## SHORT COMMUNICATION

# Patient perception and approval of faecal microbiota transplantation (FMT) as an alternative treatment option for obesity

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# **Summary**

### Introduction

Fecal microbiota transplantation (FMT) represents a treatment option for some diseases, e.g. recurring Clostridium difficile-associated colitis. However, there is also evidence that FMT can be effective in treating obesity. This pilot study established the approval and willingness of obese patients to undergo FMT.

#### Methods

We conducted a survey of adults with obesity using a questionnaire containing 21 both multiple choice and open questions was dispatched to a cohort of 101 persons with obesity. It included questions aiming at the process of FMT itself, donors as well as possible concerns. Additionally aspects of social background and disease activity were dealt with.

#### Results

The response rate amounted to 30.1% (n=31). In our population, mean BMI was  $40.5 \text{ kg/m}^2$  while the vast majority already tried out treatment modalities to lose weight before. 25.8% of persons with obesity were aware of FMT. 62.1% were willing to undergo FMT if the donor was healthy and anonymous while only 6.9% clearly refused this option. Sixty preferred an anonymous donor or a person proposed by their doctor while colonoscopy was the preferred application by 76.7%. The absence of risks of the procedure (47.8%) formed the principal motivation while reduction of medication was considered as least important reason (in 26.1). Insufficient testing of the faeces concerning infections raised the most concerns (in 61.6%).

## **Conclusion**

For the majority of the persons with obesity surveyed FMT represents a treatment option. Approximately two thirds of the questionees would consider FMT as an alternative treatment option, even in spite of a satisfactory disease response to current standard therapies. Unsurprisingly there are concerns in regard to the transmission of possible infectious agents as well as to the hygieneic implementation of FMT itself.

**Keywords:** Fecal microbiota transfer, microbiota obesity, weight loss endoscopy trial (WET).

# Introduction

Obesity represents a growing global health crisis affecting an estimated 312 million people worldwide (1). Many studies have demonstrated reduced life expectancy due to higher risks of cardiovascular, pulmonary and gastrointestinal diseases, diabetes and many types of cancer which are associated with obesity (2). However, managing obesity is often disappointing as lifestyle alterations are frequently ineffective (1). In addition, conservative treatment results only in mean weight loss of about 5 kg after one year using commercial weight loss programs and less than 2.5 kg using standard care while only two thirds complete their respective programs even in the study setting (3). Furthermore, persons with obesity (e.g. who present for bariatric surgery) often have

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unrealistic expectations regarding the amount of weight they will lose which might result in disappointment and a variety of psychosocial disorders increasing the individual risk for weight regain (4–6).

The progression of severe obesity has a strong association with numerous serious comorbidities that impair quality of life and reduce life expectancy. This clearly necessitates the development of novel therapies for the treatment of obesity.

Given the worldwide epidemic in obesity, there is interest in how interactions between human and microbial metabolomes may affect our energy balance (7). The role of gut microbial community (microbiota) has been a fascinating field of basic research during the last decade (8). Numerous milestone papers have been elucidated the gut microbiota as an important environmental factor that affects energy harvest from the diet and energy storage in the host (7–16). For example, the gut microbial community is essential for processing dietary polysaccharides, promotion of absorption of monosaccharides from the gut lumen, with resulting induction of de novo hepatic lipogenesis (7,8).

The gut microbiota constisting of trillions of microbes colonizing our gastrointestinal tract function collectively as a metabolic organ that communicates with, and complements, our own human metabolic apparatus (7,8). Weight loss results in a decrease in the ratio of Firmicutes to Bacteroidetes phyla which can also be achieved by bariatric surgery (10).

Numerous experiments using animal models of the human gut ecosystem by transplanting fresh or frozen adult human faecal microbial communities into germ-free C57BL/6 J mice have been published (10). Recently, transplant experiments with transplanted faecal microbiota from adult female twin pairs discordant for obesity into germ-free mice demonstrated that increased total body and fat mass, as well as obesity-associated metabolic phenotypes, were transmissible (11).

