

# DIGEST



*Our mission is to advance the biopsychosocial understanding and care of patients with functional GI & motility disorders through research, training and education.*

## IN THIS ISSUE:



Two new FDA approved medications for diarrhea-predominant IBS

Introduction of UNC Gastroenterology Fellows

Complementary and Alternative Medicine (CAM) for FGIDs

Patient submitted Q&A panel answered by UNC care providers

### COMPLEMENTARY AND ALTERNATIVE MEDICINE (CAM) FOR FGIDS

Functional gastrointestinal disorders (FGID) impact patients all over the world. In a recently published epidemiological paper, the two most prevalent FGIDs in the U.S. were irritable bowel syndrome (11.1% overall average; 7.9% male; 13.9% female) and functional dyspepsia (9.8% overall average; 6.2% male; 12.8% female).[2] Many primary care providers prescribe FDA approved medications to treat FGIDs, but this may not resolve or reduce all the symptoms associated with the disorder. There has been a growing trend in clinical research to identify other complementary and alternative medicines and therapies that show clinical benefits in reducing the symptoms of FGIDs.

Complementary and alternative medicine (CAM) is often described as any therapies and medical products that are not typically considered part of conventional medicine.[1] CAM interventions have not only become more popular among patients, but clinical research into CAM therapies have also been noticed by the National Institutes of Health (NIH). The National Center for Complementary and Integrative Health (NCCIH) is an NIH supported center that is completely devoted to CAM therapies. [6] There is a distinct difference between the use of “complementary” and “alternative” when describing different therapies. Complementary means used

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### FEATURED FELLOW AT UNC SARINA PASRICHA

In continued efforts to enhance the relationship that patients have with their providers, the Digest is highlighting several UNC Gastroenterology fellows with a goal of making information about the fellows more accessible. As fellows train under UNC School of Medicine faculty gastroenterologists, they learn the skills needed to become the next generation of gastroenterologists in North Carolina and throughout the nation. Depending on the educational tract

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### LEADING EUROPEAN GASTROENTEROLOGIST COMING TO UNC

In August, Magnus Simren, MD will be traveling from the University of Gothenburg in Sweden to UNC – Chapel Hill to spend a year sabbatical with the Center for Functional GI and Motility Disorders. The research sabbatical is supported by the Ferring Pharmaceuticals Visiting scientist fellowship.

Dr. Simren is senior researcher of the Swedish Research Council and is a board member on the Rome Foundation. He also holds the position of Chair of the United European Gastroenterology Scientific Committee, and is the Clinical Editor

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## REACH OUT TO THE CENTER

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*DIGEST* is a quarterly publication of the UNC Center for Functional GI & Motility Disorders, a center of excellence within the Division of Gastroenterology and Hepatology, School of Medicine, University of North Carolina at Chapel Hill.

The Center's director is **William E. Whitehead, PhD**, Professor of Medicine and Gynecology.

Over the past decade, the UNC Center for Functional GI and Motility Disorders has enjoyed significant grant support from a number of private foundations and corporations. These grants have ranged from sponsorships of specific events (symposia or CME courses) to unrestricted grants in support of fellowships and the Center's education and training effort.

This activity is supported by an educational grant from Takeda Pharmaceuticals U.S.A., Inc. and Sucampo.

HAVE A QUESTION?

ASK THE CENTER PERSONNEL A QUESTION!

# DIGEST

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William E. Whitehead, PhD

## Center Associate Director

Yehuda Ringel, MD

## Faculty, Clinicians & Investigators

Shrikant I. Bangiwalla, PhD  
 Spencer Dorn, MD, MPH  
 Steve Heymen, PhD  
 Temitope O. Keku, PhD  
 Jane Leserman, PhD  
 Ryan Madanick, MD  
 Olafur S. Palsson, PsyD  
 Yolanda Scarlett, MD  
 Lisa Gangarosa, MD  
 Nicholas J. Shaheen, MD, MPH  
 Miranda van Tilburg, PhD  
 Danielle Maier MPAS, PA-C

## Center Coordinator

## Center Webmaster

Stefanie Twist

## Center for Functional GI & Motility Disorders

*The University of North Carolina  
 at Chapel Hill*  
 130 Mason Farm Rd.  
 CB#7080  
 Chapel Hill, NC 27599  
 (919) 843-6961  
[www.med.unc.edu/ibs](http://www.med.unc.edu/ibs)  
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<b>Cover</b>	FEATURED FELLOW AND INTERNATIONAL VISITING FACULTY
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## FEATURED FELLOW CONTINUED FROM COVER



that the fellow chooses, they can specialize on endoscopy and colonoscopy, inflammatory bowel disease, hepatology, basic science, motility disorders and several other disciplines.

Each fellow's medical training is decided based on their personal clinical interests. This edition will feature Dr. Sarina Pasricha, as her clinical interests include upper and lower motility disorders, anorectal disease, constipation, fecal incontinence, hemorrhoid management and treatment, women's health, and nutrition.

Dr. Pasricha is a third year fellow. After receiving her undergraduate degree cum laude from Harvard University, Dr. Pasricha received her medical degree from Northwestern Feinberg School of Medicine. She completed her residency in internal medicine and received her Masters of Science in Clinical Research (MSCR) in epidemiology at the University of North Carolina at Chapel Hill.

When she isn't working in the clinic, Dr. Pasricha enjoys spending time with her family, traveling, trying new restaurants in the area as well as jogging the American Tobacco Trail.

Dr. Pasricha was one of only two fellows selected by that American Gastroenterology Association (AGA) Academy of Educators to serve on an advisory board with a focus on medication education. She was also one of twenty five fellows selected nationally to present her research at the North American Conference of Gastroenterology Fellows (NACGF). In September, she will be spending a month under the direction of Satish Rao, MD, at Georgia Regents University, on the American Neurogastroenterology and Motility Society (ANMS) Fellowship Rotation.

