensin production, ↑TLRs
Zinc	↓	↓Phosphorylated occludin & claudin-1, ↑claudin-2
Anthocyanins	↓	↑ GLP-2 and MUC-2
Cysteine	↓	↑ GSH
Methionine	↓	↑Occludin, ZO-1 and claudin-3
Glutamine	↓	↑ATP, ↑ERK1/2 and JNK, growth factors EGF, TGF and IGF-1 pathways
Tryptophan	↓	AHR and PXR pathways
Arginine	↓	NOS pathway
Gluten	↑	Binding to CXCR3
Glucose	↑	Altering AJ proteins
Fructose	↑	↓ATP
Bile acids	↑	TGR5 and FXR pathways
Fat	↑	Change the microbiota composition
Ethanol	↑	Direct damage to epithelia, altering TJ proteins
Emulsifiers	↑	Change the microbiota composition



Courtesy of Arie Levine

DIETARY APPROACHES FOR TREATING IBD

- Exclusive Enteral Nutrition (EEN)
- Whole Food Therapeutic Diets:
 - Specific carbohydrate diet (SCD)
 - Crohn's disease exclusion diet
 - Semi-vegetarian diet
 - CD-TREAT
 - “Anti-inflammatory” diet



META-ANALYSIS: EEN VS STEROIDS

Induction of remission:
equivalent; OR 1.26 (0.77, 2.05) favoring EEN

Mucosal Healing:
EEN is superior: OR 4.5 (1.46, 12.23)



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CS- Corticosteroid

Swaminath A, et al. *Aliment Pharmacol Ther.* 2017;46(7):645-656.



EXCLUSIVE ENTERAL NUTRITION: PROS AND CONS



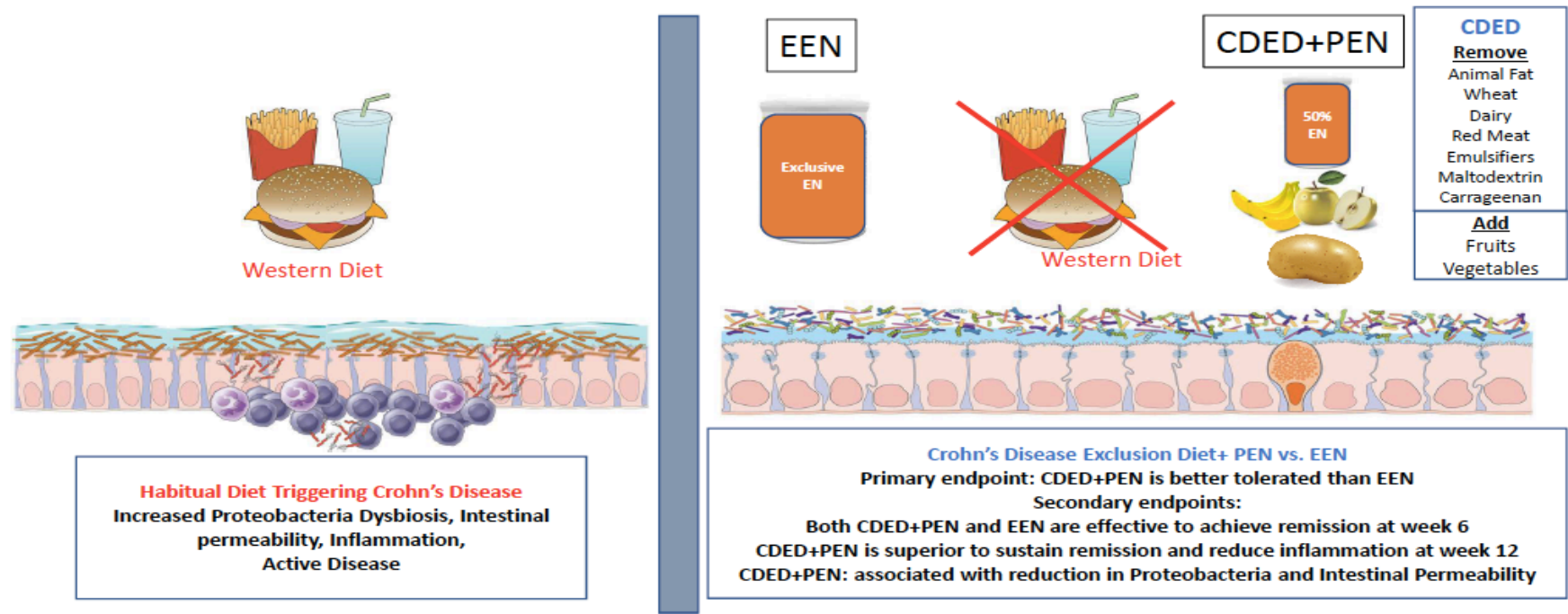
- + At least as effective as steroids
- + Associated mucosal healing
- + Works quickly
- + Improves nutritional status
- + Improves bone health
- + No side effects

- Demands resources, education, & dedication
- Limited long-term benefit
- Exit strategy?



