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## Brief report

## Stool donor recruitment – A one-year experience

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### ARTICLE INFO

#### Article history:

Received 6 October 2020

Accepted 22 January 2021

#### Keywords:

Fecal microbiota transference

FMT

Stool donor

CDI

### ABSTRACT

Stool donors for fecal microbiota transference (FMT) should be rigorously screened to identify any disorder in health status. The success of our screening protocol to identify eligible donors in the last year and a half was evaluated and compared with the published literature.

The target population was medical students who responded to 3 public calls to donate stools. Qualified donors brought stool samples to our lab.

Out of the 110 students who responded to the call, 26 were enrolled as study donors and delivered at least one stool sample. The main reason for volunteer exclusion was body mass index (BMI) <18.5 kg/m<sup>2</sup> or >25 kg/m<sup>2</sup> ( $n = 11$ ) and for the identification of ESBL *Escherichia coli* in feces ( $n = 3$ ).

Our success rate after the screening protocol was considered high. Understanding the incentives to participate is critical to the success of recruitment strategies as FMT is still a little-known practice for general population.

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## Reclutamiento de donantes de heces: experiencia de un año

### RESUMEN

Se debe seleccionar rigurosamente a los donantes de heces para la transferencia de microbiota fecal (TMF) para identificar cualquier trastorno en la salud. Se evaluó el éxito de nuestro protocolo de selección para identificar donantes idóneos en el último año y medio y se comparó con la literatura publicada.

La población objetivo fueron estudiantes de medicina que respondieron a 3 convocatorias públicas para donar heces. Los donantes aptos llevaron muestras de heces a nuestro laboratorio.

De los 110 estudiantes que respondieron a la convocatoria, 26 se inscribieron como donantes del estudio y entregaron al menos una muestra de heces. El principal motivo para la exclusión de voluntarios fue un índice de masa corporal (IMC) <18,5 kg/m<sup>2</sup> o >25 kg/m<sup>2</sup> ( $n = 11$ ) y la identificación de *E. coli* BLEE en las heces ( $n = 3$ ).

Nuestra tasa de éxito tras el protocolo de selección se consideró alta. Comprender los incentivos para participar es fundamental para el éxito de las estrategias de reclutamiento, ya que la TMF sigue siendo una práctica poco conocida para la población en general.

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#### Palabras clave:

Transferencia de microbiota fecal

TMF

Donante de heces

ICD

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## Background

Fecal microbiota transference (FMT) from healthy donor to restore a dysbiotic gut microbiota is an effective treatment for recurrent *Clostridioides difficile* infection with success rates over 90%.<sup>1</sup> Emerging evidence with various degrees of success indicate the potential indication of FMT in other conditions.<sup>2</sup>

In order to respond to the growing demand of a ready-to-use, traceable screened donor feces material to perform FMTs, public stool banks have emerged in the last years.<sup>3,4</sup>

Rigorous donor screening procedure should include a questionnaire to identify any disorders in health status, blood analysis and extensive stool examination even in asymptomatic individuals.<sup>5,6</sup> There are several aspects of donor selection that are not standardized, such as the precise exclusion criteria according to the results of the screening or the preferred type of donor (related or unrelated to the receptor).<sup>7</sup>

The aim of this study was to evaluate the success of our screening protocol to identify eligible donors in our hospital in the last 1.5 year and to compare it with others through a revision of the published literature.

## Material and methods

From February 2018 to June 2019, the authors performed 3 calls to the students of the Faculty of Medicine of the University of Barcelona (80 students per class) to donate feces and were informed about our project. The location of our hospital, close to the Faculty, greatly facilitated the participation of the volunteers.

### First stage of screening

Those who contacted us received a questionnaire about lifestyle habits, medical history and general health conditions to identify any exclusion criteria dictated by our protocol.<sup>8</sup>

### Second stage of screening

The volunteers who met the inclusion criteria were called for a personal interview in which they received detailed information about the project and signed the written informed consent. During this interview, the volunteers underwent a medical examination, blood and fecal analysis.<sup>8</sup>

Any alteration in blood or feces analyses implied the exclusion of the volunteer.

### Third stage of screening and sample processing

Those who qualified as feces donors received a donation bag containing a feces collector (Fecotainer; Excretas Medical BV, Enschede, Holland) with an anaerobe gas pack to achieve anaerobic conditions during sample transportation, ice pack, instructions for sample collection and a second questionnaire. In this document, volunteers were asked to refer any change in their health status, medication intake or risk habits between screening and donation day. Additionally, the donors were required to avoid eating common allergens within 5 days prior to stool donation (tree nuts, eggs, peanuts, and shellfish). Feces samples were maintained at 4 °C and delivered within 4–6 h after obtaining them. Donations were accepted at our lab during 2 weeks after screening.