Dr. Pasricha has had numerous peer-reviewed publications on Barrett's esophagus under the mentorship of Dr. Nicholas Shaheen, including a first-author publication in *Gastroenterology*, the leading gastroenterology journal. Additionally, Dr. Pasricha conducted research with UNC faculty Drs. William Whitehead, Steve Heymen, and Olafur Palsson on barriers to seeking care for accidental bowel leakage in

adults who are living in the community (not in skilled nursing or assisted living communities). At Digestive Disease Week (DDW) 2015, she presented her research on gender differences in reporting accidental bowel leakage to a health care provider. Based on a nationwide U.S. online survey of adults with bowel leakage, she found that men reported experiencing this problem at a younger age and that men were more likely than women to report worsening of the frequency of bowel accidents. Other important information gained from this research study includes;<sup>[1]</sup>

1. Both men and women report that they decrease the amount of food they ate before leaving their house (99% men versus 94% women), however men more often reported not eating at all when socializing outside the house (56% men versus 35.2% women) to prevent bowel accidents.
2. Men with accidental bowel leakage were more concerned about or afraid to have sex than women (59.5% men versus 40.5% women).
3. There were also similarities between men and women: (75%) in that they both actively seek out the location of bathrooms whenever they go to a new location.

When asked about most effective forms of communication between patients and physicians, Dr. Pasricha said,

*"A good relationship between patients and their medical providers depends on trust and communication. Patients can help their care by providing a list of their medications and having an idea of their prior work up. Sometimes it can take a few sessions for the work up to be completed. Our goal is to work together as a team to best manage patients' medical care."*

Additional information about the fellows studying at UNC Chapel Hill Department of Gastroenterology can be found on Pgs 14-15.

1. Pasricha S, Heymen S, Palsson OS, Whitehead WE. Men report more severe fecal incontinence symptoms than women: Patients' perspective. 2015. *Gastroenterology*: 128(4); Suppl 1 S302-303.

## LEADING EUROPEAN GASTROENTEROLOGIST TO VISIT UNC: CONTINUED FROM COVER



of Neurogastroenterology & Motility. His main research areas include functional GI disorders, including pathogenesis and pathophysiology, new alternative treatments, quality of life of patients with GI disorders, and links between inflammation, microorganisms in the gut, and GI symptoms.

Dr. Simren has worked with the Center on several occasions in the past. In 2013, he participated in the Center's first CME program, "How to treat IBS effectively: Expert Update for Health Professionals." In addition, a nurse in Dr. Simren's clinic, Pernilla Jerlstad, spent two weeks training with Drs. William Whitehead and Steve Heymen to learn more about UNC's biofeedback clinic with the goal of establishing a pelvic floor biofeedback clinic in Gothenburg.

During his year at UNC, Dr. Simren will be giving lectures for GI Grand Rounds as well as leading educational conferences for the GI fellows core curriculum series.

We are looking forward to collaborating on research with Dr. Simren as his research interests align closely with the Center's mission to support research and patient care for functional GI and motility patients.

When asked about a recent publication he co-authored [1], Dr. Simren gave the following interview on FODMAPs, bacteria in the GI tract, and inflammation in the intestine.

**Question:** How does a diet high in FODMAPs interact with gut microbiota and consequently the symptoms that may occur as a result?

**Answer:** FODMAPs are carbohydrates that are incompletely absorbed in the small intestine and when these food constituents reach the colon they increase water retention through their osmotic activity and they are fermented by bacteria which leads to gas production - both these events lead to intestinal distension, which can generate GI symptoms. Based on this a number of

trials with diets low in FODMAPs have been performed in patients with IBS with favorable results, but at this stage more trials are needed in order to see how this treatment strategy compares with other IBS treatment options, as well as with other dietary advice given to patients. For instance, we have a paper just accepted for publication in *Gastroenterology* where we demonstrate that a diet low in FODMAPs reduces symptoms of IBS as well as traditional dietary advice. [2]

**Question:** Do microbiota colonies change in diversity/quantity when an individual changes from a high FODMAP to a low FODMAP diet?

**Answer:** There are so far no studies demonstrating that a low FODMAPs diet are beneficial for the gut microbiota; on the contrary some studies have shown that consumption of a diet low in FODMAP may reduce bacteria that are beneficial to the colon. Therefore, eating too little FODMAPs during longer periods of time may be harmful in the long run, but this has to be studied in greater detail before making general recommendations. However, at this stage it should be clear that we only have short term trials of a low FODMAPs diet, so advising people to stay on extreme forms of these diets for months/years is not advisable until we have more safety data.

**Question:** Is low grade inflammation and/or cytokine activation related to disturbances of gut microbiota colonies?

**Answer:** This is not yet known from human studies, but studies assessing this in animal models implicate an association between gut microbiota alterations and immune disturbances. There are also indications from one human study though that gut dysbiosis is associated with altered immune and barrier function in the gut.

1. 1. Gut Microbiota as Potential Orchestrators of Irritable Bowel Syndrome. *Gut and Liver*, Vol. 9, No. 3, May 2015, pp. 318-331
2. Diet low in FODMAPs Reduces Symptoms of Irritable Bowel Syndrome as Well as Traditional Dietary Advice: A Randomized Controlled Trial. *Gastroenterology* 2015

## COMPLEMENTARY AND ALTERNATIVE MEDICINE (CAM) FOR FGIDS

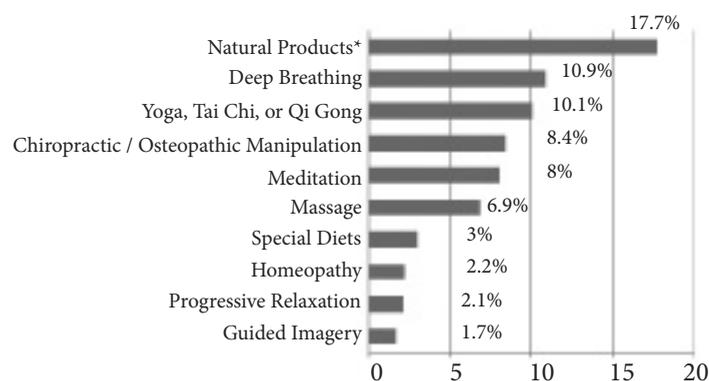
together with conventional medicine and alternative means using in place of conventional medicine.[6] CAM alternative medicine and therapies include yoga, mindfulness, psychological interventions, herbal supplements, and diet modification. [1,3] This article is intended to provide a brief overview of the most popular types of CAM interventions. You should always consult your physician prior to taking any over-the-counter medication or herbs as there may be potential adverse reactions or drug interactions that can occur. For additional information or for a referral to a specialist, consult with your primary care provider.