CROHN'S DISEASE EXCLUSION DIET IS EQUALLY EFFECTIVE BUT BETTER TOLERATED THAN EXCLUSIVE ENTERAL NUTRITION FOR INDUCTION OF REMISSION IN MILD TO MODERATE ACTIVE PAEDIATRIC CROHN'S DISEASE: A PROSPECTIVE RANDOMIZED CONTROLLED TRIAL

Dietary Therapy: Crohn's Disease Exclusion Diet + Partial Enteral Nutrition vs. Exclusive Enteral Nutrition



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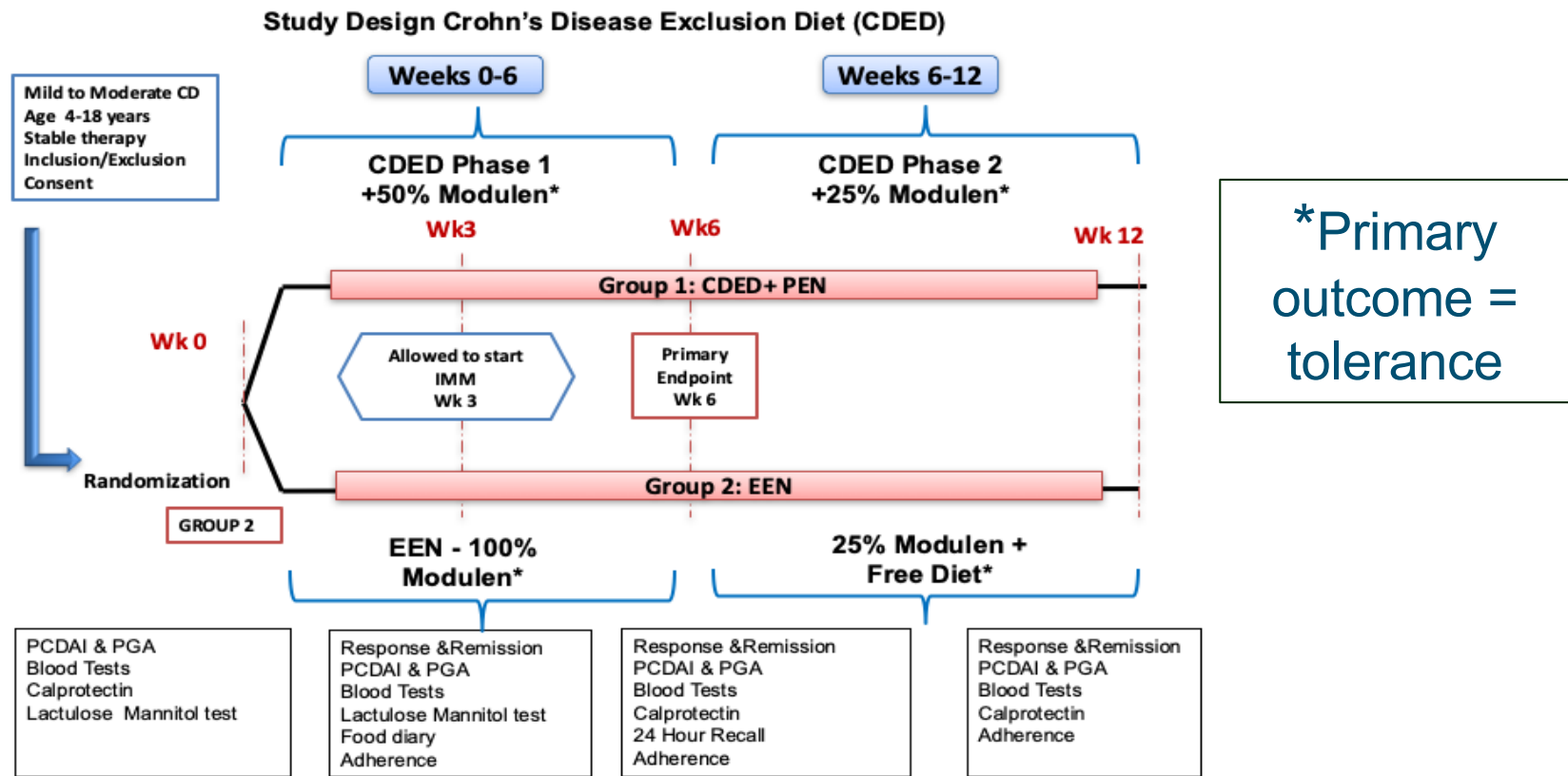
Levine A, et al.
Gastroenterology.
2019;157(2):440-450.e8.