Criteria for rejecting donations were a Bristol stool form scale of 1 or >5, stool weight <50 g, presence of macroscopic blood or receiving an opened feces collector.

After their participation, all volunteers received a payment of 25€ for completed screening procedure and per each valid stool donation. Furthermore, donors were asked to fill a short satisfaction

questionnaire about aspects related with the donation process. The study was approved by the Scientific Ethical Committee of Hospital Clinic of Barcelona (number HCB/2016/0804).

Demographic variables were summarized using descriptive statistics. Continuous variables are reported as median (minimum, maximum) and categorical variables as percentages.

## Results

From 113 volunteers who contacted us, 110 filled the first online questionnaire and only 62 passed the first screening stage. Among these, there were 66% women ( $n = 41$ ) and 44% men ( $n = 21$ ) with a median (range) age of 22 (20–48) years and a median (range) body mass index (BMI) of 21.21 (18.6–24.9) kg/m<sup>2</sup>.

The majority ( $n = 40$ ) of excluded volunteers after the online questionnaire presented a single exclusion criterion. The main reasons for exclusion were a BMI <18.5 kg/m<sup>2</sup> or >25 kg/m<sup>2</sup> ( $n = 11$ ), recent trips to developing countries ( $n = 9$ ), to have received antibiotic treatment in the past 6 months ( $n = 8$ ), or having a food intolerance ( $n = 8$ ). Less frequent exclusion criteria included atopic disease ( $n = 5$ ), high-risk behaviors associated with the acquisition of blood or sexually transmitted infections ( $n = 3$ ), irregular bowel habit ( $n = 3$ ), chronic medication ( $n = 2$ ), hemorrhoids ( $n = 2$ ), or history of a hereditary disease ( $n = 2$ ).

Twenty-four of these volunteers (38.7%) were lost to follow-up or unable to come to the personal interview.

From the 38 volunteers who continued the screening procedure, 29 successfully completed the second screening stage. At this stage participants were excluded for the identification of extended spectrum beta-lactamase (ESBL) producing *Escherichia coli* ( $n = 3$ ), *Campylobacter jejuni* ( $n = 1$ ), *Citrobacter freundii* ( $n = 1$ ), *Giardia lamblia* ( $n = 1$ ), and *Blastocystis hominis* ( $n = 2$ ) in fecal samples and serum creatinine above normal range ( $n = 1$ ). After this third stage of screening, two additional donors were excluded, one for abdominal pain, and another for ongoing antibiotic treatment. In addition, one participant was unable to bring any sample to our laboratory.

Overall, 26 of the initial 110 respondents were enrolled as feces donors and delivered at least one donation; we received 58 donations in total. The median number of donations per donor was 2 (range 1–5), and the median weight of a single donation was 92.12 (range 49–311.13) g. Twelve donations were discarded for presenting macroscopic rejection criteria.

A summary of recent reports on stool donor success recruitment are depicted in Table 1. Satisfaction surveys were answered by 23 donors and the main results are shown in Table 2.

## Discussion

Our eligibility rate for stool donors was 24%. This rate concurs with some reports indicating rates of 23–24%,<sup>1,9</sup> but substantially departs from others, showing lower rates (10–16%)<sup>3,10–12</sup> or far lower ones (2–6%) reported by Craven et al.<sup>13</sup> and Terveer et al.<sup>4</sup> Although screening protocols were similar, the target recruitment could account for the different rates reported as the majority of their volunteers are more heterogeneous population whereas our target population was young and healthy people. Due to demographic similarity between all of our participants we could not associate their willingness to donate with cultural or age reasons.

Among the main reasons to discard donations, highlights the 7.9% ( $n = 3$ ) carrier status of ESBL *E. coli* that was higher than the 4% prevalence reported in the European community.<sup>14</sup> This circumstance highlights the importance of a comprehensive screening protocol to prevent transmission of antimicrobial resistant microorganisms to the receptor.<sup>5</sup> A 5.6% ( $n = 2$ ) of asymptomatic *B. hominis* carriers were identified, which is lower than

**Table 1**

Comparison of stool donor rates acceptance. Percentages are given with respect to the number of participants who answered the electronic screening questionnaire.

