WHAT IS KNOWN ABOUT FECAL MICROBIOTA TRANSPLANTATION?

by

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ABSTRACT

Introduction

Fecal microbiota transplantation (FMT) is the infusion of a healthy individual's gut microbiota into an individual suffering from a given disease with the intent to cure the disease and return the individual to health. Many studies have been completed, each one analyzing a different question regarding FMT. The aim of this study is to determine what is known about FMT.

Methods

This scoping review gathered sources from the databases of CINAHL, Cochrane, Embase, Epistemonikos, Joanna Briggs Institute, Medline, and ProQuest. Inclusion criteria included English language, all ages, all medical diagnoses, all years, and the impact on all aspects of the microbiome (bacterial, viral, and fungal). Exclusion criteria included studies not conducted under medical supervision, no protocol, and animal subjects. The primary objective is to identify the disease processes treated with FMT and their given outcomes. Secondary objectives include identifying the potential administration routes and outcomes surrounding each one as well as the donors selected for FMT and the impact donor selection has on outcomes.

Results

A scoping review of data available was conducted electronically and 1,251 titles were identified. From these 267 titles were selected for full review after reading titles and abstracts. After full review, 185 titles met inclusion and exclusion criteria for final analysis. Data was extracted from each title by the researcher and supervising professor.

Conclusion

FMT is an effective treatment option for a variety of diseases such as clostridium difficile, graft-versus-host disease, inflammatory bowel diseases, obesity, nonalcoholic fatty liver disease, and slow transit constipation with minimal and mild adverse reactions. New areas of investigation also include universal stool banks as well as other body systems impacted by alterations in gut microbiota and can be cured with FMT. Future studies need to identify a universal protocol for FMT administration and donor selection.

INTRODUCTION

Fecal microbiota transplantation (FMT) a treatment modality in which fecal suspension from a healthy individual is infused into another individual to treat an ongoing disease process (Brandt et al., 2013). While the use of FMT is relatively new in the hospital setting, this type of treatment dates to the 4th century in China. At that time, stool was transplanted through the mouth of individuals suffering from food poisoning or diarrhea. Veterinary practice utilized FMT in the 17th century, but the first reported use of FMT in humans occurred in the 20th century and was administered by way of fecal enema to treat pseudomembranous colitis. The Food and Drug Administration (FDA) approved the use of FMT in 2016 in the United States and research has continued since then (Yoshimatsu et al., 2021).

Many studies have been completed on FMT; however, each of these studies focuses on a different disease process, method of administration, or donor pool. FMT has been used to treat clostridium difficile infection (CDI), inflammatory bowel disease (IBD) including Crohn disease and ulcerative colitis (UC), irritable bowel syndrome (IBS), slow transit constipation (STC), and a variety of other gastrointestinal and non-gastrointestinal related diseases. The gut microbiome serves an important role in the overall health and wellbeing of individuals, and small alterations in the microbiome result in disease processes that impact an individual's lifestyle. The gut microbiota has a symbiotic mutualistic relationship with the human body and functions as a primary defense system against foreign pathogens. Administration methods vary primarily between colonoscopy, enema, and oral capsules. Donors can be related to the patient, close friends, volunteers, or the stool can come from a stool bank. There is still no published protocol regarding this treatment despite overwhelmingly positive benefits to this type of treatment. The

aim of this study is to determine what is known about FMT.

Disease Definitions

Clostridium Difficile Infection

Clostridium difficile is a gram-positive bacteria strain that leads to infectious colitis in infected individuals. This bacterial strain can be acquired in the community; however, it is one of the most common hospital acquired infections to date. While this infection was primarily assumed to only affect the older immunocompromised population, scientists realized it can affect an individual of any age and any health status (Kelly & LaMont, 2008). Signs and symptoms of CDI include watery diarrhea as often as 10 to 15 times a day, abdominal pain, dehydration, colon damage, and increased white blood cell count. The infection is usually treated with the antibiotics, metronidazole or vancomycin. The main issue with clostridium difficile is recurrent infections that cause mutations in the bacterial strains leading to antibiotic resistance (Kelly & LaMont, 2008).