### Yoga and Exercise

Yoga has been practiced for centuries but few clinical research studies have investigated its effectiveness at reducing FGID symptoms. As seen in the graph below, yoga was listed as the third most common CAM in 2012.[7] Serum levels of insulin-like growth factor – 1 (IGF-1) were significantly higher in post-mindfulness-based stress reduction (MBSR) which include yoga or sitting meditation.[4] This is important as IGF-1 has anti-inflammatory properties that limit or reduce inflammation and play a large role in intestinal epithelium and smooth muscle cells in the gastrointestinal tract.[5] It is also the only growth factor that improves the regeneration of sensory and motor nerves in animals.[10]

Research has also shown that physical exercise can increase levels of IGF-1 and brain-derived neurotrophic factor (BDNF). These two chemicals play a pivotal role in the function of the hippocampus, as this is the area of the brain that researchers describe as responsible for depression.[9] When acting together, these two chemicals can produce anti-depressant like effects on the brain and may also decrease anxiety.[9,10] It is also

10 Most Common Complementary Health Approaches Among Adults in 2012[6,7]



\*Dietary supplements other than vitamins and minerals.

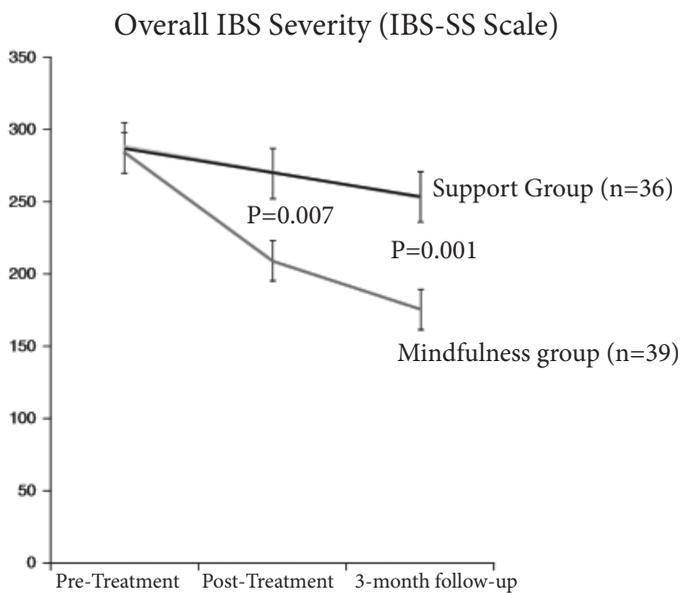
worth noting that men and women who practiced yoga saw reduced weight gain.[11]

### Psychological Interventions

Psychological interventions have also been clinically proven to help reduce symptoms of FGIDs. Examples of interventions include mindfulness, cognitive behavioral therapy (CBT), and gut-directed hypnosis. Overall, psychological interventions resulted in significant changes in IBS severity, quality of life, and abdominal pain.[12]

Mindfulness is an important CAM to consider for symptom reduction in FGIDs. Mindfulness was originally developed from the teachings of early Buddhism and involves techniques of intentional self-regulation of attention to present-moment experiences, using breathing as a focal point, and letting go of cognitive fixations on events that happened in the past or anxiety over future events.[8] The University of North Carolina Chapel Hill Center for Functional GI and Motility Disorders and the UNC Integrative Medicine Program conducted a randomized controlled trial of mindfulness' impact on reducing the severity of IBS in women. Participants who were in the mindfulness group reported significantly reduced IBS severity (IBS severity was reduced by 26.2%) than the women who were only in a support group (IBS severity was reduced by 6.2%).[8] This effect continued 3-months after initial treatment as the mindfulness post-treatment group saw a 38.2% reduction in IBS severity versus 11.8% in the support group.

Cognitive behavioral therapy (CBT) has been proven in multiple studies to be effective at reducing symptoms of FGIDs.[12] The therapy is based around the idea that thoughts or memories surrounding an event causes the patient to experience stress, anxiety, or depression, which may have a direct effect on physical symptoms such as abdominal pain, diarrhea, or nausea. The therapist's job in teaching CBT is to help patients recognize which thoughts trigger the behavior or emotion and explain how it impacts the patient's symptoms. In essence, the goal is to break the cycle of maladaptive behaviors and occurrence of GI symptoms. [22] In efforts to help reduce clinic visits and economic burden, recent studies have looked into therapies that a patient can practice on their own, with minimal interaction with a therapist. Eighty-three percent of individuals who were assigned to participated in a self-managed CBT course in conjunction with usual care from their primary care provider saw improvements in their IBS symptoms versus the control group (only received usual care from their primary care provider)



Graph showing the reduction of IBS symptom severity in the mindfulness group as compared to the support group.[8]

where only forty-nine percent reported improvement in their symptoms.[13]

Hypnosis is a special mental state in which the patient becomes more receptive to suggestions offered by the clinician. The goal is to change the way the patient perceives psychological and physical symptoms to lessen the impact of stress on GI symptoms and pain perception. A randomized controlled trial of patients reporting moderate to severe IBS symptoms compared gut-directed hypnotherapy to a control group and found that hypnosis significantly reduced the patients' IBS symptoms. Before treatment, 23.9% of hypnotherapy and 25% of controls had mild to moderate IBS, and after 10 treatment sessions, 73.1% of hypnotherapy and 45.5% of controls reported having mild or moderate IBS symptoms.[14]

### Supplements, Herbs, and Diet

There are many supplements and herbs that are currently marketed in grocery stores, pharmacies, and big box stores. However, clinical research into their efficacy is still being conducted. Supplements and herbs are not regulated by the FDA and are not scrutinized under the same lens as pharmaceuticals for adverse events, medication interactions, or how well they work. You should always consult with your care provider before starting a new supplement.

