TREATMENT PROTOCOLS, APPROACH & THINKING

for

Metabolic Syndrome/Obesity/Dysbiosis using Extended FMT Therapy

Designed by

EVELYN TULLY COSTA

Goals: To improve health markers for pre-diabetes, metabolic syndrome and obesity (e.g. elevated fasting glucose, insulin, AIC, triglyceride and weight levels) by administering a series of medically supervised FMTs over a 3 month period using rigorously screened "super donors".

Tracking Methods and Anticipated Outcomes: Monthly blood panel and microbiome DNA screenings to measure any changes in gut flora populations and blood work by correlating and tracking improvements in microbial diversity linked to measurable improvements in health markers.

THE SCIENCE BEHIND FMTs: (LEARN)

Mounting evidence linking disruptions of the gut microbiome (dysbiosis) and a host of chronic diseases is prompting multiple studies, research and treatment possibilities using FMTs and or extracted "human probiotic"(linx to poop pill study) capsules to treat, among other conditions: C.diff infections, Crohn's, ulcerative colitis, IBS, diabetes, metabolic syndrome, high blood pressure, obesity, depression, autism, autoimmune diseases (diabetes Type 1, Celiac, Parkinson's, MS, Rheumatoid Arthritis, certain skin conditions et al).

In addition to FMTs 98% success rates reported for C.diff infections, case studies are producing encouraging observational results for ulcerative colitis and Crohn's in medically supervised, (in some cases) self-administered extended treatments which have proven just as effective as GI supervised, in medical settings. ("How I donated my Stool") Donor and recipient health information regarding these cases is not readily available.

The FMT colonoscopy delivery approach currently used in hospitals and clinics also presents certain draw backs as pre-procedure "purges", antibiotic "flushes" and blending (aerating of fecal matter might very well contribute to less effective results from a microbial stand point if transferring of certain anaerobic organisms is desirable).

These "cleansing" protocols run counter to current research which clearly indicates tampering with existing microbial populations as being counter productive and harmful to restoring healthy gut microbial communities.

While it's understandable for doctors to use procedures and protocols with which they are accustomed, updating clinical practice based on new findings in the microbiome field to colonoscopic FMT procedures need to reflect a more comprehensive understanding of how microbes work within a functioning and dysfunctional gut.

Therefore until the successful development of "poop pills" (link to SER-109 and Massachusetts General Hospital trial) for ailments now linked to dysbiosis I am employing the "Fresh Direct" method as nature seems to have provided the best delivery system of viable communities of gut flora. The question is which ones and in what quantity and from whose gut?

PROPOSED REGIME AND TRACKING METHODS

1. I will take baseline blood tests and gut microbiome readings (using AGPand Ubiome) prior to trial period on a monthly basis leading up to donation period.

2. I will then start with one donor and self-administer FMTs for a 3 month period 3-5x weekly using the “Fresh Direct” method.

3. I will repeat blood and microbiome screenings on a monthly basis to track changes, if any, for 15 months starting at the beginning of donation period.

4. All donors will have their gut flora sequenced by Ubiome and AGP prior to donation period as well as other screenings.

5. Using blood work and microbe sequencing I will try to measure ANY changes in either direction and hopefully just FEEL better.

SUBJECT HISTORY

Subject is 56 year old, previously healthy, athletic, female now presenting with metabolic syndrome, pre-diabetes & obesity all of which developed over the course of 10 years of frequent antibiotic use ending with a full year of antibiotic treatment for chronic Lyme disease during which time her symptoms rapidly escalated.(see Antibiotic History)

After participating in the the American Gut Project’s open source Gut Screening Experiment in 2013 and taking numerous Ubiome screenings her microbiome’s DNA sequenced results revealed, against comparable samples, that her microbiome was severely depleted of entire classes of microbes. Current blood panels do not adequately explain symptoms, adjusting for menopausal changes, unless dysbiosis is taken into account. (LINK: My Story)

Summary Proposal, Questions and Rational:

1. FMT's 98% success rate in treating C. diff by outcompeting the pathogenic organism via the introduction of new communities of microbes seems to indicate a gut specific condition. Chronic C.diff sufferers no doubt have related and worsening health challenges but the action seems confined to the gut considering rapid recovery rates of patients after even just one FMT.

2. Attempts to treat other, more chronic, illnesses with one or two FMT applications have not proven as effective. However, case studies have shown encouraging alleviation of symptoms from longer term applications of FMTs for ulcerative colitis, Crohn's et al. As the FDA currently prohibits doctors from using FMTs for conditions other than C. diff the procedure has gone DIY. The problem with this approach is that existing health data on donors, tracking health markers and taking regular microbiome gut screenings for recipients *is lacking*.

3. For chronic, long term conditions such as mine (pre-diabetes, metabolic syndrome, obesity, GERD etc.) long term application of a donor screened for optimal gut diversity *that pertain to my symptoms* is my goal. I refer to the "Amsterdam Study", POP, and "Why I Donated My Stool". And unless I am misreading the rush to "mine" the microbiome by biotech start-ups et al, my approach, though low tech, follows the same logic. We await with great anticipation the Massachusetts General Hospital "Poop Pill" clinical trial results for obesity. Also looking forward to Seres Theraputics to readjust their recipe for the SER-109 belly flop for their C.diff pill.

4. I am proposing a DIY study on myself that will include useful tracking information. I have "during" and "after" microbiome DNA indicators but can only rely on observational symptoms for the "before" gut flora, base settings excluding blood work.

5. According to recent studies, just *one* course of antibiotics can cause gut microbiome disruptions from 3-12 months. *More* than one course (and many of us have been on more than 2 in our lifetimes) can have *permanent negative impacts* on gut diversity with possible adverse health consequences we are just beginning to realize.

6. I was taking antibiotics 1-3x yearly for 10 years before topping it off with an entire year of antibiotics to fight chronic Lyme that had gone undiagnosed for over a year. Link to antibioitc table

7. My symptoms began SLOWLY emerging (minor weight gain with commensurate rises in blood sugar following multiple courses of antibiotics) then RAPIDLY worsening during and after the Lyme treatment.

8. DNA screenings of my gut flora via Ubiome and AGP show consistant lack of diversity that have corresponding echoes in my symptoms

9. 10 years of antibiotics requires more than sour kraut and yogurt or one FMT. I am proposing a 3 month donation period of 3-5 x weekly FMTs to foster the restoration and colonization of missing microbes which will be tracked over the next 15 months. Will be interesting to see if the Boston Medical dried poop pill clinical trials vs my "Fresh Direct" method will show any similarities and or differences assuming their screening and monitoring methods are similar to mine. (see Seres Health 109 belly flop)

P.S. The Microbiome research community should consider the Lyme patient population as human "germ free" mice. Lyme doctors exist to destroy gut flora and mistakenly (I now believe) call SOME of the resulting post treatment symptoms "chronic" Lyme. Take a look at the long list of symptoms and see if massive dysbiosis doesn't leap out at you. With the depressing rate of failure to alleviate "Chronic Lyme" symptoms I am of the opinion that Lyme patients would FLOCK to any trial that involved gut restoration beyond "just take probiotics"