EN- Enteral Nutrition
PEN- Partial Enteral Nutrition



CDED TRIAL - RCT COMPARING CDED+PEN TO EEN FOLLOWED BY PEN

78 patients mild to moderate CD , mean age 14.2±2.7 years



***Primary outcome = tolerance**

*Modulen will be given ORALLY



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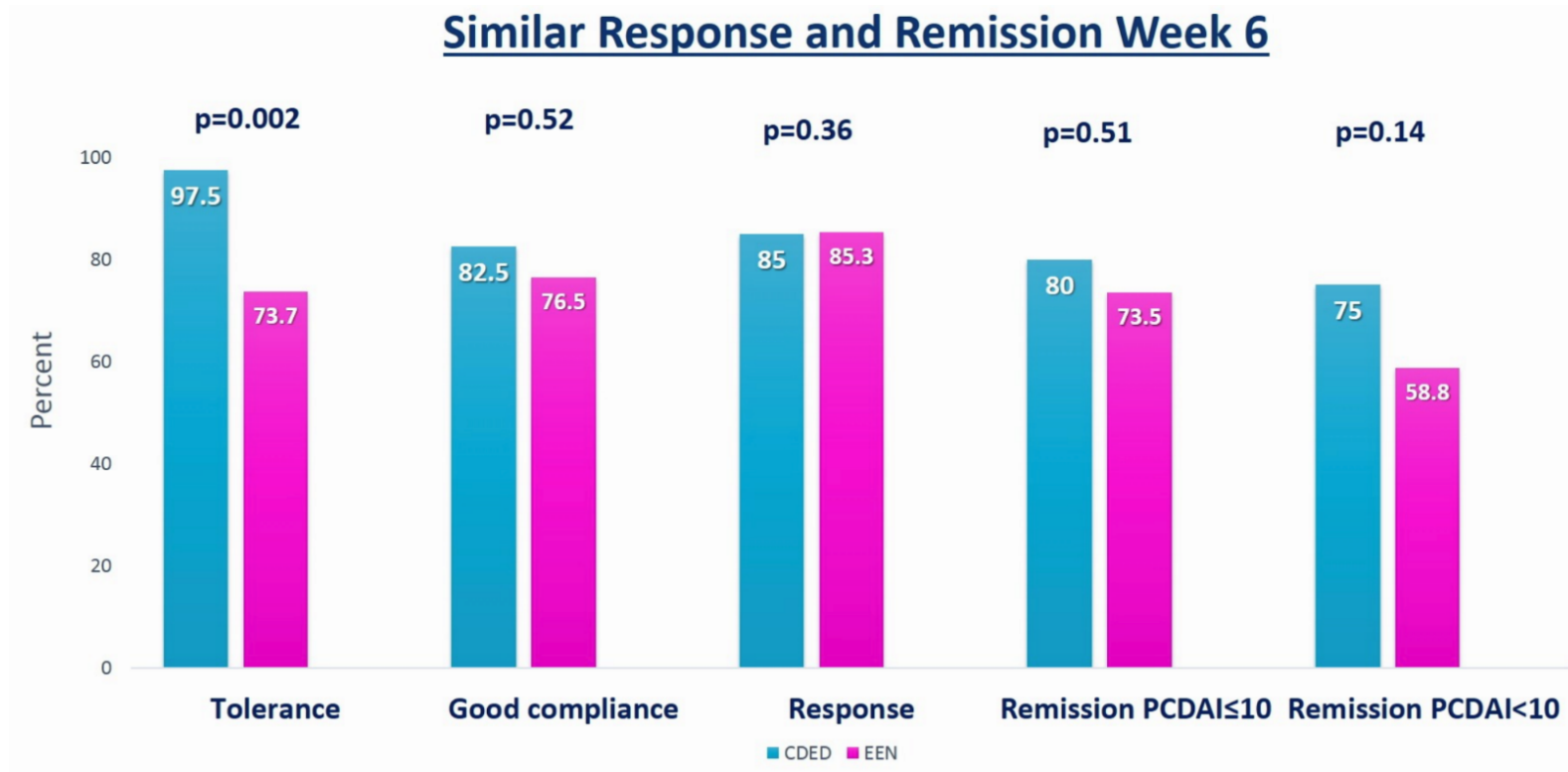


Levine A, et al. *Gastroenterology*. 2019;157(2):440-450.e8.