A few examples of individual herbs identified in clinical trials that improved FGID symptoms were enteric-coated peppermint oil, tumeric extract, chios mastic gum, ginger, and artichoke leaf extract.[15,16,17] Peppermint oil is commonly used by IBS patients. It acts as a smooth muscle relaxant, which may help reduce

GI symptoms, but it may also cause a worsening in esophageal reflux symptoms.[17] Moreover, there have been reports of allergic reactions, GI side effects, and acute illnesses requiring hospital stays due to taking various herbs.[16] There are no clear indication of how rare or common any risks may be as they are not monitored by the FDA. This is an area where research shows great promise for the treatment of FGID symptoms, but needs more clinical research to show which herbs provide the safest and best results.

Probiotics are made up of bacteria that may provide a health benefit to those who take it. It is thought that probiotics introduce strains of gut bacteria that crowd out and limit the growth of other microbes and help break down complex carbohydrates into lactic acid and butyrate, which in turn improves the integrity of intestinal epithelium and tight junctions within the intestinal wall.[18,22] Previous research has suggested that probiotics may have an effect at reducing abdominal pain, bloating, diarrhea, and flatulence.[15]

Selecting foods that are not only nutritionally beneficial to your body but are easy to digest, may also be helpful for reducing GI symptoms. This can include reducing foods that contact high FODMAPS, eating a well balanced diet, and consulting a nutritionist. FODMAP is an acronym for Fermentable Oligosaccharides, Disaccharides, Monosaccharides And Polyols. A full list of high FODMAP foods and low FODMAP substitutes are available in the Winter 2014 Digest, which is available online at [www.med.unc.edu/ibs](http://www.med.unc.edu/ibs).

Kate Scarlata, a registered dietician and published author on FODMAP foods, defines FODMAPs as;

“...small commonly malabsorbed carbohydrates that can pull water into the intestine and are rapidly fermented by gut bacteria contributing to gas. When water and gas expand the intestine, this can contribute to pain. FODMAPs are found in everyday foods from apples, pears, garlic, onion, wheat, and even in honey! The effects of FODMAPs are cumulative; you might be able to tolerate some but if you eat too many at the same time your belly may pay the price.”

Kate recommended on her blog several recipes, including low FODMAP entrees, side dishes, and desserts.[20] In addition to Kate Scarlata, Crystal Zaborowski Saltreli, CHC, who specializes in gastroparesis, also recommended recipes specifically for gastroparesis patients.[19]

A recent study examining children diagnosed with IBS looked at GI symptom differences between a FODMAP diet and a typical American childhood diet (TACD). Fewer daily abdominal pain episodes on the low FODMAP diet were reported than the TACD diet, and when the children crossed over from the low FODMAP diet to the TACD diet, the abdominal pain symptoms increased.[21] Additionally, research has suggested that the FODMAP diet is more effective than traditional dieting advice at reducing abdominal pain. [22]

The goal of a FODMAP diet is to find what foods trigger symptoms. Not everyone will react to the same food the same way. It is also not meant for long periods of time but rather as a form of food trial and error. After eating a low FODMAP diet for a trial period, try adding foods back one at a time to see if any GI symptoms return. The purpose of adding one food at a time is to see if any of the foods trigger symptoms.

If you are interested in talking with a certified nutritionist, there are several available resources to patients who live near Chapel Hill, Raleigh, and the surrounding area. UNC has nutritionists, such as Susannah Southern, RDN, LDN, (call for an appointment at 919-966-0210, or for further information, email at Susannah.southern@unchealth.unc.edu.) who offers GI specific nutrition advice. In private practice, Leslie Gaillard, MPH RD LDN, has a clinic in Durham, NC ([www.lgnutrition.com](http://www.lgnutrition.com)) that specializes in food intolerances, gastroparesis, IBS, and other diseases and disorders. If you are not close to the above listed resources, you can also use <http://www.eatright.org/programs/rdnfinder/> to locate a registered dietician near you.

Medical foods are a novel type of treatment for patients with FGIDs. EnteraGam is an orally administered medical food that requires a prescription from a physician. It is made from serum-derived bovine immunoglobulin/protein and is thought to play a role in normalizing bowel function and gut microflora.[23] In clinical research studies, EnteraGam improved stool consistency, abdominal pain, bloating, and urgency. [23]

There are multiple ways that you and your physician can work together to help manage your GI symptoms. It is a team effort to find which combination of pharmacological, complementary, or alternative treatments would be best for you.

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## RESEARCH SUBJECTS NEEDED

### Diagnostic Evaluation of Functional GI and IBS Networks (DEFINE)

The UNC Center for Functional GI and Motility Disorders is looking for eligible subjects to participate in the DEFINE study.

You may be eligible to participate if:

- You have experienced any of the following GI symptoms for at least 3-6 months without a definitive diagnosis:
  - Abdominal pain or discomfort
  - Bloating
  - Constipation
  - Diarrhea
- You have not had any definitive testing for your GI symptoms
- You are at least 18 years of age

Eligible participants may receive up to \$214 for time and travel.