Faecal microbiota transplantation (FMT), also known as stool transplant, is the delivery of liquid filtrated faeces from a healthy donor into the gastrointestinal tract of a recipient to cure a specific disease, either applied by endoscopy or administered by nasogastric tube, enema, or capsule (17–21). Remarkable success has been reported for a variety of conditions, including recurrent Clostridium difficile infection, inflammatory bowel disease (IBD, especially ulcerative colitis) and a wide range of other disorders (e.g. chronic diversion colitis, refractory irritable bowel syndrome and hepatic encephalopathy in liver cirrhosis, (22–26). However, some patients refuse this treatment for different reasons, including the "yuck factor". We conducted this pilot study to examine the approval and willingness of persons with obesity to undergo FMT. Our

hypothesis was that persons with obesity judge FMT as an alternative therapeutic option.

# Materials and methods

# Survey instrument

The survey was developed based on key findings from our focus group study, and included demographic information and a brief description of FMT using lay terminology, followed by 21 questions about FMT, disease activity, clinical effectiveness and satisfaction with current treatments (Tables 1, 2). Question formats included multiple-choice, rank order questions, and write-in a short answer.

The study was conducted at the Departments of Diabetes, Endocrinology, Gastroenterology, Hepatology and Gastrointestinal Oncology, Bogenhausen Hospital, Munich, Germany. The study protocol was in accordance with the declaration of Helsinki and approved by the local ethics board (http://ethikkommission.blaek.de).

# Patient population

Hundred and one persons with obesity (BMI of 30 kg/m<sup>2</sup> or more) who were admitted to Bogenhausen Hospital (most of them as out patients) were invited to enter the study and answer the questionnaire between October 2017 and February 2018. Most of these patients were screened to join the Weight Loss Endoscopy Trial (WET). WET is a prospective, controlled, patient and assessor-blinded multi-center efficacy trial with two intervention arms and a sham procedure control arm. Patients will be randomized in a ratio of 2:2:1 to receive either intragastric balloon (IB), duodenojejunal bypass-liner (DJBL) or sham procedure (gastroscopy with sedation). In all participating sites, adult patients ( $\geq$  18 years of age) with a BMI  $\geq$  35 kg/m<sup>2</sup> or ≥ 30 kg/m<sup>2</sup> and obesity related comorbidities (e.g. arterial hypertension or diabetes), will be screened for eligibility for the trial. WET will be conducted as a multi-center trial in Germany including the Division of Gastroenterology and Rheumatology together with the Clinical Trial Center, both at the University of Leipzig, Bogenhausen hospital in Munich, the Sachsenhausen Clinic in Frankfurt, University Medical Center in Freiburg and University Medical Center Hamburg-Eppendorf in Hamburg. The trial is sponsored by the German Research Foundation (DFG, trial registration: DRKS00011036 (27).

## Statistical analysis

Qualitative variables were expressed as percentages, whereas quantitative variables were expressed as median.

