EFFECTIVENESS OF MANUAL LYMPH DRAINAGE WITH DR VODDER’S METHOD AND PROBIOTIC THERAPY VS. PROBIOTIC THERAPY IN CHRONIC CONSTIPATION TREATMENT. A PILOT STUDY.

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SUMMARY

Introduction: Constipation is a gastrointestinal functional ailment with a duration of over three months and, as in other functional problems, where there is no evidence of any organic disorder. Constipation’s prevalence in young healthy women in Spain is of 28,8%. Our main objective is to find out if the combined treatment of manual lymphatic drainage with probiotics is more effective than the treatment with only probiotics when dealing with chronic constipation.

Materials and Methods: A multicentre clinical research was carried out in several Spanish provinces, with a total of 10 participants distributed in 2 different intervention groups. The first group received manual lymphatic drainage treatment (MLD) following Dr Vodder’s method and probiotics (n=5) the second group was treated solely with probiotics (n=5). Treatment time was two months (April-May 2013).

Results: The value of statistical significance was set at p=0,005. Statistically relevant differences were not observed when comparing the results obtained using the T-Student test for independent samples. However differences were found when comparing each group’s statistical averages regarding the frequency of evacuation, time taken in evacuating, the difficulty in evacuating and the total result of the Cleveland Clinic Florida constipation scoring system.

Conclusions: Both groups experienced an improvement, being this improvement bigger in the group that also received the MLD using the Dr Vodder method. Although the results were not statistically significant that could be due to the small simple size that was used. Further research is necessary with a bigger sample size.

Key words: Constipation, Manual Lymphatic Drainage, Probiotics, Dr. Vodder’s method
Chronic constipation is a gastrointestinal functional ailment with a duration of over three months and, as in other functional problems, without evidence of any organic disorder. As a consequence of this there is a decreases in the quality of life which has negative effects on the patient. There are some authors who consider the process has to have gone on for six months before they can confirm the diagnosis. Chronic constipation is presented with persistently difficult evacuation, which includes: excess effort, incomplete evacuation, hard stools, prolonged length of time per attempts, manual assistance for evacuation and any of the previous separate or combined.

Constipation is a subjective phenomenon which can have a different meaning for each patient. Therefore, the first thing to do is to enquire into what meaning the concept has for the patient.

Constipation is a relatively common pathology, particularly in industrialized countries. Based on the epidemiological data available, the prevalence of chronic constipation varies enormously depending on the diagnosis criteria employed and the population studied, ranging between 2% and 28% of the general population. Talley found a higher frequency in people over 65 years old, this fact has been proven in many studies, and is due mainly to the alterations suffered by aging that are related to the development of constipation.

Everhart found a prevalence of 21% in females and 8% in males, with a 3:1 ratio. If we consider the situation in Spain, a recent epidemiologic study concluded that chronic constipations amongst healthy young women is a very common disorder showing a high 28,8% prevalence in this population. For this reason and because of the health problem it represents in our society we have decided to focus our study solely in the female sex.
Some other demographic data of interest is as follows. It affects all ages, a third of the children with severe constipation will continue to suffer from it when they reach an adult age. It affects more commonly non-Caucasian and in particular it is more common in black people, lower income rate people and in those living in rural areas\textsuperscript{10}. There are other illnesses that have been associated to constipation. A higher risk of suffering urinary infections, pudendum nerve injury, faecal incontinence, rectal prolapse, hemorrhoidal pathology, unnecessary surgery in young women, a higher risk of sigmoid volvulus and ischaemic colitis has been observed amongst people suffering from constipation. Solitary rectal ulcers can also be added to these complications when considering patients with a pelvic floor dyssynergia\textsuperscript{11}.

Amongst the risk factors associated with the worsening of the constipation condition are: lack of physical activity, low caloric intake, low education and income range\textsuperscript{12}, poor health, opiaceous derivatives, psychotropic or antiepileptic calcium channel blockers and anticholinergic medication intake, illnesses such as diabetes, hypothyroidism, porphyria, amyloidosis, pseudo obstruction and hypercaelcemia, together with the psychological state such as depression and stress.