Study Title: The development and validation of a blood test to identify IBS: DEFINE (Diagnostic Evaluation of Functional GI and IBS Networks)  
IRB #13-2900

**Principal Investigator**  
**Dr. Yehuda Ringel,**  
**MD**

### Contact Information

Charles McLendon  
919-843-1003  
aycockmc@email.unc.edu

## CAUSES OF SYMPTOMS STUDIES

## NICK TALLEY, MD VISITS UNC ON ROME FOUNDATION VISITING PROFESSORSHIP AWARD



Dr. Nicholas J. Talley, Laureate Professor and Pro Vice-Chancellor of Global Research at the University of Newcastle in Australia, visited UNC on Monday May 11-13. He is one of the world's most respected leaders in functional gastroenterology, specializing in functional dyspepsia and irritable bowel syndrome.

While at UNC, Dr. Talley gave two talks, the first to GI faculty and GI fellows at the monthly fellows core curriculum conference titled, "Functional Gastrointestinal Disorder – Diagnosis and Management," and the second for Gastroenterology Grand Rounds titled, "Pathways in Gut-Brain Communication: Evidence for Distinct Gut-to-Brain and Brain-to-Gut Syndromes."

## UNC INVESTIGATORS IN THE NEWS

### UNITED EUROPEAN GASTROENTEROLOGY WEEK

OCTOBER 24-28, 2015  
BARCELONA, SPAIN

The United European Gastroenterology Week (UEGW) is the largest GI meeting in Europe with an expected 14,000 medical professionals and researchers to attend this year. The University of North Carolina will be well represented with three oral presentations and two poster presentations.

Tuesday, October 27

**Abstract Title:** The Restore-4 study: A double-blind, randomized, placebo-controlled, parallel-group phase II study assessing the efficacy and safety of ONO-2952, a novel an selective antagonist of translocator protein.  
**Presenting Author:** William Whitehead  
**Location:** Room E1

Tuesday, October 27

**Abstract Title:** Principal component analysis (PCA) with replication confirms four independent etiological factors in Irritable Bowel Syndrome (IBS)  
**Presenting Author:** William Whitehead  
**Location:** Room B3

Monday, October 26

**Abstract Title:** Constipation symptoms in the U.S. general population: Results from the Rome normative gastrointestinal symptoms survey (RNGSS)  
**Presenting Author:** Olafur Palsson  
**Location:** Room E1

Monday, October 26

**Abstract Title:** The frequencies of both hard and soft stools are major risk factors for fecal incontinence  
**Presenting Author:** Olafur Palsson  
**Location:** Poster Area

**Abstract Title:** Excess medical diagnoses in families of patients with irritable bowel syndrome (IBS)  
**Presenting Author:** Olafur Palsson  
**Location:** Room Poster Area

### NORTH AMERICAN SOCIETY FOR PEDIATRIC GASTROENTEROLOGY, HEPATOLOGY AND NUTRITION (NASPGHAN)

OCTOBER 7-11, 2015  
WASHINGTON, D.C.

Friday, October 9

**Invited Presentation:** Functional Abdominal Pain: Implementing nonpharmacologic therapies into your practice.  
**Presenting Author:** Miranda van Tilburg will co-present with Bruno Chumpitazi, MD

Saturday, October 10

**Invited Presentation:** Abdominal Pain: Integrating Psychological treatments into medical care  
**Presenting Author:** Miranda van Tilburg

Saturday, October 10

**Invited Presentation:** Parent-only intervention reduces symptoms and disability in abdominal pain patients.  
**Contributing Authors:** Levy, Rona L; Van Tilburg, Miranda; Langer, Shelby L; Romano, Joan M; Mancl, Lloyd A; Whitehead, William E; Feld, Shara A; Walker, Lynn S.

## WHERE CAN I FIND INFORMATION ON PARTICIPATING IN A CLINICAL TRIAL?

Clinical trials are the gateway to learning novel information about new pharmaceuticals, medical devices, efficacy of complementary and alternative medicines, psychological therapies, or finding the cause of a disorder. The very heart of clinical trials beats because of volunteers who participate in research to help further our knowledge into clinical and academic endeavours.

There are several ways to find out more information about how to participate in a clinical research trial. As with all research studies, it is completely voluntary and you make the decision to participate. If at any time you have questions about a research study, you can always contact the research coordinator, study investigator, or the institutional review board (IRB). You should never feel coerced or pressured to participate in a research study. You also have the right to remove yourself from the research at any time and for any reason. The research investigator also has the ability to withdraw you from a study if s/he believes that it is unsafe for you to continue to participate. After all, your health and safety is paramount.

UNC Chapel Hill has a website specifically designed to match researchers to eligible research participants. This includes individuals who are healthy and looking to participate as a control and those with specific diseases or symptoms.

Join the Quest (<https://jointhequest.org>) helps research participants search through the open clinical trials within the University of North Carolina at Chapel Hill. The research studies vary and include surveys, drug clinical trials, device clinical trials, procedure clinical trials, medical outcome studies, and research which needs healthy volunteers, which may also be referred to as a “control.”

Another resource available to patients who do not live near Chapel Hill is [www.clinicaltrials.gov](http://www.clinicaltrials.gov). This is operated under the National Institutes of Health (NIH) and has information about clinical research studies available in the United States and globally. As of July 31, 2015, there were 86,702 studies in the United States and 12,658 were in North Carolina alone.

Most studies that involve a drug, device, or procedure

must report their findings to the FDA if they want their product to be approved for sale. To learn more about the FDA’s role in clinical trials, visit <http://www.fda.gov/ForPatients/ClinicalTrials/ucm20041753.htm>

The FDA also offers a simplified step by step process of how the drug approval review process is completed. The steps are listed below.[1]

1. Pre-clinical (animal) testing.
2. An investigational new drug application (IND) outlines what the sponsor of a new drug proposes for human testing in clinical trials.
3. Phase 1 studies (typically involve 20 to 80 people). These test the safety of the compound.
4. Phase 2 studies (typically involve a few dozen to about 300 people).
5. Phase 3 studies (typically involve several hundred to about 3,000 people).
6. The pre-NDA period, just before a new drug application (NDA) is submitted. A common time for the FDA and drug sponsors to meet.
7. Submission of an NDA is the formal step asking the FDA to consider a drug for marketing approval.
8. After an NDA is received, the FDA has 60 days to decide whether to file it so it can be reviewed.
9. If the FDA files the NDA, an FDA review team is assigned to evaluate the sponsor’s research on the drug’s safety and effectiveness.
10. The FDA reviews information that goes on a drug’s professional labeling (information on how to use the drug).
11. The FDA inspects the facilities where the drug will be manufactured as part of the approval process.
12. FDA reviewers will approve the application or issue a complete response letter.