Graft-versus-Host Disease

Graft-versus-host disease occurs after hematopoietic stem cell transplant when the transplant recipient experiences a tissue reaction to the donor stem cells. Tissue reaction usually includes the skin, liver, and gastrointestinal tract. Signs and symptoms of graft-versus-host disease vary depending on which organs are affected (Jacobsohn & Vogelsang, 2007). This disease will be staged (0-5) on severity by the extent of organs involved and organ damage. Patients experiencing stages 3 or higher typically have a poor outcome. Treatment usually includes immunosuppressive drugs such as methylprednisolone. About half of the patients diagnoses with acute graft-versus-host disease will develop chronic graft-versus-host disease (Jacobsohn & Vogelsang, 2007).

Inflammatory Bowel Disease

Inflammatory bowel disease (IBD) is an overarching term referring to Crohn disease and ulcerative colitis.

Crohn Disease

Crohn disease is a relapsing inflammatory disease of the gastrointestinal tract that also results in extraintestinal symptoms. This disease can be caused by genetic mutations or triggered by environmental factor that result in an impaired interaction between the normal gut microbiota and the individual (Baumgart & Sandborn, 2012). Signs and symptoms include diarrhea, abdominal pain, cramping, blood in stool, reduced appetite and weight loss, and anemia. The goals of treatment are to achieve remission and to prevent the progression of destructive disease (Baumgart & Sandborn, 2012). If unable to achieve remission individuals with Crohn disease often require surgical intervention such as ostomy placement.

Ulcerative Colitis

Ulcerative colitis (UC) is an inflammatory bowel disease defined by inflammation of the mucous membranes in the colon resulting in patches of ulcers (Encyclopedia Britannica, 2017). The exact cause of UC remains unknown, but it has been hypothesized that stress, diet, immune response, and genetics can contribute to the disease process. Individuals diagnosed with UC may experience bloody diarrhea, abdominal and rectal pain, and urgency to defecate. Treatment consists of corticosteroids, antibiotics, and other immunosuppressive drugs. If medication treatment does not induce remission, the individual may have a portion of the colon removed (Encyclopedia Britannica, 2017).

Irritable Bowel Syndrome

Irritable bowel syndrome (IBS) is a common disorder of the intestines in which an individual experiences severe diarrhea, constipation, or both. IBS results from a disruption in the

motility of the intestinal tract which can be caused by the consumption of certain foods, alcohol, or caffeine as well as many other environmental factors and personal stress. Individuals with IBS may also experience abdominal pain, intestinal gas, and cramping which can be relieved after defecation (Encyclopedia Britannica, n.d.). Treatment for IBS includes exercise, patient avoidance of foods that trigger symptoms, fiber, and antidiarrheal medications. IBS results in a major disruption of lifestyle and activities of daily living for individuals affected by the disease (Encyclopedia Britannica, n.d.).

Multidrug-Resistant Organisms

Multidrug-resistant organisms are types of bacteria that have developed a resistance to typical antimicrobial drugs which are used to treat a variety of disease processes such as CDI. These organisms are categorized as multidrug-resistant, extensively drug-resistant, and pan drug-resistant based on the number of antimicrobial drugs they have developed resistance for. Multidrug-resistant organisms increase the burden on healthcare because they prevent typical antimicrobial drugs from treating patients effectively and efficiently (Qureshi et al., 2021).