Gout

None

**Table 1** Results of the questionnaire (n = 31, absolute numbers and percentage)

Question	All responders, n (%)	
Have you heard about FMT as a treatment option?		
• Yes	8 (25.8)	
• No	23 (74.2)	
2. Would you consider FMT as a possible treatment option?		
• Yes	13 (41.9)	
• No	4 (12.9)	
Not sure	14 (45.2)	
3. Which donor would you prefer? *, **		
<ul> <li>Family member</li> </ul>	7 (14)	
<ul> <li>Spouse</li> </ul>	8 (16)	
<ul> <li>Partner</li> </ul>	1 (2)	
<ul> <li>Friend</li> </ul>	2 (4)	
<ul> <li>Anonymous donor</li> </ul>	13 (26)	
<ul> <li>Person proposed by the therapist</li> </ul>	17 (34)	
4. Would you consider FMT as a treatment, if the donor is exclusively healthy a	and anonomous? #	
• Yes	18 (62.1)	
• No	2 (6.9)	
<ul> <li>Not sure</li> </ul>	9 (31)	
5. There are different possibilities to perform FMT. If all applications are equally	efficient, which one would yo	ou prefer? ##
Colonoscopy (one time, application period 1 hour)	23 (76.7)	·
<ul> <li>Rectal enema (up to 5 times, each application period 5 minutes)</li> </ul>	4 (13.3)	
<ul> <li>Feeding tube (one time, application period 1 hour)</li> </ul>	3 (10)	
6. Arrange the reasons why you consider FMT as a treatment in proper order (		= least important reason)###, *
would consider FMT as a treatment option,	,	, , , , , , , , , , , , , , , , , , , ,
	most important reason	least important reason
• if there are no risks	11 (47.8)	1 (4.3)
• if it works	2 (8.7)	1 (4.3)
<ul> <li>regardless of medical studies since I am concerned about side effects</li> </ul>	0 (0)	5 (21.7)
of my current medication	- (-)	- (
<ul> <li>because it represents a natural therapy</li> </ul>	0 (0)	5 (21.7)
<ul> <li>because my doctor told me to do it</li> </ul>	2 (8.7)	0 (0)
• if all other options failed (excluding operation)	2 (8.7)	3 (13)
• if I could reduce my medication	0 (0)	6 (26.1)
7. Arrange your concerns about FMT according to your personal importance (1		3 (231.)
Cleanliness and hygiene of the transplant	4 (15.4)	
Insufficient testing of the faeces concerning infections	16 (61.6)	
Application is not safe	0 (0)	
Deterioration of overweight	1 (3.8)	
Interference with current treatment	1 (3.8)	
No concerns	4 (15.4)	
Which other treatment modalities to lose weight have you already tried out?		
• Diet	28 (71.8)	
Bariatric Operation	1 (2.6)	
Medical therapy	4 (10.3)	
Metabolic endoscopy	2 (5.1)	
Other §	3 (7.7)	
	3 (1.1)	
Are you suffering from any additional diseases?     High Blood pressure	14 (45 0)	
9 1	14 (45.2)	
Diabetes mellitus (OAD)     Diabetes mellitus (Insulin)	5 (16.1)	
Diabetes mellitus (Insulin)     Fat metabolism disease (a.g. high abalastayala)	7 (22.6)	
Fat metabolism disease (e.g. high cholesterole)	7 (22.6)	

Continues

2 (6.5)

14 (45.2)

Table 1. Continued

Question	All responders, n (%)	
10. How do you feel in general? #		
<ul><li>Very good</li></ul>	8 (25.8)	
<ul> <li>Average</li> </ul>	15 (48.4)	
Below average	7 (22.6)	
<ul> <li>Poorly</li> </ul>	0 (0)	
11. How difficult was it for you to pursue sport or free	time activities within the last two weeks? #	
<ul> <li>Very difficult, not possible</li> </ul>	3 (9.7)	
<ul> <li>Very difficult</li> </ul>	5 (16.1)	
<ul> <li>Minor problems</li> </ul>	16 (51.6)	
No problem	5 (16.1)	

<sup>\*</sup>more than one answer possible

# Results

# Patient population

In total, 31 persons with obesity completed the survey resulting in a response rate of 30.1% [13 male, 18 female; mean age 46.6 years (range 24-65)]. Body Mass Index (BMI) was 40,5 (range 31,7-65,4) kg/m<sup>2</sup>. The vast majority of the patients already tried out treatment modalities to loose weight before including diet (28, 90%), bariatric operation (1, 2.6%), medical therapy (4, 10.3%), metabolic endoscopy (2, 5.1%) and other options such as formula products or alternative therapy (3, 7.7%). A remarkable proportion was suffering from associated metabolic diseases such as arterial hypertension (14, 45.2%), Diabetes mellitus (necessitating a therapy with oral antibiabetic drugs; 5, 16.1%), Diabetes mellitus (necessitating a therapy with Insulin; 7, 22.6%), fat disorders (e.g. hypercholesterolemia; 7, 22.6% and gout (2, 6.5%) while 14 subjects (45.2%) reported denied such disorders.

Patient awareness and approval of faecal microbiota transplantation (FMT)

Patients were first questioned whether they had heard about FMT in the past and whether they could imagine to undergo FMT on the basis of their current state of knowledge. No additional information material regarding FMT was supplied.

While 25.8% of patients were aware of FMT, 41.9% reported that they consider FMT as a possible treament

option for obesity while 45.2% were not sure yet and 12.9% refused this option. However, 62.1% were willing to undergo FMT if the donor was healthy and anonymous while only 6.9% still rejected such an intervention.