The Center for Functional GI and Motility Disorders has research opportunities for pediatric and adult patients and will add more throughout the year. You can find more information about these studies online at <http://www.med.unc.edu/ibs/research/research-subjects-needed>

1. FDA’s Drug Review Process: Continued. <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm289601.htm>. Accessed August 3, 2015.

## TWO NEW FDA- APPROVED MEDICATIONS FOR DIARRHEA-PREDOMINANT IRRITABLE BOWEL SYNDROME

OLAFUR S. PALSSON, PSY.D.



*Dr. Palsson is a clinical psychologist and health researcher with a long-standing interest in the relationship between mind and body in the determination of health and illness. Dr. Palsson is an internationally recognized expert in the use of hypnosis for gastrointestinal disorders. He developed a unique standardized*

*hypnosis treatment protocol for treating irritable bowel syndrome, which has been tested in a number of published studies and is used by hundreds of clinicians throughout the U.S. and several other countries.*

Irritable bowel syndrome is one of the most common health problems of the gastrointestinal tract, affecting 10 to 15 percent of all adults. Drug treatments for this problem have been investigated for decades, but in spite of intensive research and large unmet needs, very few medications have been found to be sufficiently safe and effective to be approved in the U.S. for treating IBS. Moreover, the few medications that have been approved for IBS treatment have only been for certain subsets of patients with the disorder rather than for IBS in general.

Until May of this year, there were only three medications in use that had current approval as IBS treatments by the U.S. Food and Drug Administration (FDA).[1] These are (1) alosetron (Lotronex), a drug used for female IBS patients with treatment-refractory severe diarrhea, which slows the movement of stools through the intestines; (2) lubiprostone (Amitiza), which increases fluid secretion into the intestines and is used for constipation-predominant IBS (and also chronic constipation without IBS); and (3) linaclotide (Linzess), a medication for constipation-predominant IBS and chronic constipation without IBS, which makes bowel movements more frequent and reduces pain and bloating.

On May 27, however, the arsenal of IBS-specific drugs expanded significantly, with the first-ever simultaneous approval of two new medications for IBS by the FDA. These new drugs were both approved for IBS with

diarrhea (IBS-D) specifically, but they are very different in nature and work in entirely different ways in the body.

One of them, rifaximin (Xifaxan)[2], is an antibiotic (bacteria-killing) medication that stays in the bowel but is not absorbed into the tissues of the body. It is taken orally three times a day for 14 days. It has been shown to improve diarrhea and abdominal pain significantly in IBS. Patients who experience a recurrence of symptoms after they finish their treatment course can be re-treated with additional 14 day treatments, up to two times. Although rifaximin is newly approved in IBS-D treatment, it was previously approved as treatment for travelers' diarrhea caused by E. coli bacteria, as well as for some liver problems. Because it is in use for other purposes, rifaximin is already available and can be prescribed for IBS. Common side effects of rifaximin are nausea and increase in liver enzymes in the blood. The latter indicates that it could adversely affect the liver of some people with impaired liver functioning, so this medication will not be suited for those individuals.

The other new IBS medication, eluxadoline (Viberzi) [3], works on receptors in the nervous system and causes the bowel to reduce its contractions. It is taken twice a day with food. Like rifaximin, it reduces both abdominal pain and diarrhea. One limitation of this medication, however, is that it is a narcotic (or opioid) drug, which is a class of medication that generally has some addiction and abuse potential. It will therefore have to be treated as a controlled substance, but the FDA has yet to decide how strictly the use of this medication will be controlled. This will take some time to sort out, but eluxadoline is expected to be available for prescription next year (2016). The most common side effects of this medication are nausea, constipation, and abdominal pain.

It remains to be seen from experience how widely these new medications will be prescribed for IBS-D and how broadly they will be embraced by patients. There are some reasons to believe that they hold a relatively limited promise for IBS treatment. This is first of all because they only are suited for treating IBS-D, which is a subtype of IBS that constitutes a minority

of individuals with the disorder. Secondly, the large outcomes research studies on which FDA approval for these medications was based show that they help less than half of the IBS-D patients in those trials. Only 41%[2] of patients gained adequate relief of their IBS symptoms from rifaximin, and 24-45%[3] of patients tested on eluxadoline showed treatment response according to FDA outcome criteria.

Thirdly, these medications will have to compete with already available inexpensive non-prescription anti-diarrheal medications, such as Imodium, that are not specifically approved for IBS but which IBS patients nonetheless sometimes use to treat diarrhea symptoms.

However, both of these new medications are certainly welcome addition to the very limited range of prescription drug options approved by the FDA for IBS in the U.S., and the pharmaceutical companies who made these, Valeant/Salix (rifaximin) and Actavis/Allergan (eluxadoline) deserve much credit for their persistence and innovation in bringing these new options to market in this greatly underserved therapeutic area. Diarrhea is a highly distressing and often unpredictable symptom that can in some cases limit the lives of IBS patients substantially, for example by reducing their ability to travel, work or participate in social activities. The only FDA approved medication that has been available for IBS-D until now, Lotronex, is so restricted in its use that it is not even an option for most patients (i.e., it is only approved for women, only for patients with severe symptoms, and only to be used after those patients have proven unresponsive to other treatment)[4]. Therefore, these new treatment options will without doubt be very welcome news to the many IBS patients who have pronounced symptoms of diarrhea and pain, and to the doctors who until now have had few good pharmaceutical options for helping those individuals.