As a consequence, patients afflicted with severe chronic constipation increase their stress level and this in turn may lead to changes in their evacuatorial habits. The brain is a powerful inhibitor of colonic function. Psychological factors may be the cause of constipation, as is the case sometimes in depression, for instance\textsuperscript{13}. The deliberate suppression of the defecatory act, the lack of attention to the impulse of defecating will also decrease the frequency of defecation, the faeces weight and colonic transit; this need to defecate may take several hours to return\textsuperscript{14}. Psychological problems are more often admitted by patients suffering from constipation.
Clinical evaluation of constipation is based on an initial diagnostic evaluation of the patient where a clinical history has to be taken and a full physical examination. Amongst the diagnostic tests taken are colonic structural examination and physiological tests. In the physiological examination, the colonic marker study, anorectal manometry, balloon expulsion test and defecography are included. Functional chronic constipation may be classified in: slow transit constipation, functional defecatory disorders and anatomical exit tract obstruction syndromes. Some of the measures that may be taken in order fight against constipation are: increasing liquid intake, physical exercise, defecatory reflex conditioning, dietary control with an increase of fibre intake proportion, faeces bolus forming agents control and defecation postures conductual therapy recomendations. The medical treatment of this pathology may include: laxatives, which are the standard medication for constipation, enemas, suppositories, serotonergic agents, lubiprostone, and probiotics. In order to explain the basis and motive of our research, we will go on to explain briefly the gastrointestinal system’s most important anatomical, physiological and neurological aspects. The gastrointestinal tract’s is a long tube whose main function is to mobilize water, nutrients and electrolytes between the inside and outside of the body. The nutrients that are ingested are done so mainly as macromolecules and due to their great size it is not possible for them to be absorbed by the cells. It is in the gastrointestinal tract where the mechanical and chemical fractioning of food takes place turning it into small enough molecules to be able to cross the cell’s plasmatic membrane with the aim of providing the energy and nutrients that are necessary for life.
There are five fundamental processes through which the gastrointestinal system carries out its function\(^\text{19}\).

- **Motility:** this is based on the intestine’s smooth muscles’ movements that mix food and secretions and make the gastric contents progress through the digestive tube.
- **Secretion:** in order to be able to carry out its digestive function, the digestive system has need of a series of juices, produced by glandular cells from within the walls of the gastrointestinal tract itself and a series of exocrine glands: salivary glands, pancreas and liver.
- **Digestion:** it consists in the mechanical and chemical degradation of ingested food and the transformation of macromolecules into smaller sized molecules that may be absorbed through the intestine’s epithelium tissue.
- **Absorption:** is the passage of useable nutrients to the blood and lymphatic streams for them to be used by the entire organism.
- **Defecation:** disposal of waste, indigestible substances and useless leftovers by our organism.

With the study we are going to develop, we mean to have a direct effect on the motility process and this way to obtain an indirect response on the defecation phenomenon. This system’s basic histological outline, with a few area differences depending on the segments specific function, is made up of four different tissue layers whose disposition is as follows:

- The mucosa is the layer directly in contact with the digestive tract’s lumen. It is divided in turn in three more layers which are as follows:
  - A layer of epithelial cells.
- The lamina propria is formed mainly by more or less lax connective tissue which is abundantly irrigated and contains both glans and lymphatic vessels.
- There is a fine third layer made out of smooth muscle called muscularis mucosae.

- The submucosa layer is formed by more or less dense connective tissue. It contains the largest nervous trunks and the intestinal wall’s blood vessels and some glands. In addition, the submucosa is where the plexus of the submucosa or Meissner’s plexus, which is network of nervous cells, is located.

- The muscularis propria makes up the gastrointestinal tract wall’s most exterior part and is made out of two layers of smooth muscle: an inner circular one and a more external longitudinal one. Between these two layers lies the myenteric plexus also known as Auerbach’s plexus.

- The serose or adventitia is the most external layer of the gastrointestinal tract wall and is made mainly by connective tissue. It is the continuation of the peritoneal membrane that surrounds the abdominal cavity.

The two previously cited plexus are formed by a network of nervous cells and together with the rest of neurons that innervate the gastrointestinal tract make up the so called enteric nervous system that helps integrate the digestive system.  