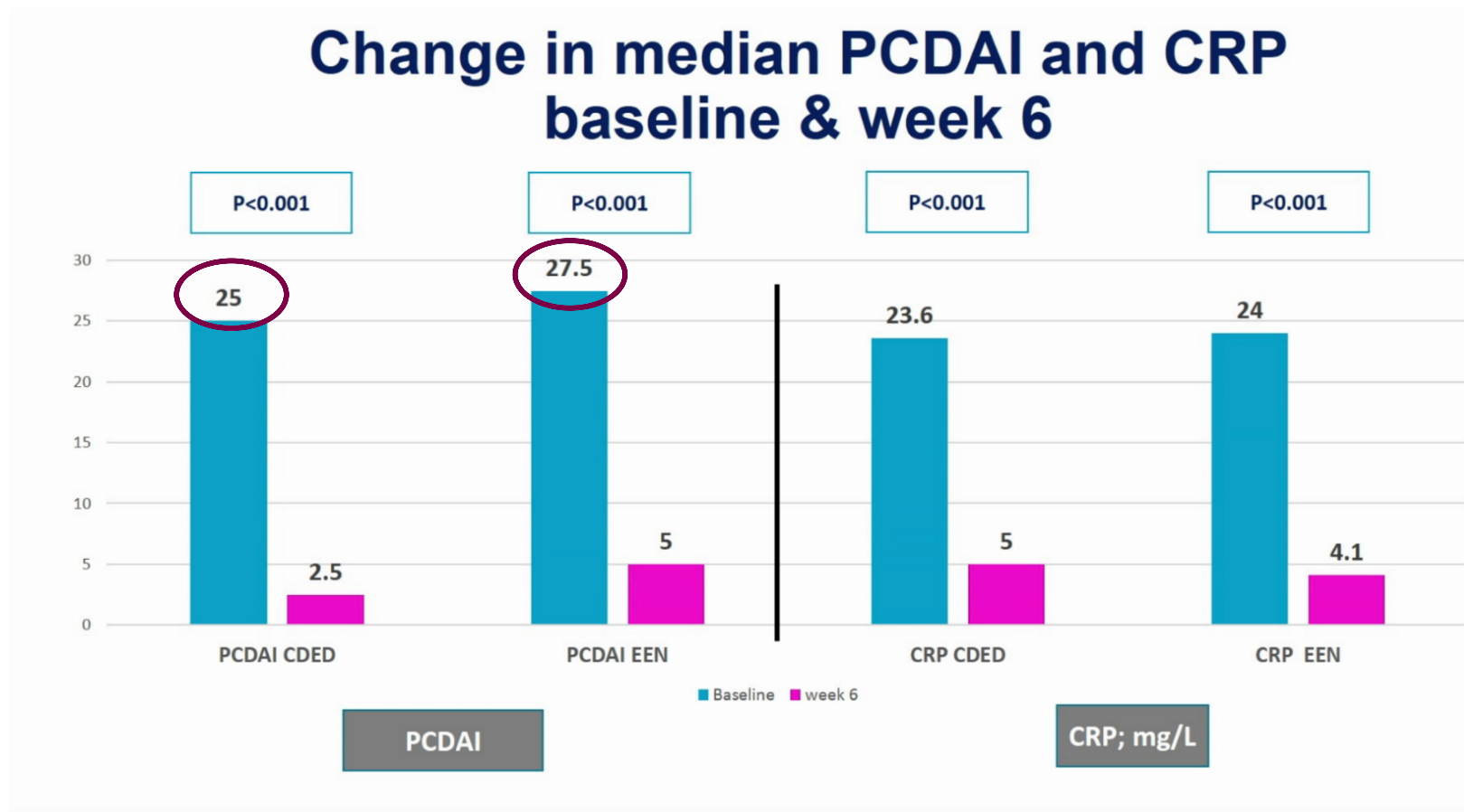
RCT- Randomized Controlled Trial
 IMM- immunomodulator
 PCDAI- Pediatric Crohn's Disease Activity Index
 PGA- Physician Global Assessment