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## UNC GASTROENTEROLOGY FELLOWS



**Maisa I. Abdalla, MD, MPH**

Dr. Abdalla is an advanced training fellow in the Division of Gastroenterology. She received her medical degree from the University of Jordan, completed her internal medicine residency at Advocate Christ Medical Center and completed her gastroenterology fellowship at

University of Rochester, NY. Dr. Abdalla's clinical interests include quality measures and improving health outcomes for inflammatory bowel disease patients.

When asked about most effective forms of communication between patients and physicians, Dr. Abdalla said,

*"Inflammatory bowel disease as any of the other chronic illnesses require close collaboration between the patient and the treating physician. The first encounter between the two is usually the beginning of a long, sometimes lifelong relationship. For such relationships to succeed, measured by the patient's satisfaction and clinical outcome, both parties should be fully invested and dedicated. They need to be honest, forward and work together as a team. I would ask my patients to feel comfortable asking questions, try to understand the rationale of any treatment option I may propose and bring on any concerns for discussion."*



**Swathi Eluri, MD, BS**

Dr. Eluri is a second year gastroenterology fellow in the Division of Gastroenterology. She received her medical degree and completed her residency at Johns Hopkins University

School of Medicine. Her clinical interests include esophageal diseases and inflammatory bowel disease.

When asked about most effective forms of communication between patients and physicians, Dr. Eluri said she would like patients to,

*"maintain an open line of communication to discuss any issues that they would like with me."*



**Asher Wolf, MD MPH**

Dr. Wolf is a second year gastroenterology fellow in the Division of Gastroenterology. He received his medical degree from the University of North Carolina at Chapel Hill and completed his MPH at Yale University School of Epidemiology and Public Health. His clinical interests include eosinophilic esophagitis and nutrition. His academic interests also include socioeconomic determinants of disease outcomes and interactions of diet and gastrointestinal disease. Dr. Wolf has taught clinical epidemiology to medical students at UNC Chapel Hill as well as held the position of Senior Research Associate at the Center for Science in the Public Interest in Washington D.C.



**Diane Arsene, MD**

Dr. Arsene is a first year gastroenterology fellow in the basic science tract of the Division of Gastroenterology. She received her medical degree from the University of Miami Miller School of Medicine and completed her post graduate and internal medicine residency training at Los Angeles County and USC Medical Center. Dr. Arsene's clinical interests include IBD, hepatology, and gastroenterology as a whole.

When asked about most effective forms of communication between patients and physicians, Dr. Arsene said,

*"I'd encourage them to bring as many questions as come to mind to each appointment and to bring a list of current medications, supplements, and over-the-counter medications they are taking. I'd also ask them how I can better assist them in addressing concerns their primary care physicians may have and how to best communicate with them."*

## UNC GASTROENTEROLOGY FELLOWS



**Neil Shah, MD**

Dr. Shah is a second year gastroenterology fellow in the Division of Gastroenterology. He received his medical degree at the University of North Carolina School of Medicine and completed his residency at University of Virginia Health System. While in residency at UVA Health System, he volunteered as a clinic provider at the Charlottesville Free Clinic. Dr. Shah's clinical interests include chronic liver disease, anticoagulation in liver disease, medical education, and latino health.

Dr. Shah is originally from Charlotte, NC and has a sister who is currently studying pharmacy at UNC-Chapel Hill. He loves spending time outdoors and is an avid sports fan. He particularly loves football, basketball and soccer.

When asked about most effective forms of communication between patients and physicians, Dr. Shah said,

*"Take responsibility for your own health. I am here as a guide to help you become more healthy, but ultimately you are the one that can make yourself feel better. That includes taking all of your medicines as prescribed, bringing your medicines to each appointment, coming to appointments on time, getting studies/labs performed when asked and taking my advice when it comes to behavior changes.*

*Communicate with me when you are having difficulties. In today's age, there are a lot of ways to get in touch with another person and the same applies with the medical world. If you can't get in touch with me via phone, then you can now e-mail me or even use our electronic medical record system to send a message to me directly. But keeping in communication with me, I can help you out the most and tackle problems before they get out of hand."*



**Craig Reed, MD**

Dr. Reed is a first year gastroenterology fellow in the Division of Gastroenterology. He received his medical degree at Wake Forest University. He completed his internal medicine residency at the University of North Carolina at Chapel Hill. Dr. Reed's clinical interests include the socioeconomic factors affecting medical care and the disparities in health care practice and outcomes.

Dr. Reed describes himself as a true North Carolinian. His hobbies include running, watching UNC basketball, and playing the guitar.

When asked about most effective forms of communication between patients and physicians, Dr. Reed said,

*"I believe that it is paramount to ensure that patients have an understanding of their disease process and treatment options. As such, a patient is empowered to make informed decisions. The teach-back method helps to ensure that I have clearly conveyed medical information. I attempt to stress the patient's right to autonomy ensuring they do not feel coerced into decision making.*

*I hope to make both myself and a patient accountable in the therapeutic relationship. I hope to emphasize that I will do my best, ie staying up-to-date on medical practices, but I hope that the patient will be forthright in their participation in care (taking meds, lifestyle changes, etc.)."*

## FUNCTIONAL GI QUESTION AND ANSWER

This section of the Digest is specifically for patient submitted questions that are answered by UNC faculty, gastroenterologists, or external experts in their respective fields. If you have a question you would like to be answered, please submit them us!

E-Mail: sjeremia@med.unc.edu  
 Twitter: @FGIFYI  
 Mail: 4161-G Bioinformatics Building  
 ATTN: Stefanie Twist, CB#7080  
 130 Mason Farm Rd  
 Chapel Hill NC 27599

### Question from a patient:

For patients with gastroparesis, why does drinking, even sipping, plain water sometimes make symptoms of nausea or vomiting worse compared to sipping juice, frozen drinks, and smoothies?