GASTROINTESTINAL SYSTEM NERVOUS CONTROL

Neurons in the gastrointestinal system control muscle contraction, secretion, intestinal absorption and the blood flow to the oesophagus, stomach, intestine and gallbladder.
The gastrointestinal system’s nervous control is carried out by the extrinsic innervation of the autonomous nervous system in both its sympathetic and parasympathetic divisions together and by the intrinsic innervation made up by enteric nervous system\(^\text{18}\). Because of the kind of intervention we are carrying out with our study we will consider mainly the extrinsic nervous control system.

The extrinsic nervous innervation is formed by postganglionar fibers of the major splanchnic, minor splanchnic and hypogastric nerves. Sympathetic stimulation of the digestive system has mainly an inhibitory effect over motor and secreting functions.

The parasympathetic innervation comes from preganglionar fibers that proceed mostly from the pneumogastric nerves. Their innervation comprises from the final two thirds of the oesophagus to the right side halve of the transverse colon. The remaining colon, rectum and anus are innervated by pelvic nerves. Parasympathetic stimulation of the digestive system mainly increases its function; exocrine glands increase their secretion, longitudinal external muscles contract and sphincters relax\(^\text{18}\).

Since one of our main objectives is to have an effect on gastrointestinal motility we will proceed to explain briefly the underlying mechanical principles of this system. All along the gastrointestinal tract there are two basic movements. One of them are the peristaltic movements which allow the food bolus to travel downwards, its specific characteristics depend on each segment’s particular anatomy and the specific control of each case. The second kind of movements are the segmentation contractions whose aim is to mix the bolus by increasing its contact with the gastrointestinal juices and enzymes in order to improve digestion, these movements also increase contact with the intestinal tract’s mucosa increasing this way its absorption. These last movements are more common in the small intestine and colon\(^\text{19}\).
Dr VODDER’S MANUAL LYMPH DRAINAGE

The main motive for doing this study is the proven effectiveness of Dr Vodder method of Manual Lymph Drainage (MLD) which we will go on to summarise. The technique is based on the manual activation of interstitial fluid drainage from the tissues to the vascular lymphatic system and by activating the circulation of lymph within the lymphatic vessels. Dr Vodder’s method of MLD is carried out following some basic principles; this technique does not produce hyperaemia or vasodilatation because the strokes are very soft, slow and tangential to the skin without there ever being any excessive pressure or friction on it. The pressure generally employed is of 40 mm/Hg. The hands have to be relaxed and must adapt to the body part being treated, they must move the skin over the underlying tissues but must not glide over the skin. The strokes are regular, rhythmic and slow in order to adjust to the lymphatic vessels’ rhythm which is an average 10 to 14 contractions per minute.\textsuperscript{21,22}

The most outstanding effect of Dr Vodder’s MLD is the anti-oedema or draining effect, however it is not the only one. It has also an effect on the organism’s immune-defensive response because it helps prevent the accumulation of waste material in the tissues and this way allows for a better immune response.\textsuperscript{23} However this team in primarily interested in the effect MLD has at a neural and muscular level. MLD has a direct effect on the autonomous nervous system having a clear relaxing and sedating effect which proves the activation of the parasympathetic system through MLD’s sympatholytic action.\textsuperscript{24} This is all achieved though the slow, monotonous rhythm and softness in the strokes applied. Hutzschenreuter in 1986 and 1988 was the first author and we could almost say the only one to date, due to the lack of bibliography about this matter, to describe the effects of MLD on the autonomous nervous system.\textsuperscript{25} He proved that the reflex sympatholysis was generated when applying the drainage.\textsuperscript{26} This effect becomes
one of the main motives for us to carry out this study, because if we generate this sympathectomy, the fact of indirectly activating the parasympathetic nervous system at a gastrointestinal level will improve its function, especially regarding secretions and motility\textsuperscript{18}.

On the other hand, Dr Vodder’s MLD has an effect on both striated and smooth muscle fibers. MLD has an effect on the first kind of fibres by normalizing their tone, particularly in cases where there is hypertonia. On smooth muscle fibres it is capable of improving and influencing their automatism. This way MLD has an influence on the intestinal wall by way of regulating peristalsis. All this justifies using MLD to treat constipation\textsuperscript{23}. This becomes another reason for us basing our research on this topic.