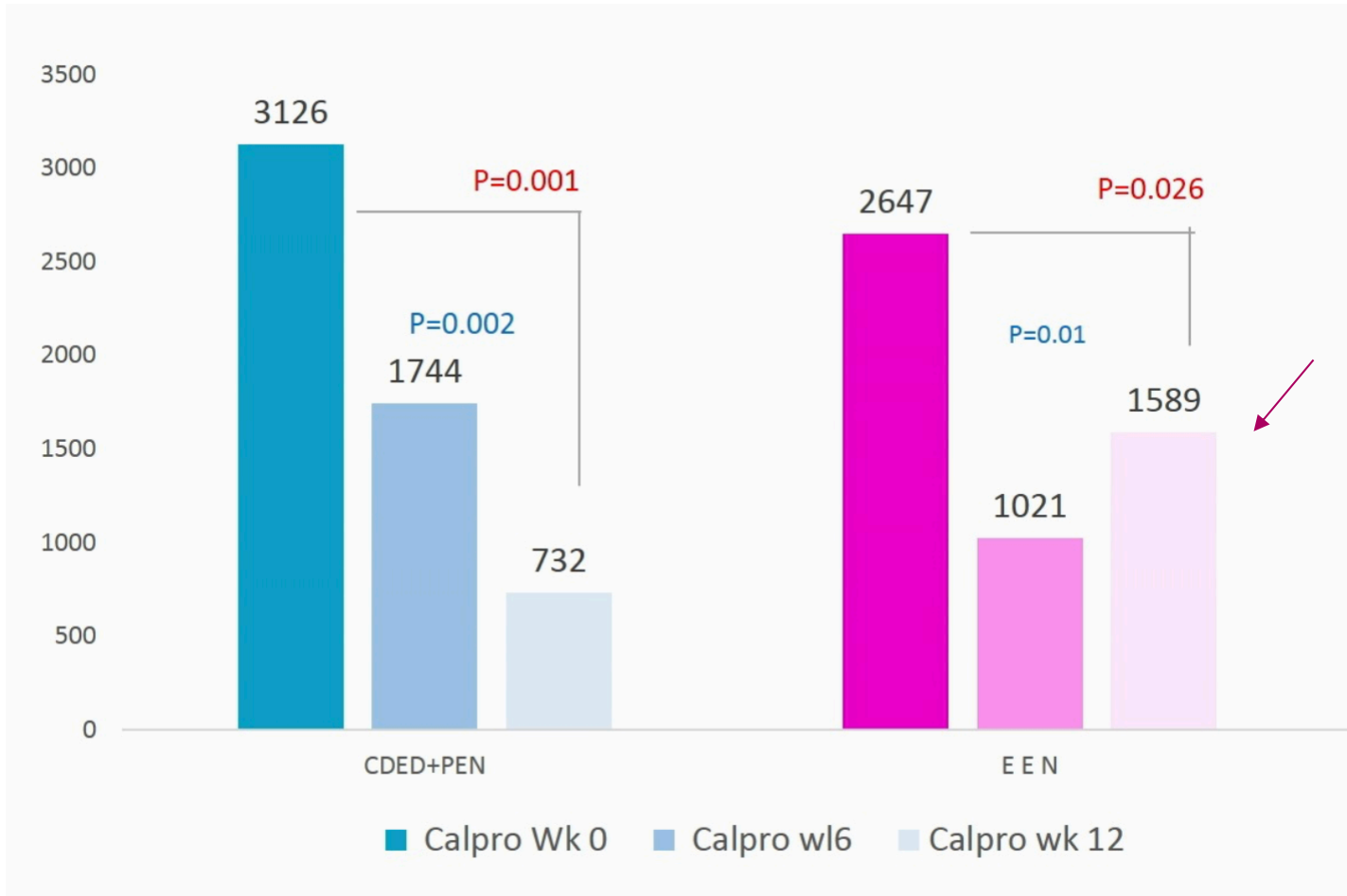
WEEK 6: COMPARISON EEN VS CDED + PEN (50% CALORIES FROM FORMULA)