### Answer from Danielle Maier, PA-C:

Honestly, it might be partially a functional issue, but also there is quicker absorption of fluids when they are mixed with salts, small amount of carbohydrates and other electrolytes. So, other fluids tend to be absorbed a little more quickly as opposed to just water, which may sit for a little longer in the stomach and cause more issue with patients that have a significant delay in their emptying.

The difference in the osmolality of water vs other mixed fluids may also have something to do with absorption rates as well.

The same idea applies as to when you are recovering from a nausea and vomiting bug; most people will have a better response with a small consumption of something like Gatorade vs plain water.

But remember that when the carbohydrate percent in what you drink goes above 6%, gastric emptying and absorption may be slowed. This is why regular Gatorade is at 6% carbohydrates, and mixture of electrolytes maximizes absorption and rehydration. More complex carbs or beverages that have higher than a 6% composition of carbs or other ingredients like fats actually slow down emptying.

Emptying water from the stomach into the duodenum is inversely related to volume. Higher volume, quicker emptying; smaller volume, slower emptying. Due to osmotic gradient, water is not absorbed as quickly as you might think.

Research surrounding gastric emptying and absorption can be found at <http://jap.physiology.org/content/84/5/1581>

### Question from a patient:

Are there any new promising medications?

### Answer from Sarina Pasricha, MD:

This is an exciting time to be in medicine as there are lots of new clinical trials and drugs emerging. One of the latest drugs on the market is Movantik (naloxegol). This is an oral medication for opioid-induced constipation. I should emphasize that constipation is a well-known side effect of opioids. Our primary recommendation for patients with constipation on opioids is always to try to diminish and ideally terminate any opioid use. However, in certain situations this is not possible.

Opioids bind to  $\mu$ -opioid receptors in the enteric nervous systems (nerves in the walls of the gut). This has multiple effects on the gastrointestinal system including delaying gastric emptying, increasing non-propulsive intestinal contractions, delaying intestinal and colonic motility time, and limiting water and electrolyte secretion into the intestinal lumen (1, 2). Many of these mechanisms can cause and worsen constipation.

Naloxegol is an oral medication taken daily that acts peripherally as a  $\mu$ -opioid receptor antagonists. (blocker) Therefore, it does not cross the blood-brain barrier. In double-blind studies, patients who received naloxegol were less likely to experience constipation compared to the placebo group (3). Importantly, patients were still able to maintain the analgesic effect of the medication so their pain continued to be controlled.

## FUNCTIONAL GI QUESTION AND ANSWER

### **Question from a patient:**

I have gastroparesis. What information would help me decide between enteral feeding tubes versus total parenteral nutrition (TPN)?

### **Answer from Sarina Pasricha, MD:**

Enteral nutrition is defined as a method of feeding in which the gastrointestinal (GI) tract is used to obtain some or part of a person's caloric intake. Enteral feeding is typically the preferred method for obtaining nutrition and hydration. If oral feeding is unable to be achieved, then gastrostomy tubes or jejunostomy tubes can be placed so that patients continue to achieve enteral feeding. In patients with gastroparesis, we often place a jejunostomy tube instead of gastrostomy tube to bypass the delayed gastric emptying of the stomach.

Total parenteral nutrition (TPN), in which nutrients are injected directly into the blood stream, is not usually recommended, but in patients unable to tolerate enteral feeding this becomes necessary. There does not appear to be any difference in mortality in patients with enteral or parenteral nutrition. However, a meta-analysis of 6 randomized trials showed that patients on TPN are more likely to develop an infection compared to patients obtaining enteral feeding (4).

If you are unable to maintain appropriate hydration with oral intake, then receiving water through a vein (IV) may be necessary. However, your doctor will determine whether you need a hydration port based on your labs and clinical exam.

### **Question from a patient:**

How can patients and their support teams have their voices heard?

### **Answer from Sarina Pasricha, MD:**

Trust, open communication, and respect are crucial in the development of a good physician-patient relationship. As physicians, we want to make sure that our patients' opinions and thoughts are heard. We greatly value input from patients and their support teams since this information is used to help guide our clinical treatment plan. I do want to point out, however,

that time in our clinic visits are often limited. Therefore, in order to make best use of the time and to make sure that patients have their voices heard, I recommend that patients and their support teams write down areas of concern and questions for their physicians ahead of time and bring this in to the clinic visit. This ensures that important details and questions that the patients have are not forgotten in the office setting. I advise my patients to focus on the 2-3 most important points that they want to address in clinic.

Please remember that this relationship is a partnership. Many patients have complicated medical problems that have been ongoing for years. There is often no "quick fix" or "magical pill" to suddenly get rid of the symptoms. It often takes time, diagnostic testing, and multiple clinic visits to understand what is the cause of the symptoms. We are here to provide guidance and work along side patients to provide relief.

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**Ryan Madanick, MD**

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Director, GI Motility Lab

**Lisa Gangarosa, MD**

Functional GI Services

**Robin Dever, RN**

Nurse Coordinator

**Danielle Maier, MPAS,  
PA-C**

GI Motility Services

**Jennifer Layton**

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## RESEARCH TEAM

**Steve Heymen, PhD**

Associate Professor of  
Medicine

**Miranda van Tilburg, PhD**

Associate Professor of  
Medicine

**Olafur Palsson, PsyD**

Professor of Medicine

**Christina Campbell**

Research Assistant

**Renuka Kelapure**

Project Manager

**Charles McLendon**

Research Coordinator

**Stefanie Twist**

Center Coordinator



THE UNIVERSITY *of* NORTH CAROLINA *at* CHAPEL HILL  
CENTER FOR FUNCTIONAL GI & MOTILITY DISOR-  
DERS  
CB 7080, Bioinformatics Building  
Chapel Hill, NC 27599-7080

Phone: (919) 966-0144  
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