

What is the MELODY Trial?



The MELODY Trial will test whether a non-invasive diet intervention during the third trimester of pregnancy can beneficially shift the bacterial flora of the body, or the microbiome, in patients with Crohn's disease (CD) and in their babies.

CD, a type of inflammatory bowel disease (IBD), is a chronic condition of the gastrointestinal tract that is associated with an imbalance in the gut microbiome (the makeup of bacteria in the stomach). Diet may play a role in the development and treatment of CD. Growing evidence suggests that maternal health and diet during pregnancy have an impact on the baby's microbiome. This is important as the early life microbiome informs the immune system development, with long-term health consequences, including an increased risk of CD and other diseases caused by weakening of the immune system.

By changing the maternal microbiome during pregnancy through diet, we hope to be able to promote healthier immune system development in infants born to mothers with CD.

Who is eligible to participate?

Any woman who is currently pregnant (less than 27 weeks).
You may or may not have Crohn's disease.

There are 3 groups of participants in this trial:

- 1) Women with CD following diet intervention.
- 2) Women with CD following their usual diet.
- 3) Women without CD, following their usual diet.

If you have CD, you may choose whether to follow the IBD-AID diet or your regular diet.

What does participation involve?

During third trimester of pregnancy:

- Collection of maternal stool, saliva and vaginal samples (up to 3 times) at home
- Completion of health history questionnaires
- Weekly web-based diet assessments
- Phone-based diet assessments (up to 3 times)

At birth:

- Collection of umbilical cord blood sample
- Questionnaire about your delivery

Follow up:

- Collection of baby's stool sample at 14, 30, and 90 days, and 6 and 12 months after birth
- Collection of maternal stool and saliva samples at 6 and 12 months after birth
- Collection of breast milk sample (if breast-feeding)
- Completion of diet assessment questionnaires, web-based or through phone calls with the research team

		Pregnancy			Delivery	After Birth				
Timeline		27-29 w (Baseline)	35 w	37 w		14 d	1 mo	3 mo	6 mo	12 mo
	Samples	Stool Saliva VS	Diet intervention: 30-37 weeks Stool Saliva VS	Stool Saliva VS	Umbilical cord blood VS Placenta	Breast milk	Breast milk	Breast milk	Stool Saliva Breast milk VS	Stool Saliva Breast milk VS
	Questionnaires (Q)	24HR Basic Info Q Health history/ Reproductive Q		24HR	Delivery/ Postpartum Q				FFQ 24HR Follow-up Q	FFQ 24HR Follow-up Q
	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

24HR=24 Hour Diet Recall (by phone, three separate days) 20-30 minutes

Frequently Asked Questions:

Is there any cost or travel required to participate?

There is no cost or travel required to participate. All samples and clinical information can be collected by mail or over the phone. We will provide everything needed to collect and ship the samples.

How long will my participation last?

Your participation will last from the beginning of your third trimester through your baby's first birthday.

Is there compensation for participation?

Participants will be compensated up to \$200, which is paid in installments throughout the study period.

Do you need to be local to participate?

No, you do not need to live in Massachusetts to participate. Anyone in the United States can participate.

At what time point during my pregnancy can I enroll?

You can enroll at *any* timepoint before week 27 of your pregnancy.

Is there any risk involved?

There is minimal risk involved in the collection of stool, saliva, umbilical cord blood, and breast milk. Your samples will be immediately de-identified upon receipt. The diet intervention has been adapted for safety in pregnancy.

How do I enroll in the study?

Contact our Research Coordinators at melodytrialumass@gmail.com or 650-880-1655

Contact the Research Team:

Principal Investigators:

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the
MELODY
Trial

*Modulating Early Life
Microbiome through
Prenatal Dietary Intervention
in Crohn's Disease*