WEEK 6 PCDAI AND CRP



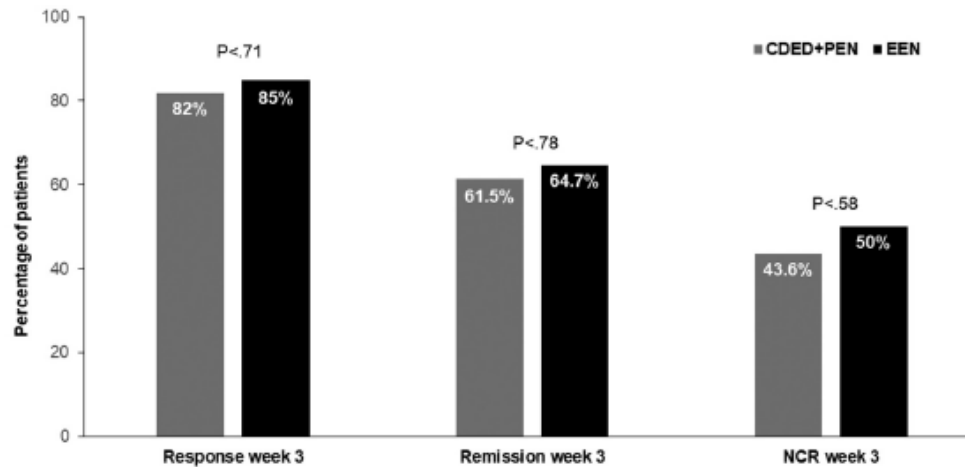
MEDIAN FCP WEEKS 6 AND 12



Rebound at week 12 in EEN group with transition to 25% formula, 75% free diet

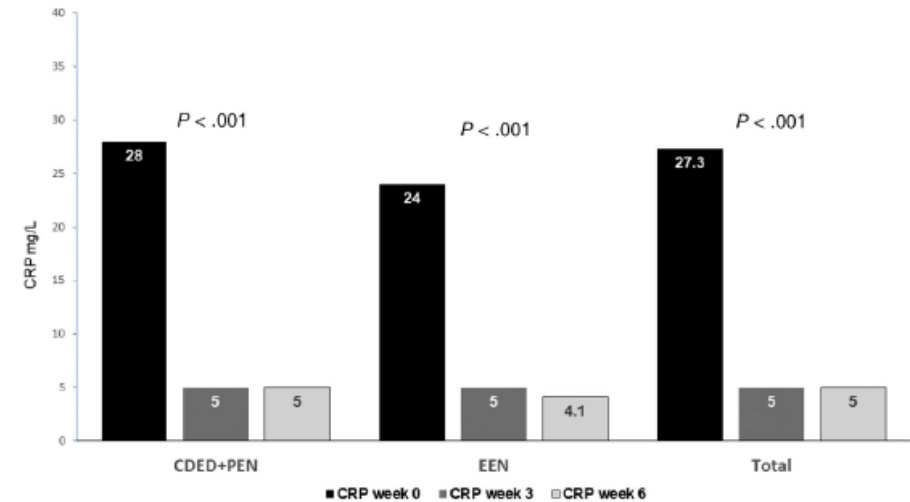
RAPID RESPONSE TO DIETARY THERAPY

Response, Remission,
normal CRP at week 3



CRP at weeks 0, 3, 6

CDED EEN Total



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Sigall Boneh *et al.*, Clin
Gastro and Hepatology
2020;46:546-56.

NCR- Normal C-Reactive
Protein remission



CEDED RCT CONCLUSIONS

- Large (relatively)! and randomized, controlled!
- Not powered to be an efficacy trial but as good (? better) than EEN for induction of remission
- Mild disease cohort with short disease duration (< 36 mos)
- No mucosal healing endpoint, but significant reduction in fecal calprotectin
- Long term outcomes unknown
 - Will patients achieve mucosal healing with diet alone by 6 months?
 - Is the diet sustainable long term?
- Is the formula required? Which formula?



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INTRODUCTION TO CROHN'S DISEASE EXCLUSION DIET (CDED)

Jennifer Smith, MS, RD, CSP, LD, LMT
Clinical Dietitian
Nationwide Children's Hospital

WHAT THE INCLUDED FOODS ARE TRYING TO ACCOMPLISH

- Healthy balanced diet
 - Includes nourishing foods from many food groups
- Encourages growth and lean body mass
 - Enough macro- and micronutrients to maintain good nutrition
- Pleasant tasting
 - Foods which can keep patients feeling satisfied and are enjoyable
- Maintainable
 - Encouraging a life long change
 - Variety to keep taste buds happy



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HOW DOES THIS HAPPEN?

- The initial phases are important for the clinical success of the diet
- There are 3 phases in total
- All include partial enteral nutrition
- Mandatory foods to ensure high quality nutrition and changes in the bacteria of the gut
 - High quality, lean protein
 - Resistant starch
 - Fiber
- Allowed foods to offer necessary nutrition to promote growth and development
- Excluded foods to prevent inflammatory process



WHAT THE DIET AVOIDS/LIMITS

- High fat
- Animal fat
- Red meat
- Soy
- Dairy
- High sugar
- Low resistant starch
- Low fiber
- Gluten
- Insoluble fiber
- Artificial sweeteners
- Emulsifiers
- Carrageenan
- Taurine
- Alcohol
- Sulfites
- Titanium dioxide
- Maltodextrins
- Yeast



PHASE 1 AND 2

- Phase 1 is weeks 0-6
 - Complete nutrition formula/shake should constitute 50% of total energy intake
 - 5 mandatory foods
 - List of allowed foods
- Phase 2 is weeks 7-12
 - Complete nutrition formula/shake should constitute 25% of total energy intake
 - 5 mandatory foods
 - Expanded list of foods
 - Additional fruits and vegetables allowed for weeks 7-9 and others allowed starting week 10



