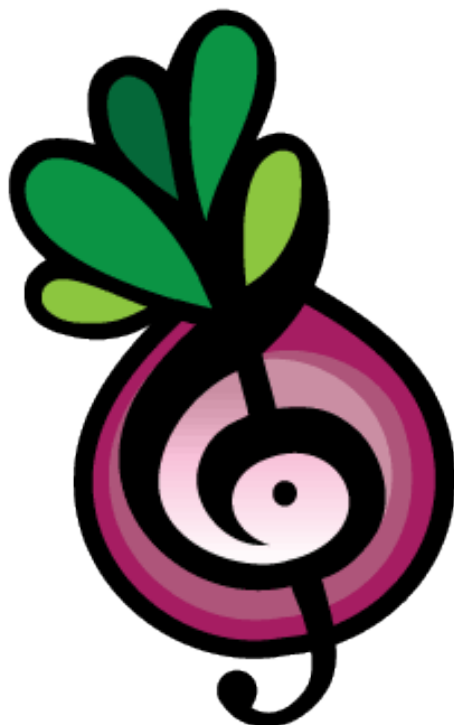




Icahn  
School of  
Medicine at  
Mount  
Sinai



# the **MELODY** Trial

January 2020

*1st Annual Newsletter*

Modulating *E*arly *L*ife Micr*O*biome through *D*ietar *Y* Intervention in Pregnancy



## INSIDE THIS ISSUE

Happy New Year from  
the MELODY Trial!  
..... page 1

Meet the Study Teams  
..... page 2

Project  
Updates  
..... page 3

Participant  
Testimonials  
..... page 4

Stress and the  
Microbiome  
..... page 5

Research  
Results  
..... page 6

Baby Wall of Fame  
..... page 7

Happy New Year from the MELODY Trial  
Team!

We are excited to share with you the *1<sup>st</sup> Annual* MELODY Trial Year-end Newsletter, where we will share updates about the research, our team, and the MELODY Trial community. We are so grateful for your dedicated participation. This research would not be possible without you!

Keep reading for research updates, future directions, interesting related research, and more! We hope you enjoy it!

Best wishes for a happy and healthy new year,  
The MELODY Trial Team





## Meet the Study Teams!



**The team at the University of Massachusetts Medical School, Worcester, MA (left to right):**

Chris Frisard; Masha Zabruk; Barbara Olendzki, RD MPH LDN; Caitlin Cawley; Dr. Ana Maldonado-Contreras

**Not pictured:** Victoria Andersen; Rene Maserati; Camilla Madziar; Karla Menger; Shauna Simpson

DEPARTMENT OF  
GENETICS & GENOMIC SCIENCES



**Icahn  
School of  
Medicine at  
Mount  
Sinai**

**The team at the Icahn School of Medicine, New York, NY (left to right):** Sierra White; Dr. Leonid Tarassishin; Dr. Inga Peter; Paulette Magnas; Kelly Hawkins; Alexa Rendon; Dr. Anketse Debebe; Caroline Eisele

**Not pictured:** Dr. Jean-Frederic Colombel; Dr. Jianzhong Hu; Dr. Joanne Stone; Dr. Marla Dubinsky; Dr. Eunsoo Kim

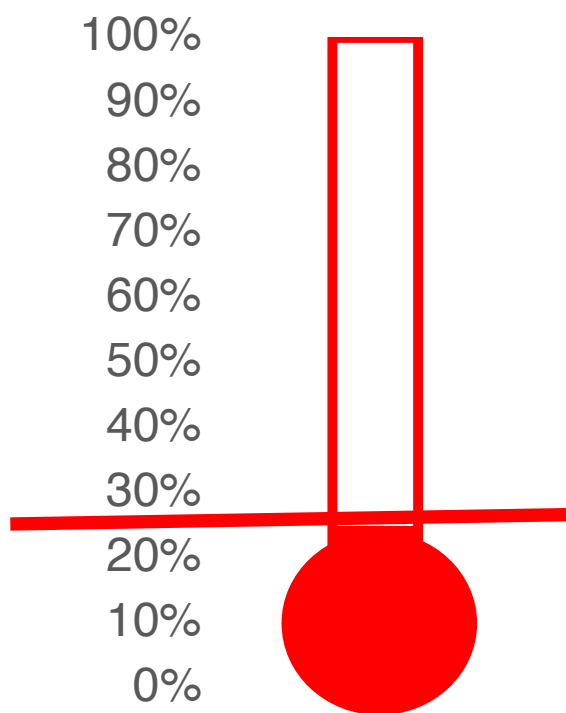


## Project Updates

### Sample Collection:

We have already collected over **280** samples from 52 families participating in the MELODY Trial! MELODY Trial moms have completed over **420** diet assessments!