Nonalcoholic Fatty Liver Disease

Nonalcoholic fatty liver disease (NAFLD) is defined by the presence of greater than or equal to 5 percent of hepatic steatosis without any other competing liver disease processes such as hepatitis, the use of hepatotoxic medications, or significant alcohol consumption (Younossi et al., 2016). This disease process can lead to the development of nonalcoholic steatohepatitis which is a more severe and progressive form of liver disease. Many patients diagnosed with NAFLD also suffer from obesity which increases the number of comorbidities such as type 2 diabetes, hypertension, and cardiovascular disease. Patients with this disease, and those with nonalcoholic steatohepatitis, have a high rate of liver-specific mortality and overall mortality

(Younossi et al., 2016).

Obesity

Obesity is defined as a body mass index (BMI) of greater than 30. Obesity rates are increasing at a rapid rate and the disease is associated with metabolic syndrome, type 2 diabetes, cardiovascular disease, and premature death. This increase in obesity rates is due to increasing urbanization and sedentary lifestyle as well as the decrease in diet quality. The treatment for obesity is simply lifestyle changes such as diet and exercise (Phillips, 2013).

Slow Transit Constipation

Slow transit constipation (STC) is defined as two or fewer bowel movements each week or having to strain more than 25 percent of the time. STC is caused by decreased motility of the colon; however, the etiology of this decreased motility is not well understood. The etiology could be from a lack of fiber, autonomic neuropathy, or a disfunction of the nervous system controlling gastrointestinal motility (Frattini & Nogueras, 2008). Symptoms of STC may include pain with defecation, abdominal distension, frequent straining, and the sensation of incomplete emptying of the bowels. Treatment usually consists of dietary changes and well as a medication regimen that increases intestinal motility and softens stool (Frattini & Nogueras, 2008).

METHODS

This scoping review was completed using the Joanna Briggs Institute (JBI) framework of evidence synthesis. This methodology consists of 5 steps: identifying the research question, identifying the relevant studies, study selection, presenting the data, and collating the results (Khalil et al., 2016).

The aim of the study is to determine what is known about FMT. The primary objective is to identify the disease processes treated with FMT and their given outcomes. Secondary objectives include identifying the potential administration routes and outcomes for each route as well as the donors selected for FMT and the impact donor selection has on outcomes.

A literature search of CINAHL, Cochrane, Embase, Epistemonikos, Joanna Briggs Institute, Medline, and ProQuest was performed using the search terms “Fecal Microbiota Transplantation AND Outcome”, “Fecal Microbiota Transplantation”, “Fecal Microbiota Transplantation AND Outcome AND Human AND Gut”, “Fecal Microbiota Transplantation”, “Fecal Microbiota Transplantation”, “Fecal Microbiota Transplantation AND Outcome”, and “Fecal Microbiota Transplantation AND Outcome” respectively. Filters of “English AND Human” were additionally used with CINAHL and Medline databases. Inclusion criteria included English language, all ages, all medical diagnoses, all years, and the impact on all aspects of the microbiome (bacterial, viral, and fungal). Exclusion criteria included studies not conducted under medical supervision, studies without a protocol, and animal subjects.