PHASE 3

Maintenance

- Complete nutrition formula/shake should constitute 25% of total energy intake
- There are no mandatory foods, however, potentially harmful foods should continue to be limited or avoided
- Goal is to maintain phase 2 diet (with additional foods listed in the previous slides) 5 days per week
- Allowed 2 homemade “free” meals 2 days per week (some allowance for restaurant meals)
- There are few foods not allowed at all



FOOD GROUPS

Protein

- Fresh chicken breast 5 oz or more (mandatory food) included in all phases of the diet, other chicken parts except wings, skin, and internal organs allowed in stage 3
- Eggs 2 per day (mandatory food) included in all phases of the diet
- Fresh fish 1 serving once weekly to substitute for serving of chicken included in all phases of the diet
- Tuna canned in olive or canola oil twice weekly allowed in phase 2 and 3
- Fresh seafood or salmon 1 serving allowed once weekly in phase 3
- Lean beef steak (such as sirloin) 6 oz once weekly. Allowed in phase 2 and 3, however, recommended to avoid if possible
- Almonds or walnuts, unprocessed, unroasted, unsalted, 6-8 per day allowed in phase 2 and 3
- Raw tahini, free from preservatives and sulfites, 2 tablespoons per day allowed in phase 2 and 3



FOOD GROUPS

Dairy

- Yogurt, natural, unprocessed, full fat, without additives, 1 serving allowed daily in phase 3

Legumes/beans

- Lentils, beans, peas, chickpeas, dried, ½ cup (uncooked), not frozen or canned allowed in phase 2 and 3

Fats/oils

- Olive oil allowed in all phases
- Canola oil allowed in all phases



FOOD GROUPS

Fruits

- Banana, 2 daily (mandatory) allowed in all phase
- Apple, 1 peeled (for first 6 weeks) and cooked daily (mandatory) allowed in all phases
- Avocado, 1 per day (1/2 per meal) allowed in all phases
- Strawberries, 5 per day allowed in all phases
- Melon (cantaloupe or honey dew), 1 slice allowed in all phases
- Orange juice, freshly squeezed 1 glass per day allowed in all phases
- Pear, kiwi, and peach, allowed in phase 2 and 3
- Blueberries, 10 as a substitute to strawberries allowed in phase 2 and 3
- Mango, pineapple, oranges, ½ cup cubes allowed after week 10
- Other fruits allowed in phase 3 except pomegranate, permission, cactus, and passion fruit



FOOD GROUPS

Vegetables

- Potatoes, 2 peeled (for the first 6 weeks), cooked, and refrigerated per day (mandatory) allowed in all phases
- Tomatoes, 2 allowed daily in all phases
- Carrots, 2 peeled allowed in all phases
- Spinach, fresh, uncooked 1 cup allowed in all phases
- Lettuce, 3 leaves allowed in all phases
- Sweet potato or yam, ½ substitute for potato allowed in phase 2 and 3
- Zucchini (1 large or 2 small), 4-6 mushrooms, 2 flowerets of broccoli or cauliflower (not at the same time) are allowed in phase 2 and 3
- Other vegetables allowed after week 10 except kale, leeks, asparagus, and artichoke



FOOD GROUPS

Starches/grains

- Rice, unlimited, including rice flour and rice noodles allowed in all phases
- Quinoa, unlimited allowed in phase 2 and 3
- Oatmeal, ½ cup allowed in phase 2 and 3
- Bread, homemade made with baking powder instead of yeast, 1 slice per day allowed in phase 2 and 2 slices allowed in phase 3
- Pasta, 1 cup cooked as a substitute for bread allowed in phase 3



FOOD GROUPS

Other

- Pure spices allowed in all phases
- Fresh herbs allowed in all phases
- Water and sparkling water allowed in all phases
- Herbal teas
- Honey, 3 tablespoons per day allowed in all phases
- Table sugar, 4 teaspoons per day allowed in all phases
- Onions, garlic, ginger, and fresh lemon juice allowed in all phases
- Baking soda and baking powder allowed in phase 2 and 3



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Levine A, et al. *Gastroenterology*. 2019;157(2):440-450.e8.