**PROBIOTICS**

As an introduction to probiotics, we will say in the first place that the human intestine is in fact the natural habitat of a wide range of bacteria that have evolved and adapted to the intestine’s ecosystem, it is also known as “intestinal flora”. Each individual can harbour some 100 billion bacteria belonging to 400 different species\textsuperscript{27}. The main function of intestinal flora is to protect, preventing the invasion of pathologic microorganisms. It also has nutritional and metabolic functions as a result of the flora’s biochemical activity; it also modulates the immune system\textsuperscript{17}. This is the reason why in the last few years food that contains agents that specifically strengthen gastrointestinal microbiota, as is the case of probiotics, is gaining such importance\textsuperscript{28}.

In 2001, Schrezenmeir and De Vrese defined probiotics as “viable, defined and in a sufficient number of non-pathological microorganisms that alter the microflora in a host’s compartment and have beneficial effects in the host’s health”\textsuperscript{28}. The success of probiotic therapy is manifested by normalization of intestinal permeability, the
improvement of its function as an immune barrier and the improvement of intestinal inflammatory responses.

Bifidobacterium and lactobacillus are the most common commercial presentations of probiotics\textsuperscript{29}. The use of probiotics is becoming more extensive all the time and there is a great array of studies regarding their effectiveness when dealing with gastrointestinal problems. The fact that we chose probiotic therapy on its own or in conjunction to MLD is due to the fact that there is clear scientific evidence regarding its effectiveness of probiotics when dealing with gastrointestinal problems. When looking at constipation in particular, it has been proven that there is a significant improvement in the number of weekly depositions and in the main problems associated with evacuations, in particular the faeces’ consistency and the effort involved in the act\textsuperscript{4, 16, 30}. This way neither group is excluded from receiving a certain therapy and we make sure of the ethical safety of the research study.

In this research study the effectiveness of combined probiotics and Dr Vodder’s MLD is compared to the exclusive use of probiotics in the treatment of chronic constipation.

**MOST RELEVANT BIBLIOGRAPHY**

Our main purpose with this research project was to prove the effectiveness of the Dr Vodder MLD method in improving constipation. The main bibliography therefore that has been consulted has been that based on Hutzschenreuter’s\textsuperscript{24, 25} researches. In his work he proves that manual drainage has an effect on the autonomous nervous system producing a reflex sympatholysis. This is one the key facts that supports our research project because it is through this sympatholitic effect that the parasympathetic nerves
are indirectly stimulated who in turn are able to generate an increase in intestinal peristalsis at a digestive system level. Secondly, peristaltic movements are also favoured by the effect MLD has on the muscles\textsuperscript{22}. With our intervention we want to prove the truth in these effects which we will do by obtaining an improvement in chronic constipation cases.

**HYPOTHESIS**

**General Hypothesis:** Dr Vodder’s method MLD in combination with probiotic intake improves chronic constipation.

**Specific Hypothesis:** Dr Vodder’s method MLD in combination with probiotic intake compared to exclusive probiotic intake treatment will have a better improvement effect on patients with chronic constipation pathology.

**OBJECTIVES**

**General:**

1. To find out whether Dr Vodder method MLD in combination with probiotic intake is more effective than treatment exclusively with probiotics in improving chronic constipation.

**Specific:**

1. To determine whether Dr Vodder method MLD in combination with probiotic intake compared to treatment exclusively with probiotics increases the frequency of evacuations.
2. To determine whether Dr Vodder method MLD in combination with probiotic intake compared to treatment exclusively with probiotics decreases evacuation time.

3. To determine whether Dr Vodder’s method MLD in combination with probiotic intake compared to treatment exclusively with probiotics decreases difficulty in evacuating.

MATERIALS AND METHODS

DESIGN

The kind of study we are going to develop is a clinical trial in which the study unit will be the patients. These kind of studies are used to evaluate a new kind of treatment in two or more groups of patients that are receiving different interventions. We chose this kind of design because we have two groups in which we are going to apply two different kinds of treatments to show that one of them is more effective than the other. It is a pilot study with an experimental design.

- **Group 1:** Five women underwent Dr Vodder’s method MLD in combination with probiotic intake for a period of two months. The Dr Vodder’s method MLD treatment consisted on a total of 16 sessions distributed in 2 weekly sessions of 40 minutes each distributed as follows: 5 minutes colon strokes, 10 minutes treatment of the colon, 5 minutes weight reduction technique, the remaining 20 minutes were employed on the remaining strokes. Which are described in detail in the intervention epigraph. The probiotic treatment consisted in the intake of one pill a day for the two month duration of the study.
• **Group 2**: Five women who took probiotics for two months (one pill a day).