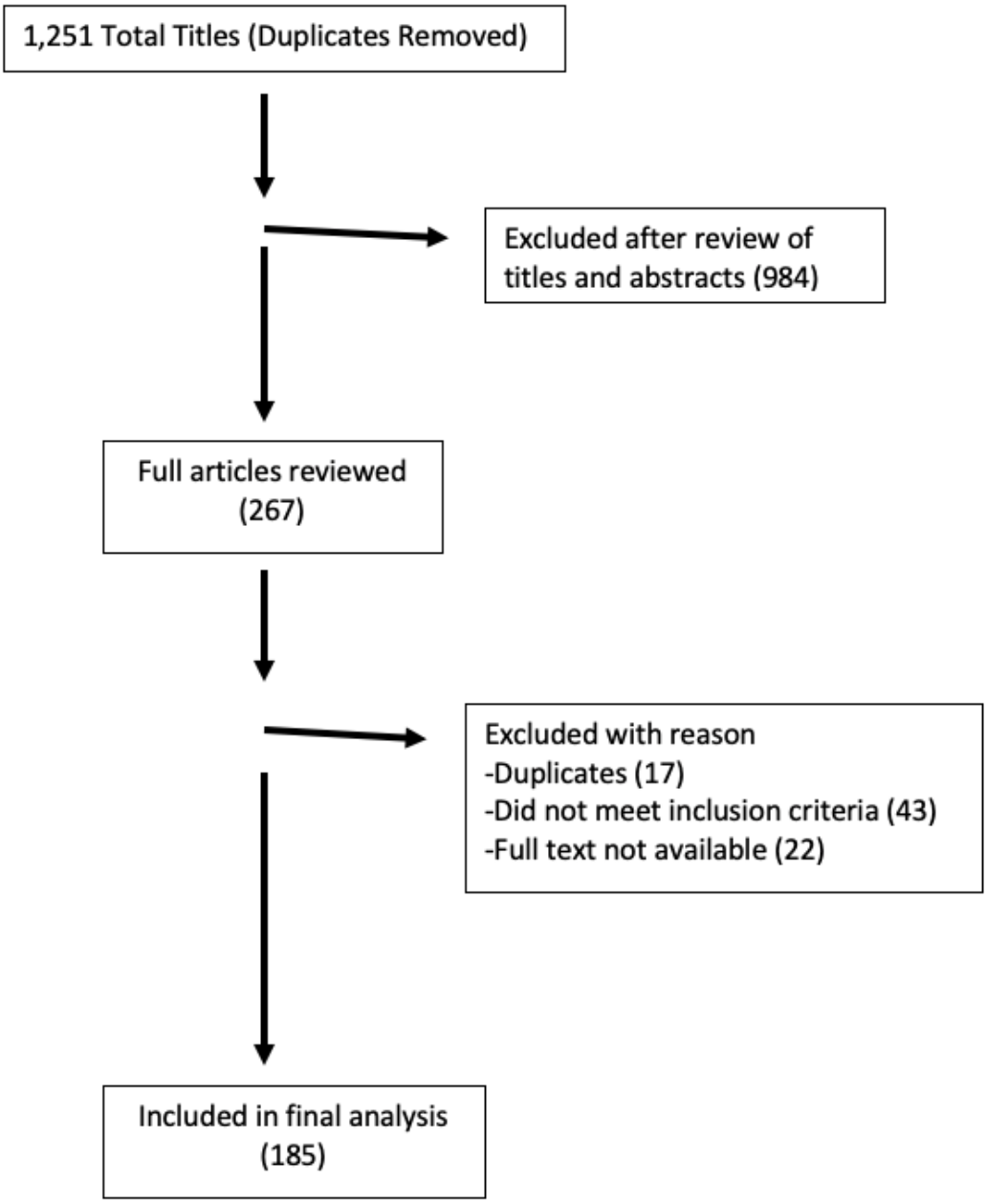
The researcher completed a preliminary review of abstracts from selected articles utilizing the identified inclusion and exclusion criteria. A secondary review of remaining articles was completed by analysis of the entire article. Data from articles that met inclusion and exclusion criteria was extracted into a table for further analysis of information and trends by the

author and supervising professor.

RESULTS

Literature Review

The electronic search of available databases resulted in 1,251 total titles excluding duplicates. All titles and abstracts of identified titles were reviewed by the researcher. From these, 267 were identified to meet inclusion criteria based on title and abstract and were reviewed in full by the researcher and supervising professor. Of the 267 titles, 17 were excluded as duplicates not identified during the initial search. Finally, 43 additional titles were excluded due to failure to meet inclusion criteria, and 22 more titles were excluded because the full text was not available to the researcher.