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IMPLEMENTATION CROHN'S DISEASE EXCLUSION DIET (CDED)

HOW TO INTRODUCE

- Background
 - Begin by introducing diet as treatment for Crohn's Disease
- Discuss efficacy of the diet with current research
- Highlight pros to use of CDED
 - No side effects
 - The diet changes overtime
 - Goal of a healthy lifestyle
- Help families feel confident
 - Give them plenty of tools for success
 - Follow-up support



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ASSESSMENT

- Discuss weight goal for patient (weight gain or weight maintenance)
- Spend time discussing current food allergies, food intolerances, and food avoidances and beliefs
- Current diet
 - Who cooks?
 - Time spent on meal prep
 - Where are meals eaten (home vs out, together vs individually)
 - Where do you shop
- Family schedule
 - Home life
 - School
 - Sports/Clubs



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EDUCATION

- Determine the goal for nutrition shakes/formula per day for phase 1 and phases 2 and 3
- Review mandatory, allowed, and disallowed foods focusing on phase 1
- Describe what a typical day could be giving goals for food amounts to ensure weight goal will be achieved
- Shopping lists and introduce family to meal planning and prepping (if not already doing at home)
- Encourage many types of cooking
 - Grilling, air frying, baking, broiling/roasting, boiling
- Recipes
- Problem solving
 - Holidays
 - School lunch



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SUPPORT

- Enthusiasm and confidence
- In-person or virtual education with dietitian
- Handouts
- On-line support
- Regular check in with dietitian
 - Week 0, 1, 6, 8, 12, ongoing as needed
- Ways to contact dietitian along with way with questions
- Social media support (patient support groups)

SUMMARY

- Crohn's Disease Exclusion Diet may be as good (if not better) than exclusive enteral nutrition for induction of remission for Crohn's disease (more research needed)
- There are limitations to the clinical data for dietary therapy in inflammatory Bowel Disease (IBD), however, this should not necessarily be a deterrent for use in patients
- Crohn's disease exclusion diet offers a balanced diet free of foods which may cause inflammation. CDED adds more foods overtime which may promote long lasting compliance
- Families can follow this diet with success if given important resources and support



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DISCUSSION

HOW DO YOU CONVINCe PROVIDERS THAT DON'T BELIEVE FAMILIES WILL BE ABLE TO MAKE DIET CHANGES?



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**WHAT IS THE BEST PIECE OF ADVICE YOU
WOULD GIVE TO PROVIDERS AND DIETITIANS
FOR INTRODUCING CDED TO PATIENTS AND
THEIR FAMILIES?**



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**FOR STUDENTS ATTENDING SCHOOL,
WHAT IDEAS DO YOU HAVE FOR THEM
FOR LUNCHTIME WHILE ON CDED?**



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FOR ATHLETES, HOW DOES A FAMILY PLAN MEALS AND SNACKS DURING A BUSY SPORTS SEASON ON CDED?



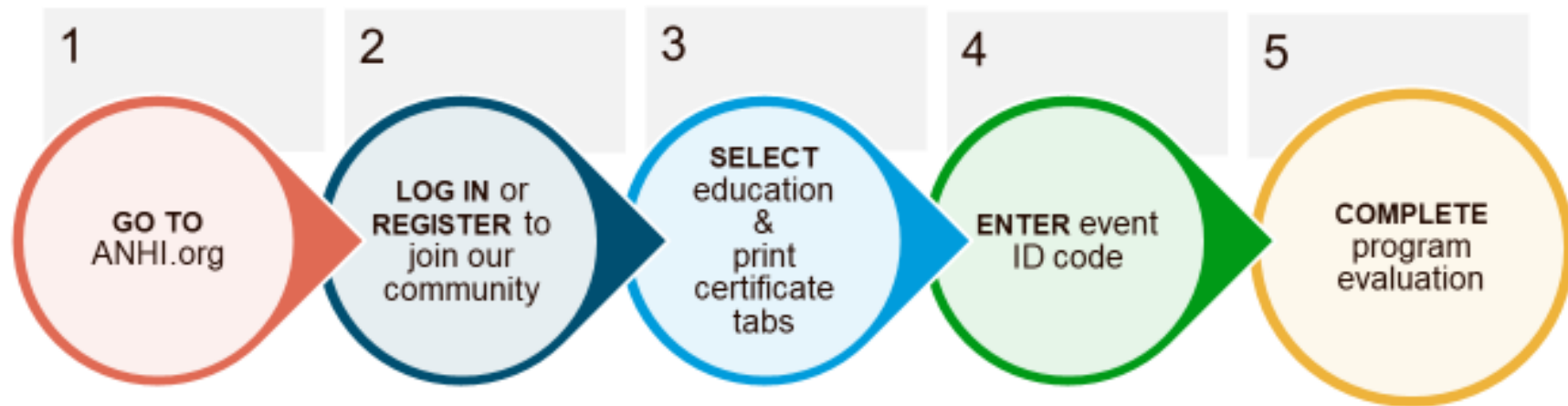
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THANK YOU