**INTERVENTION**

Regarding the *manual lymph drainage* therapy on the study subjects it will be performed following Dr Vodder’s method. The application was centred on the abdomen area where we carried out the basic sequence preceded by the short neck treatment.

First we started with the short neck sequence:

The therapist stands next to the table, facing the patient. The patient is supine. All circular movements of the hands are towards the little finger side.

- **Effleurage**: Five fan-shaped strokes with thumbs flat. lateral starting from the sternum. The last stroke is along the clavicle (collarbone), 1 time.

- **Profundus to Terminus**: Stationary circles from the profundus middle, along the side of the neck, to the terminus. Five circles per position, two positions of the neck, one position in the supraclavicular fossa, 3 times.

- **Occipitus to Terminus**: Stationary circles from the occiput along the middle of the nape to the terminus. Five circles per position, two positions on the back of the neck, one position on the supraclavicular fossa, 3 times.

The basic sequence for the abdomen was carried out as follows:

The therapist stands at the patient’s right side. The patient is supine.

- **Effleurage**: Parallel rotary technique from the pubic bone to below the sternum, once.

- **Solar Plexus**: Strokes over the solar plexus with the flat hand, several repetitions, 5 times.
- Colon Strokes:
  - Strokes along the descending colon (alternating hands), 3 times.
  - Strokes in a triangular pattern with both hands along the descending, ascending and transverse colon, 3 times.

- Treatment of the Colon: Stationary circles (han don top of hand) along the descending colon (3-4 positions, 5 oval circles per position) emphasizing in the direction of the colon during the pull-pressure phase. Along the ascending colon (3-4 positions, 5 oval circles per positions) push toward the fingertips. Along the transverse colon (5-6 positions, 5 oval circles per position) also push toward the fingertips, 3 times.

- Weight Reduction Technique (treatment of the small intestine): Alternating rotary technique back and forth across the lower abdomen, staying below the navel if possible, 3 times.

- Treatment of deep lymph vessels/nodes: Deep stationary circles with fingers places flat on the lateral aspect of the pubic bone and next to the rectos abdominus muscle. Before the pressure phase, the skin is pushed distally, i.e. toward the feet, without pressure. Pressure is then exerted downward (into the table) and toward the cisterna chyli. Keep movements slow and observe the patient (treatment may cause pain), 5 circles in the right and 5 circles on the left side, 3 times.

- Final Effleurage with breathing: Flat rotary circles from the pubic bone to below the sternum during inspiration; during expiration, parallel strokes with the thumbs along the costal arches, then with the fingers along the iliac crest and the inguinal ligaments to the pubic bone, 1 times.
Regarding the **probiotic** therapy, each participant was given a total 60 capsules of the probiotic PROTRANSITUS LP®, which contains a specific probiotic strain, *Lactobacillus plantarum 299v* which is commercialized by the Salvat, S.A laboratories (Annex I).

**PARTICIPANTS**

Ten women aged between 20-50 years old who suffered chronic constipation participated in this study. The sample was selected using convenience non probability sampling method. A multicentre study was carried out where the participants came from different Spanish provinces (Almería, Huelva, Madrid y Málaga).

Inclusion Criteria:

∴ Healthy women who score 15 or higher on the Cleveland Clinic Florida constipation scoring system.

∴ Age ranging from 20 to 50 years old.

Exclusion Criteria:

∴ Men.

∴ Patients with constipation secondary to any other diagnosed pathology.

∴ Patients outside the age range.

**VARIABLES**

Predictor or Independent variable:

1. Intervention: *Qualitative nominal variable*. The reason for collecting this variable’s data was to be able to classify the participants in either study group. One group received MLD with Dr Vodder’s method and probiotics. The second group received only probiotic treatment.
Response or Dependent variable:

1. Frequency of bowel movements: *Quantitative Ordinal variable*. The reason for taking this variable into consideration is to be able to account for the participants’ improvement or not. It is collected using the Cleveland Clinic Florida constipation scoring system.