Characteristics of Included Reports

185 total titles (see Table 1) were included in the final data extraction process. Data on each title was collected on author, year, database, journal name, country, study objectives, design, sample, donors, type of stool preparation, interventions, outcomes measured, results,

conclusions, implications, and comments. The research design of each title selected include the following: 29 systematic reviews, 53 randomized control trials, 31 observational studies, 8 case series, 37 retrospective studies, and 27 others that did not fall into the before mentioned categories. Periods of data collection span from 2011 to 2021 despite titles from any year meeting inclusion criteria. Donor selection included patient relatives, patient friends, anonymous donors, the use of a stool bank, or a combination of multiple listed donor types. Stool was either administered in the fresh liquid form or a frozen capsule form.

Disease Processes

Titles included the following patient diagnoses: CDI (n = 59), crohn disease (n = 8), graft versus host disease (n = 4), IBD (n = 9), IBS (n = 11), multidrug-resistant organisms (n = 3), NAFLD (n = 1), obesity (n = 6), STC (n = 3), UC (n = 31), other diseases (n = 42), and a combination of multiple listed diseases (n = 7).

Clostridium Difficile Infection

Primary cure was achieved in 86% (n = 30) of cases in a study conducted by Duarte-Chavez et al. (2018). In a study conducted on pediatric patients, all 12 patients experienced clinical resolution of CDI by three months post-FMT (Fareed et al., 2018). Another study found a resolution of diarrhea due to CDI without a relapse in symptoms in 16 of 19 patients surveyed (Lui et al., 2019). In a randomized control trial completed by Youngster et al. (2014), a resolution in symptoms was achieved in 70% (n = 14) of patients after one FMT and 90% (n = 18) after multiple FMTs. In the studies reviewed, FMT was highly successful in patients treated for CDI. Most patients experienced few side effects from FMT which typically included abdominal pain and diarrhea.

Crohn Disease

He et al. (2017) conducted a study of 25 patients diagnosed with Crohns disease and found the proportion of patients achieving clinical remission at 6, 12, and 18 months after FMT was 48% (n = 12), 32% (n = 8), and 22.7% (n = 5) respectively. Another study found steroid-free remission was achieved in 87.5% (n = 7) patients after 10 weeks and 50% (n = 4) after 24 weeks (Sokol et al., 2020). Yang et al. (2020) completed a randomized control trial which resulted in 77.8% (n = 21) of participants experiencing a clinical response and 66.7% (n = 18) entering clinical remission in 2 weeks. This study also found there was no significant difference in clinical response between gastroscopy and colonoscopy routes of FMT administration.

Graft-versus-Host Disease

Five of nine patients (56%) in Spindelbock et al.'s (2019) study achieved complete clinical response with no complains of gastrointestinal adverse effects. In another study 11 of 15 patients (73%) showed a complete response, defined by researchers as a resolution of all graft-versus-host disease symptoms, 4 weeks after FMT (van Lier et al., 2019). In a final study, decolonization of disease was achieved in 70% (n = 7) of participants (Battipaglia et al., 2019). Few side effects were noted in each study with constipation and diarrhea being the most common after FMT.

Irritable Bowel Syndrome

Twelve patients with IBS, both diarrhea predominant and constipation dominant were included in a study by Cho et al. (2020). Seven (58%) reached clinical response after one FMT and four (33%) who did not respond to the first FMT responded to a second one (Cho et al., 2020). Another study completed by Mizuno et al. (2017) noted 6 of their 10 participants achieved a clinical response and an increase in microbiota diversity was noted in participants 4 weeks after FMT. A significant improvement in IBS scores after 3 months was noted as well as

an increase in fecal microbiota diversity in participants receiving FMT compared to those in the placebo group of a randomized control trial completed by Halkjaer et al. (2018). One study (n = 254) did find no significant difference in improvement of IBS symptoms between FMT participants and those who received a placebo treatment (Xu et al., 2019).