We cannot thank you enough for taking the time to collect your samples and complete the diet questionnaires. These surveys give us valuable information about what you are eating and how that influences the bacterial composition of your (and your baby's!) gut microbiome.



### Project Enrollment:

We have already enrolled **56 families** to participate in the MELODY Trial!

Our recruitment goal is **200** mothers and their babies. We are greater than **25%** of the way towards our goal!





You can help to spread the word about the study. Let your pregnant friends and family members and your health care providers know about the study. Enrollment is open now!

### To Enroll, Contact Us:

themelodytrial@gmail.com

347-620-0210

<https://www.umassmed.edu/nutrition/melody-trial-info/>

		Pregnancy			Delivery	After Birth				
Timeline		27-29 w (Baseline)	35 w	37 w		14 d	30 d	90 d	6 mo	12 mo
 Crohn's disease + IBD-AID diet  Crohn's disease + no diet  Control + no diet	Samples	Stool Saliva	Stool Saliva	Stool Saliva	Umbilical cord blood	Breast milk			Stool Saliva	Stool Saliva
	Questionnaires (Q)	24HR Basic Info Q Health history/ Reproductive Q FFQ weekly throughout		24HR	Delivery/ Postpartum Q		FFQ (diet arm only)	FFQ (diet arm only)	FFQ 24HR Follow-up Q	FFQ 24HR Follow-up Q
 <b>Babies</b>	Samples				Meconium	Stool	Stool	Stool	Stool	Stool
	Questionnaires					IDD	IDD	IDD Rome IV	IDD 24HR	IDD 24HR

w=gestational weeks; d=days old; mo=months old  
 FFQ=Food Frequency Questionnaire (online) <30 minutes  
 24HR=24 Hour Diet Recall (by phone, three separate days) 20-30 minutes  
 IDD=Infant Diet and Development Questionnaire (online) 10 minutes  
 Rome IV=Assess functional gastrointestinal disorders in infants (by phone)





## A Patient Journey

### By Laura Downton

This week, marks two and a half years since I received the diagnosis of Inflammatory Bowel Disease (IBD) and began my journey of learning to heal from the inside out.

I remember the day of my diagnosis, looking at my gastroenterologist at the time and asking: "What can I do? What changes to my diet can help?" Her answer was grim. "Dietary and lifestyle changes will not help. The problem is your immune system. But there is ultimately a cure if you need it: removing your colon." In just one moment, my view of the future I had imagined collapsed. I had gone from having symptoms I did not understand to being told that this condition would impact me for the rest of my life - no exit, no solutions.

She went on to describe the medications available and there was something profoundly missing from her words: healing. I wanted to know how to address the root causes of the disease in my body but the medications would, at best, relieve symptoms and at worst, bring with them a new set of serious health risks and life-altering side effects.

In the initial weeks that followed, I learned that I am severely allergic to the 'safer' gold standard medications traditionally used to treat IBD with fewer side effects, and was presented with only one option: indefinitely taking strong, expensive medications whose side effects can be worse than the condition itself. My diagnosis evolved over time from Colitis to Crohn's as I navigated symptoms that were becoming more complex and painful. In my heart of hearts, I knew there had to be another way.

While I was able to find my way somewhat, it became clear I needed more help to learn how to get all the nutrients I needed to make the changes sustainable. In May, in a flurry of emails to experts and leading researchers all over the U.S. whom I wrote to asking for their guidance on healing IBD with diet, I wrote to Nutritionist Barbara Olendzki at UMASS Medical School, Director of the Center for Applied Nutrition. I was impressed with the Center's goal of establishing dietary guidelines for people with IBD. Had such dietary guidelines been shared with me on the day of my diagnosis one year ago, I would have had hope.