<table>
<thead>
<tr>
<th>1-2 times per 1-2 day</th>
<th>2 times per week</th>
<th>Once per week</th>
<th>Less than once per week</th>
<th>Less than once per month</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

2. Time: minutes in lavatory per attempt: *Qualitative interval Scale*. The reason for collecting this variable’s data is to be able to check the decrease in the time taken to evacuate as treatment progresses. It is collected using the Cleveland Clinic Florida constipation scoring system. The measuring scale has the following values:

<table>
<thead>
<tr>
<th>Less than 5</th>
<th>5 - 10</th>
<th>&gt;10 - 20</th>
<th>&gt;20 - 30</th>
<th>&gt;30</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

3. Difficulty: painful evacuation effort: *Qualitative ordinal variable*. The reason for collecting this variable’s data is to be able to check the decrease in the difficulty to evacuate as treatment progresses. It is collected using the Cleveland Clinic Florida constipation scoring system. The measuring scale has the following values:

<table>
<thead>
<tr>
<th>Never</th>
<th>Rarely</th>
<th>Sometimes</th>
<th>Usually</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
4. Assistance: Type of assistance: *Qualitative Nominal variable*. The reason for collecting this variable’s data is to be able to check whether with the treatment participants were able to go without these additional aids. The measuring scale has the following values:

<table>
<thead>
<tr>
<th>Without assistance</th>
<th>Stimulative laxatives</th>
<th>Digital assistance or Enema</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

5. Completeness: feeling incomplete evacuation: *Ordinal Qualitative variable*. The reason for collecting this variable’s data is to verify whether with the treatment participants were able to decrease this sensation. It was collected using the Cleveland Clinic Florida constipation scoring system. The measuring scale has the following values:

<table>
<thead>
<tr>
<th>Never</th>
<th>Rarely</th>
<th>Sometimes</th>
<th>Usually</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

6. Failure: unsuccessful attempts for evacuation per 24 hours: *Ordinal Qualitative variable*. The reason for collecting this variable’s data was to verify whether with the treatment there was a decrease in the number of bowel evacuation failed attempts. It was collected using the Cleveland Clinic Florida constipation scoring system. The measuring scale has the following values:

<table>
<thead>
<tr>
<th>Never</th>
<th>1 - 3</th>
<th>&gt; 3 - 6</th>
<th>&gt; 6 - 9</th>
<th>&gt; 9</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

7. Pain: Abdominal pain. *Ordinal Qualitative variable*. The reason for collecting this variable’s data was to verify whether with the treatment there was a decrease in this variable’s value. It was collected using the Cleveland Clinic.
Florida constipation scoring system. The measuring scale has the following values:

<table>
<thead>
<tr>
<th>Never</th>
<th>Rarely</th>
<th>Sometimes</th>
<th>Usually</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

8. History: duration of constipation (years). *Ordinal Qualitative variable*. The reason for collecting this variable's data was to know the length of the ailment’s evolution in the participants. It was collected using the Cleveland Clinic Florida constipation scoring system. The measuring scale has the following values:

<table>
<thead>
<tr>
<th>0</th>
<th>1-5</th>
<th>&gt;5-10</th>
<th>&gt;10-20</th>
<th>&gt;20</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

Control Variables:

1. Age: *Quantitative continuous*: The reason for taking this variable into account was to analyse if there was a difference in the improvement of the variables related to different age groups. It was recorded on the first interview with the participant.

2. Weight: *Quantitative continuous*: this variable was recorder to obtain the BMI (body Mass Index). It was obtained directly using scales during the personal interview.

3. Height: *Quantitative continuous*. This variable was recorder to obtain the BMI (body Mass Index). It was obtained directly using a tape measure during the personal interview.

4. Body Mass Index (BMI): *Quantitative continuous*. The reason for taking this variable into account is to analyse whether there is a change in the improvement
depending on the participant’s BMI. It is recorded using the formula: BMI = Weight / Height^2

5. Physical Activity: *Qualitative Ordinal*. The reason for obtaining this variable’s value was to know the participant’s physical activity state because it strongly influences constipation treatment. It was recorded during the personal interview and the following are the answer options:

<table>
<thead>
<tr>
<th>Never</th>
<th>1-2 days</th>
<th>3-5 days</th>
<th>Daily</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

6. Alcohol: *Qualitative Ordinal*. The reason for obtaining this variable’s value was to know what influence alcohol intake has on constipation. It was recorded during the personal interview using the UBE (Spanish Initials for: Weekly Standard Drink Units) measuring scale.