Multidrug-Resistant Organisms

Ghani et al. (2020) found 41% (n = 7) of patients experienced decolonization of multidrug-resistant organisms by six months post FMT in their study. A systematic review of 192 total patients found the decolonization rate ranged from 37.5% to 87.5% with no serious adverse events reported (Saha et al., 2019). The third study found 68.6% (n = 24) of participants experienced decolonization within one year of FMT (Seong et al., 2020).

Nonalcoholic Fatty Liver Disease

The only study investigating the role of microbiota on NAFLD (n = 21) found FMT does alter the intestinal microbiota and decrease the inflammation of the liver. This study also used only vegan donors who follow a plant based, low-protein diet (Witjes et al., 2020).

Obesity

A systematic review found two studies that reported improved insulin sensitivity and lower HbA1c levels 6 weeks post FMT for patients (n = 76) with obesity; however, no differences in fasting glucose, BMI, and cholesterol markers were noted between the FMT group and control group (Zhang et al., 2019). This same study found short-term benefits of FMT on insulin sensitivity, but these were not maintained long term. Xi et al. (2019) explored the effect of FMT on BMI and noted a small decrease (0.7% to 3.7%) in BMI in participants with CDI (n = 8) or UC (n = 12) receiving FMT.

Slow Transit Constipation

In their study of 52 patients, Ding et al. (2018) found colonic transit time decreased significantly from 78.8 hours at baseline to 49.4, 55.1, and 64.0 hours at weeks 4, 12, and 24 respectively. Another study reached a STC cure rate of 36.7% in the FMT group (n = 30) in comparison to 13.3% in the control group (n = 30) of a randomized control trial (Tian et al., 2017). This study also noted side effects were transient and varied between mild to moderate venting, nausea, abdominal pain, and diarrhea. A final study showed improvement and remission in 50% (n = 12) of their participants who noted and increased frequency of stool from a mean of 1.8 to 4.1 times per week post FMT without the use of laxatives (Tian et al., 2016).

Ulcerative Colitis

An observational study enrolled 30 participants with steroid dependent UC and clinical remission was reached in 11 (36.7%) participants, clinical response was achieved in 16 (53.3%) participants, and endoscopic remission was seen in 3 (10%) participants (Ghandi et al., 2019). This study also had 10 participants (33%) stop steroids 8 weeks post FMT suggesting a decrease in disease severity. Another study whose primary outcome was to achieve steroid-free clinical remission in participants found this outcome was achieved in 46.3% (n = 16) (Mahajan et al., 2018). Chen et al. (2020a) noted a higher clinical response rate in participants with mild active UC in comparison to participants with moderate active UC in an open-label study (n = 47). Another study found all participants experienced a short-term clinical improvement of symptoms within the first 2 weeks post FMT; however, none of the participants reached clinical remission (Krump et al., 2013). Similarly, Tian et al. (2019) found improvement of symptoms for diarrhea, abdominal pain, and bloody stool in participants post FMT. This finding suggests if patients receiving FMT to treat UC do not enter clinical remission symptoms of UC may improve and allow patients to return to more activities of daily life.

Donor Selection

In the titles selected, donors were either autologous, related, close friends, study volunteers, or associated with a stool bank. Of the 185 titles selected, a stool bank was utilized in 70 (38%) studies, family was utilized in 14 (8%) studies, and both the bank and family donors were utilized in 41 (22%) studies. Some titles compared patient outcomes based on different donors. These titles showed that autologous donation did not result in a change in the patient's baseline condition. One study by Costello et al. (2019) (n = 69) found donor FMT resulted in a higher likelihood of remission at 8 weeks compared to autologous FMT. Holster et al. (2019) stated IBS symptoms significantly decreased after FMT with donor stool (n = 8), while only a small improvement was noted in the group receiving their own stool (n = 8) via FMT.