Barbara wrote back to me, "Laura, can I help you?" Yes. I had seen many gastroenterologists from March to August, each insisting that dietary changes "would not work" and "are not proven," and the most recent one was insisting I begin a strong drug that week. Instead of the drug, I began working with Barbara at UMASS on my treatment plan to heal: the IBD-Anti-Inflammatory Diet (IBD-AID™). IBD-AID™ is an updated version of SCD based on the latest research into the microbiome. For the past 10 years, Barbara and her colleagues at UMASS Medical School have been studying the impact of these dietary interventions on reversing autoimmunity and healing the gut. Now, they are taking that research a big step forward by using the diet in pregnant women with IBD to help the babies.

My wonderful daughter was born in October, and is beautiful, precious, and healthy.

I want to close this update with a reminder from one of my favorite poets, who sums up well what this healing journey is all about:

"look down at your body  
whisper  
*there is no home like you*  
*thank you*"  
-rupi kaur

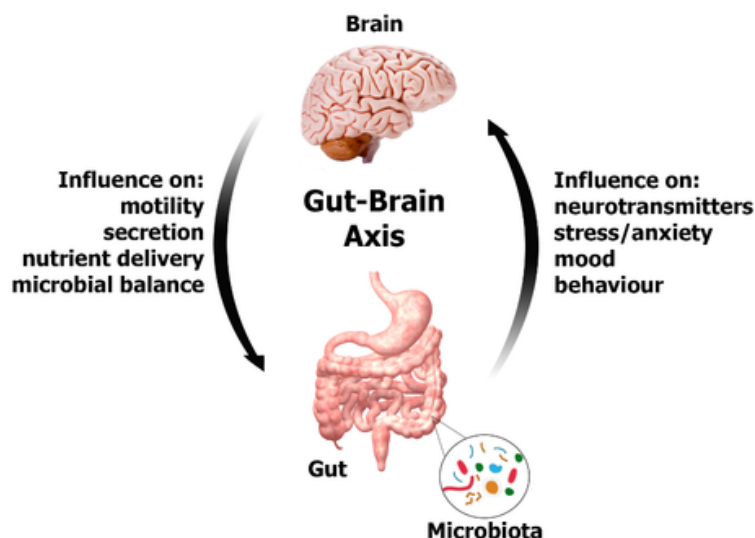
Thank you for being on the road with me.  
Love always,  
Laura



## The Connection between Stress and the Microbiome

There are many different channels through which stress can affect health. The gut-brain axis refers to the relationship between the gastrointestinal (GI) tract – or gut – and the brain. The gut-brain axis involves a ton of two-way communication between those two (just think of hunger....this comes from the gut, and you are aware of it in the brain).

Of course, our gut microbiome *also* plays a huge role in this relationship. Several lines of evidence support the suggestion that gut microbiota influence stress-related behaviors, including those relevant to anxiety and depression.<sup>1</sup> Diet is one of the most important drivers shaping our microbiota and in turn it's impact on the gut-brain axis. Thus, let's consider the holidays and the different (usually sweet and fatty) foods typical of the season, the pressures of friends and family, entertaining, long days, and having kids or being pregnant. Perhaps a time of stress and poor food choices! Let's be prepared!



Recognizing that **STRESS** has a strong hold over us is the first essential step if we want to minimize its effect. What happens when **STRESS** sets in upon us? First off, blood levels of **STRESS** hormones – adrenaline, noradrenaline, and cortisol – get elevated. At the same time, other neurochemicals that regulate our mood and brain functions (e.g. GABA, serotonin, dopamine, and melatonin) start to swing out of their normal levels. The increase of those neurochemicals are associated with specific gut bacteria.<sup>1</sup> Thus, as much as possible, we want to be careful of our foods choices during the holidays keeping in mind the importance of the microbiome in regulating stress. Our advice is to plan ahead and to do your best to always have delicious and healthy food with you.

Like Honey and Vanilla roasted pears....