<table>
<thead>
<tr>
<th>0 UBE</th>
<th>1-5 UBE</th>
<th>6-10 UBE</th>
<th>11-17 UBE</th>
<th>More than 17</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

1 glass of wine/ glass of beer = 1 UBE 1 shot = 2 UBE

7. Tobacco: *Qualitative Ordinal*. The reason for taking this variable into account is to see the influence smoking tobacco has on constipation. It was recorded during the personal interview using the following measuring scale.

<table>
<thead>
<tr>
<th>0 cigarettes/day</th>
<th>1-5 cigarettes/day</th>
<th>6-15 cigarettes/day</th>
<th>16-22 cigarettes/day</th>
<th>More than 22 cigarettes/day</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

8. Work activity: *Qualitative Ordinal*. The reason for taking this variable into account is to see the influence it may have on constipation. It is recorded during the personal interview using the following measuring scale:

<table>
<thead>
<tr>
<th>Standing</th>
<th>Sitting</th>
<th>Both</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>
9. Medication: *Qualitative Ordinal*. The reason for taking this variable into account was to see the influence smoking tobacco has on constipation. It was recorded during the personal interview using the following measuring scale:

<table>
<thead>
<tr>
<th>Does not take any medication</th>
<th>Yes, takes medication but it does not affect constipation</th>
<th>Yes, takes medication and it does affect constipation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

The total number of variables taken was 30. 18 were taken in the first interview and 12 of them were taken again in the second interview. The data regarding age, height, type of intervention, work activity, constipation duration in years and medication taken were only recorded on the first interview.

To be able to assess whether there was an underlying pathology we used a constipation measuring system developed in 1996 by Agachan y Wexner, at the Cleveland Clinic in Florida (Annex II). It consists of eight parameters which were selected from a total eighteen because of their statistical significance.

This was done after doing a clinical and physiological correlation with the aim of simplifying constipated patients’ evaluation and undertaking. These eight parameters are: frequency of evacuations, difficulty in evacuating, incomplete evacuation sensation, abdominal pain, time needed to evacuate, assistance to defecate, number of failed attempts in 24 hours and duration of constipation in years. This punctuation system goes from 0 to 30, 0 indicating the normal situation while 30 indicates severe constipation. The cut parameter in Wexner’s original study that indicated the presence of constipation was 15, this being the minimum value needed for the inclusion of the participants in our study.
DATA COLLECTION AND ANALYSIS

To collect the data the participants were interviewed individually with one of the physiotherapists taking part in the study. In the first interview they were informed of the purpose of the study and what it was going to be about, they were handed the informed consent form (Annex III), the initial questionnaire was taken (Annex IV) and they filled in the Cleveland Clinic Florida constipation scoring system form.

If the participant belonged to group 2 (probiotics exclusively) she was explained she had to take a probiotic pill daily for the 2 month duration of the study. Once this time had elapsed she was given a second appointment where the information regarding the final questionnaire (Annex V) and the Cleveland Clinic Florida constipation score was collected.

On the other hand if the patient was included in group 1 (Dr Vodder’s method MLD and probiotics) in addition to the daily probiotic pill intake, she was given two appointments a week for the MLD treatment previously described for the full two month duration of the study. The MLD treatment took place in the patients’ home on a portable plinth. The treatment session had a duration of 40 minutes. Once the two months of the study were over, the participants took the final questionnaire and the final constipation scoring questionnaire.

Both the final questionnaire and the constipation scoring test are detailed in the Annex epigraph.

**Statistical Analysis:** We used the statistic software programme IBM SPSS Statistics, version 21, we had to use parametric statistic tests.
Firstly we did a descriptive statistical analysis of the data for the quantitative variables using the mean and standard deviation and using percentages for the qualitative variables.

After obtaining the mean values these were analysed using the T-student test for independent samples comparing the mean values.

Finally we did a Spearman correlation graph to find out whether there was a statistically significant difference between two numerical variables

The statistical significance level was established at $p=0.05$.