Any other sources of donation did show a good outcome and positive improvements in the patient's condition. A study by Minkoff et al. (2020) (n = 89) found no significant association between donor source (direct family donor vs. stool bank) and efficacy of FMT or recurrence of CDI after FMT. Fecal suspension provided by a central stool bank resulted in effective and safe administration of FMT for CDI (Terveer et al., 2020). A study completed by Uygun et al. (2017) utilized donors (n = 30) including partners, relatives, and volunteers and found no significant difference among donors in the rate of remission and clinical response to FMT. No one type of donor was more effective than another, as long as the donor was not also the patient.

Stool Administration

There are primarily two ways to administer stool during FMT according to the selected sources. The first is fresh stool administration which allows larger quantities of stool diluted in saline to be administered either rectally via colonoscopy or nasally through a nasogastric tube.

The other option is a frozen capsule of stool that is administered rectally, similarly to a suppository, or swallowed orally by the patient. 84 titles utilized fresh stool while 38 titles used frozen stool and 7 titles analyzed both fresh and frozen stool. Selected titles that compared efficacy of fresh compared to frozen stool administration for FMT stated that there was no significant difference in outcomes between the two types (Fang et al., 2018). A study conducted by Quraishi et al. (2017) found no difference between fresh (n = 8) and frozen (n = 3) stool on treating CDI recurrence with success rates of 92% and 93% respectively. One study stated that more microbiota and stool could be administered with a fresh FMT; however, further studies that analyze the effects of the stool quantity on outcomes are needed (Agarwal, 2021). The type of stool administered is based on physician and patient preference. Additionally, Chen et al. (2020b) found clinical outcomes did not differ between the administration of fresh stool via nasojejunal tube (n = 5) or via transendoscopic enteral tubing (n = 3), allowing for more patient and physician preference on how FMT will be administered.

DISCUSSION

Synthesized evidence from the 185 titles selected demonstrates that FMT is an effective treatment for a variety of gastrointestinal diseases. These titles also show that there are minimal adverse effects experienced by patients, and most adverse effects include abdominal pain and diarrhea. No serious adverse events or death were noted as a result of FMT. The treatment of CDI was successful in approximately 85% patients after one round of FMT. This success rate climbed to over 90% on average after two or more rounds of FMT. In comparison to antibiotics for the treatment of CDI, FMT was more effective and did not lead to the development of multidrug-resistant organisms, unlike antibiotic treatment. The choice of donor did not play a role in the efficacy of FMT treatments; however autologous donation by the patient was not effective in the treatment of disease. The type of stool suspension administered during the FMT procedure did not matter. Fresh stool and frozen stool showed the same rates of positive outcomes, and one is not considered significantly better than the other. Larger amounts of stool product can be administered with the fresh stool suspension; however, frozen capsules are easier to administer and require less patient preparation.

The future of FMT is promising, but future studies are needed to establish a protocol for this treatment. As there is no universal protocol, this is a necessary next step for FMT to be used as a common treatment for a wide range of disease processes. Additionally, some countries are working to establish a nationwide stool bank which screens donors and processes stool for later use. The establishment of stool banks will aid in the creation of a universal protocol.

There are limitations to this study. Due to the nature of a scoping review, some titles had to be discarded because the researcher did not have access to the full text. Additionally, because of the time constraints and the volume of data meeting criteria, the researcher and supervising

professor completed data extraction on separate articles from the studies meeting criteria which could lead to bias in analysis. However, because data extracted was quantitative and systematically reported across studies, the risk of bias is deemed to be minimal. Data on the extraction table was organized by key words to help identify patterns; however, the data was coded by the researcher rather than an electronic system, which has the potential to result in errors.

In conclusion, based on this scoping review of 185 studies, FMT is an effective treatment option for a variety of diseases with minimal and mild adverse reactions. For this reason, FMT has the potential for improving quality of life for patients living with debilitating disease that are typically refractory to routine medical treatment. Future studies need to identify a universal protocol for FMT administration and donor selection to assure ready adoption of this promising treatment.

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APPENDIX

Table 1

Studies Meeting Inclusion/ Exclusion Criteria
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