<https://www.umassmed.edu/nutrition/ibd-aid/desserts/honey-and-vanilla-roasted-pears/>

Or a salad!

We have so much more to learn.

Thank you for being part of our journey!



<sup>1</sup> Foster, J. A., Rinaman, L., & Cryan, J. F. (2017). Stress & the gut-brain axis: Regulation by the microbiome. *Neurobiology of stress*.

<sup>2</sup> Image credit: <https://mappingignorance.org/2016/08/04/gaba-link-gut-brain/>





## Research Results

We are very excited to share the published results from our team's MECONIUM Study (Exploring MEchanisms Of disease traNsmission In Utero through the Microbiome).

The paper was published in the scientific journal *Gut* in April, 2019. The full text is available on the MECONIUM Study website if you are interested in reading further!

<http://labs.ica hn.mssm.edu/peterlab/newsletter-and-preliminary-results/>

*Gut*. 2019 April 29. PMID: 31036757

### Infants born to mothers with IBD present with altered gut microbiome that transfers abnormalities of the adaptive immune system to germ-free mice

#### Background

The development of a baby's microbiome, starting in early life and even before birth, is thought to play a major role in shaping the immune system. Studies show that early life exposures that alter the microbiome are linked to an increased risk of developing IBD later in life.

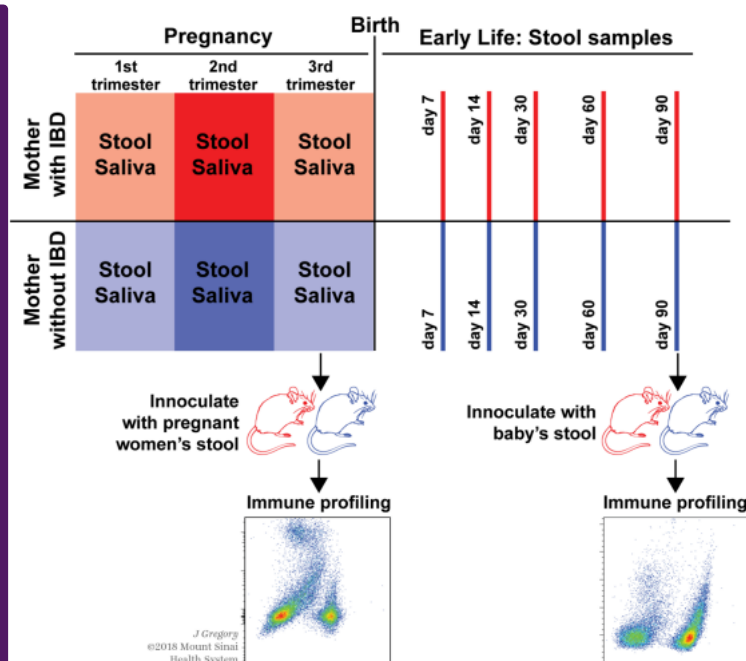
For the MECONIUM Study, we assessed the effect of maternal IBD on the infant's gut microbiome.

#### What did the results show?

Pregnant women with IBD and their offspring had less diverse gut microbiomes compared to control women and their babies. When germ-free mice (mice bred to be completely sterile, with no prior exposure to bacteria) were exposed to the microbiome of infants born to mothers with IBD, they developed imbalanced immune systems. These results suggest that maternal IBD may have an impact on the immune system development of offspring through transmission of the microbiome.

**Note:** This is preliminary data and does not mean your child is highly susceptible to getting IBD or other immune-related disease. However, it will help in making informed decisions about managing your and your kids' health via diet, monitoring, and treatment.

Research like this is important to help us understand how we can possibly prevent development of IBD in high-risk individuals in the future.



#### What is the potential impact?

The microbiome can be manipulated through means such as diet, probiotics, and more. This makes it a potential area to target in order to decrease risk of IBD. By improving the microbiome in women with IBD during pregnancy, or in babies during early life, it may be possible to foster development of a healthy microbiome in childhood, thereby promoting growth of a strong immune system and reducing babies' future risk of IBD!

The MELODY Trial is doing just that! Your participation in this research is helping us to learn more about the connection between mother and infant microbiome and potential interventions.