Willingness to undergo FMT differed between sexes resulting in a higher reluctance of female compared to male subjects (Figure 1).

Preferred donor and application method, motivation and concerns about FMT

In 60%, an anonymous donor or a person proposed by their doctor was preferred while the preferred delivery system of FMT was colonoscopy in 76.7% (Table 1). The absence of risks of the procedure (47.8%) formed the principal motivation followed by failure of all other therapies, efficacy and recommendation by the doctor (in 8.7%, respectively). Reduction of medication was considered as least important reason (in 26.1%, Figure 2). Insufficient testing of the faeces concerning infections raised the most concerns (in 61.6%), followed by worries about cleanliness and hygiene of the transplant (in (15.4%) while 15.4% were not concerned about FMT at all (Figure 3).

To evaluate the disease burden patients were asked how they felt in general and wether they had any difficulties pursuing sport or free time activities. Only 8 (25.8%) reported a very good wellbeing while only 5 (16.1%) denied any problems when pursuing sport or free time activities within the last two weeks. Of note, the majority completed a graduation, reported a regular consumption of mass media such as newspapers or watching

<sup>\*\*</sup>additional comments: "Super-Donor", "the one who fits best"

<sup>#2</sup> patients did not answer this question

<sup>\*\*\*</sup>more than one answer possible, 5 patients did not answer this question

<sup>§</sup>Formula products, alternative therapy

<sup>###8</sup> patients did not answer this question or made mistakes

<sup>####5</sup> patients did not answer this question or made mistakes

<sup>\*\*\*</sup>additional comments: "Curiosity", "improvement of migraine", "therapy without hard work"

<sup>\*\*\*\*\*</sup>additional comments: "Damage to my microbiota", "acquisition of other diseases", "rejection"

**Table 2** Demographic data (n = 31)

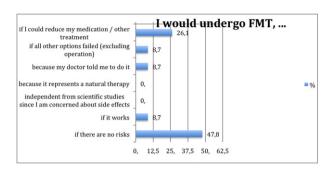
Age (y	ears)	range 24-65, mean 46,6 years §
Gender (n/ %)		male 13/41.9, female 18/58.1
Body Mass Index (kg/m²)		range 31,7-65,4; mean: 40,5 +
Relation	onship (n/ %) *	
•	Single, never married	9/29
•	Partner	7/22.6
•	Married	13/41.9
•	Divorced	0/0
•	Widowed	0/0
Educa	tional level (n/ %)	
•	No graduation	0/0
•	Secondary school	19/61.3
•	University entrance	8/25.8
•	Degree	4/12.9
Insura	nce status (n/ %)	
•	Legally insured	27/87.1
•	Privately insured	4/12.9
Watch	ing television (n/ %)	
•	>3 hours/day	15/48.4
•	< 3 hours/day	14/45.2
•	never	2/6.5
Readir	ng newspaper (n/ %)	
•	Every day	17/54.8
•	Never	5/16.1
•	Sometimes	9/29.1

<sup>§1</sup> patient did not answer this question

television while living in a partner relationship. The detailed clinical characteristics of all patients are presented in Table 2.

# **Discussion**

Faecal microbiota transplantation (FMT) represents a treatment option for some diseases, e.g. recurring



**Figure 2** Motivation for decision-making. Absence of risks of the procedure (47.8%) formed the principal motivation followed by failure of all other therapies, efficacy and recommendation by the doctor (in 8.7%, respectively).

Clostridium difficile-associated colitis. However, there is also evidence that FMT can be effective in treating obesity (11).

However, proof-of-concept studies in humans are sparse. Vrieze et al. studied in a small study the effects of infusing intestinal microbiota from lean donors to male recipients with metabolic syndrome on the recipients' microbiota composition and glucose metabolism (28). Six weeks after infusion of microbiota from lean donors, insulin sensitivity of recipients increased along with levels of butyrate-producing intestinal microbiota. The authors conclude that intestinal microbiota might be developed as therapeutic agents to increase insulin sensitivity in humans. Alang et al. published a case of a woman successfully treated with FMT who developed new-onset obesity after receiving stool from a healthy but overweight donor (29).