	Our results	Tariq et al., 2018 <sup>1,b</sup>	Jorgensen et al., 2018 <sup>9</sup>	Burns et al., 2015 <sup>3</sup>	Youngster et al., 2014 <sup>12</sup>	Paramsothy et al., 2015 <sup>11,a</sup>	Hota et al., 2019 <sup>10</sup>	Terveer et al., 2017 <sup>4</sup>	Craven et al., 2017 <sup>13,c</sup>
<i>Rates acceptance</i>									
Asked for participation (n)	113	N/A	155	459	N/A	N/A	322	165	N/A
Answered electronic screening (n)	110	21	137	77	37	116	20	71	46
Underwent blood and fecal screening [n(%)]	38 (35)	9 (43)	58 (42)	27 (35)	12 (33)	38 (33)	5 (25)	21 (30)	23 (50)
Became a donor [n(%)]	26 (24)	5 (24)	31 (23)	12 (16)	5 (14)	12 (10)	2 (10)	4 (6)	1 (2)
<i>Demographic data</i>									
Female gender [n(%)]	17 (65)	4 (44)	7 (23)	N/A	N/A	8 (67)	N/A	N/A	25 (54)
Median age [years (R or IQR)]	22 (R 20–48)	35 (R 33–60)	39 (IQR 28–51)	N/A	N/A	40 (R 19–57)	N/A	N/A	35 (R 20–73)
Median BMI [kg/m <sup>2</sup> (R or IQR)]	21.21 (R 18.6–24.9)	24.66 (IQR 24.1–28.6)	24.39 (IQR 22.3–26.3)	N/A	N/A	24 (R 19–29)	N/A	N/A	N/A

n = number of volunteers, N/A = data not available R = range; IQR = interquartile range, and BMI = body mass index.

<sup>a</sup> Results expressed as mean.<sup>b</sup> Gender and median age data correspond to volunteers who underwent blood and fecal screening.<sup>c</sup> Gender and median age data correspond to all pre-screened volunteers.**Table 2**

Answers from satisfaction surveys.

Question	Yes	No	Other
Did you know FMT before participating in the study?	65.2% (n = 15)	34.8% (n = 8)	
Did you know that you can donate feces for FMT procedures?	43.5% (n = 10)	56.5% (n = 13)	
If participation was not remunerated, would you participate as a volunteer?	60.9% (n = 14)	39.1% (n = 9)	
Do you consider that the screening process was quick and easy to do?	95.7% (n = 22)	4.4% (n = 1)	
Was the kit for sample collection for donation easy to use?	87% (n = 20)	13% (n = 3)	
Did you find the schedule for sample delivery at hospital too tight?	60.9% (n = 14)	39.1% (n = 9)	
Would you repeat as a donor?	34.8% (n = 8)	13% (n = 3)	Only if paid 52.2% (n = 12)
Was it a limitation to avoid food allergens during your participation as a donor?	43.5% (n = 10)	56.5% (n = 13)	

other studies reporting up to 30% among Europeans.<sup>15</sup> Despite the conclusions of some studies affirming that *Blastocystis* spp. is associated with higher microbial diversity and richness, and that it may be linked to certain beneficial health indices,<sup>15</sup> these volunteers were discarded as stool donors.

In the future, it will be necessary to re-evaluate the need to discard these donors.

From the satisfaction surveys, 65.2% of our participants were aware of FMT as a potential therapeutic strategy, a similar percentage observed by Tariq et al.<sup>1</sup>, but 56.5% did not know that they could become stool donors.

Although the role of remuneration as an incentive is still a controversial topic, when participants were asked if they would become a frequent stool donor, 52.2% would do it only if they were remunerated. This support previous observations that economical compensation is a clear motivator.<sup>2</sup> Perhaps, obtaining samples from donors for an approved treatment as in *C. difficile* recurrence might be achieved without any remuneration if the entire community is informed about the potential benefits and advantages of their stool donation as it may be perceived as an altruistic act. On the other hand, stool samples for research procedures could prove more challenging to obtain and, in these cases, either an economic incentive or a compensation for time and travel could be considered to motivate donors.

It is important to remember that there is still a lack of worldwide consensus for screening protocols. Consequently, the comparison of different eligibility rates is difficult and it is not possible to determine if there are some specific populations that are more suitable to become stool donors.

In conclusion, the recruitment of stool donors among a population of young university students may be associated with higher donor eligibility rates and higher number of valid donations. Additionally, the use of remuneration as an incentive to participate is highly recommended to increase the recruitment rate as FMT is still a little-known practice among the general population.

## Limitations

As limitations of our study, almost 40% of screened volunteers finally did not turn into donors because of schedule problems. Only 23 of the 29 donors filled out the satisfaction survey, which thus may not fully represent the opinion of the entire group of our donors.

Donor demographic data was not available in several of the publications analyzed, which makes it difficult to draw demographics-based conclusions on the causes of different screening success rates regarding to these studies.

## Funding

This work was supported by the Instituto de Salud Carlos III under Grant “PI/1601023” (Co-funded by European Regional Development Fund “Investing in your future”); and by Hospital Clínic de Barcelona under Grant Resident Award Emili Letang.

## Conflicts of interest

A. Soriano has received grants from Pfizer and is part of the speaker bureau of Pfizer, MSD, Angelini, Shionogy and Menarini. He has been participated in advisory meetings for Pfizer, MSD, Menarini and Shionogy.

## Acknowledgements

We acknowledge all volunteers for participating in the project and the Departments of Infectious Diseases and Microbiology for their contribution.

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