Although there are still many unanswered questions regarding FMT, including donor selection and screening, standardized protocols, long-term safety, and regulatory issues, these findings have implications for ongoing trials in humans to investigate the impact of microbiota transfer in the treatment of obesity. At the moment, 12 clinical trials

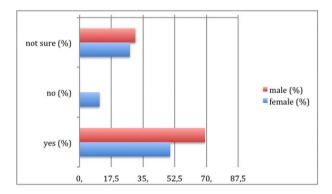


Figure 1 Patients acceptance for FMT. Willingness to undergo FMT differed between sexes resulting in a higher reluctance of female compared to male subjects.

<sup>&</sup>lt;sup>+</sup>2 patients did not answer this question

<sup>\*</sup>additional comment: "chaotic"

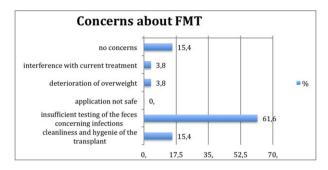


Figure 3 Insufficient testing of the faeces concerning infections raised the most concerns (in 61.6%), followed by worries about cleanliness and hygiene of the transplant (in (15.4%) while 15.4% were not concerned about FMT.

(most of them randomized and Placebo-controlled) are recruting actively to evaluate the impact of FMT in obesity (https://clinicaltrials.gov/ct2/results?term=fmt+obesity&S earch=Search, search performed 5/4/2018, (30).

However, the view of the patients with obesity confronted with this treatment is less clear. Some studies evaluating patient perception of FMT for ulcerative colitis demonstrated a strong interest, but also various concerns (31,32). Patients suffering from ulcerative colitis are used to regular endoscopic procedures and often familiar with issues affecting the bowel. Therefore, the high interest of IBD patients in FMT cannot be extrapolated simply to other diseases. Furthermore, specific concerns of lean IBD patients about FMT might differ from non-IBD patients with obesity since there are fundamental differences between clinical symptoms and medication. This pilot study established the approval and willingness of obese patients to undergo FMT. To the best of our knowledge, there are no quantitative studies in obese subjects determining patient preferences (e.g. concerning donor and delivery methods) and concerns.

Altogether, 25.8% of all patients were aware of FMT. This rate of awareness is lower than previously described in IBD-patients. Surprisingly, 62.1% of all subjects were willing to undergo FMT if the donor is healthy and anonymously while only 6.9% clearly refused this option. Interestingly, willingness to undergo FMT differed between sexes resulting in a higher reluctance of female compared to male subjects (Figure 1). This is in contrast to previously published data about patients with ulcerative colitis where no significant differences could be found between women and men (19,20). In relation to donor and delivery, 60% preferred an anonymous donor or a person proposed by their doctor while colonoscopy was the preferred application by 76.7%. The absence of risks of the procedure (47.8%) formed the principal motivation while reduction of medication was considered as least important reason (in 26.1). Remarkably, proven efficacy came second (in 8.7%) which might stress the motivation of affected patients to "reach for the straw"since all other options are disappointing or invasive. Insufficient testing of the faeces concerning infections raised the most concerns (in 61.6%). No specific concerns were reported in 15.4% which is surprising regarding the relatively low awareness of FMT in our population (Figure 3).

One limitation of this study is clearly the small sample size due to the low response rate which was recruited from a single tertiary centre. However, the aim of this study was to evaluate whether persons with obesity could imagine FMT after all as a new treatment option to lose weight or whether there are any barriers which might prevent its implementation into practice. A larger sample size would not necessarily have altered the findings of this pilot study.

In summary, FMT represents a potential therapeutic option also in persons with obesity in the future. The majority of the questionees would consider FMT as an alternative treatment option, even in a population with a moderate disease burden as assessed by comorbidities and physical limitations. Unsurprisingly there are concerns in regard to the transmission of possible infectious agents as well as to the hygieneic implementation of FMT itself. Therefore, this issue should be carefully addressed if FMT might become part of the armamentarium to fight obesity one day.

# **Conflicts of interest**

None.

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