STUDY LIMITATIONS

- Convenience sampling: because our access to the patients was limited we were forced to ask people close to the research team for their voluntary participation in the research study. A possible solution could have been taking this project to a medical and professional environment that would have brought us closer to patients.

- Feeding habits: because of the direct influence different kinds of diets have on our digestive system. A possible solution would have been to modify and control each patient’s diet in order to achieve an improvement in their constipation.

- Evacuation position: Because the basic defecation position is counterproductive for an optimal evacuation, a possible solution would have been to apply conduct therapy in which we would have taught the participants the most favourable position for the expulsion of faeces.

- Not having differentiated the kind of constipation: Because in certain kinds of constipation processes the physiotherapy approach does not improve the
pathology. A possible solution would have been to have done more thorough diagnosis tests.

- Sample size: The sample is not representative and therefor the results cannot be extrapolated to the general population. A possible solution would have been to increase the sample’s size.

Biases:

- Voluntary participant selection bias

Possible solutions: If we had had more economic means and a broader access to patients with the pathology we intended to study we would have eliminated the voluntary participation in this research study eliminating this way the bias.

RESEARCH TEAM

The research team is made up by the 5 physiotherapists specialised in Dr Vodder’s method MLD, who participated in the Universidad Europea de Madrid (Spain), Msc programme in Women’s advanced physiotherapy techniques.

∴ Domínguez Velasco, Alejandra (postgraduate student)

∴ López Fernández, José (postgraduate student)

∴ López Fernández, María (postgraduate student)

∴ Alvarez Harris, Sara (postgraduate student)

∴ Robledo Do Nascimento, Yolanda (lecturer)

CONFLICT OF INTEREST

We contacted the SALVAT, S.A. laboratories from Esplugues de Llobregat (Barcelona) who supplied a total 600 pills free of cost to carry out this research with the only request to forward them the final results of the study.
WORK SCHEDULE

DEVELOPMENT STAGES

- Research Theme planning (January 2013)
- Research question definition (January 2013)
- Bibliographic research (January – May 2013)
- Study design (February 2013)
- Participants research (March 2013)
- Pre-Data collection (March 2013)
- Intervention period (April-May 2013)
- Post-Data collection (June 2013)
- Data analysis (June 2013)
- Project writing (June 2013)

PLACE OF DEVELOPMENT

We developed a multicentre study where the patients came from different Spanish provinces (Almería, Huelva, Madrid and Málaga).

With the group treated solely with probiotics both the data collection and intervention took place in the Spanish cities of Almería, Huelva and Málaga.

With the group treated Dr Vodder’s method MLD and probiotics both the data collection and intervention took place in Madrid, the MLD taking place in the participant’s home.

The project was put together and edited at the Universidad Europea de Madrid (Spain)
RESULTS

Our study started off with 10 participants, who were divided into two intervention groups (n=5). During the time the study took place one of the participants from group 1 left the study due to a change of residence, ending group 1 with n=4 and group 2 with n=5.

Graph 1. Study flowchart.

In the table 1 the adjustment variable has been analysed before and after carrying out the treatment calculating both intervention groups’ means. Mean age for group 1 was 24,80 and 33,60 for group 2, which means there is a significant difference between both groups’ ages of 8,8 years. The mean age of the whole study group was 29,20 years.

The mean total BMI before the study was 23,29, there was no significant difference between both groups, being this of 0,81. However, physical activity and tobacco
smoking before the study do present a significant difference, because although these are of 1 and 0.8 respectively, they imply a jump from one to the next range in the measuring scale. For that same reason, alcohol intake, medication and work activity previous to the study do not represent a significant difference being the difference between both groups’ means 0,2, 0,2 y 0,4 respectively.

Both BMI and alcohol intake after the study do not present a significant difference, these being 0,24 y 0,25.

On the other hand, physical activity and tobacco smoking after the study present a difference of 0,7 y 1,05 each, which is significant to our study.

The P value of all the results is not statistically significant since the P value in each parameter is never smaller than 0,05.

Table 1. Demographic Graph Pre and Post Study

<table>
<thead>
<tr>
<th>Parameters</th>
<th>MLD + probiotics Group x (σ)</th>
<th>Probiotic Group x (σ)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>24,80 (2,280)</td>
<td>33,60 (8,735)</td>
<td>0.061</td>
</tr>
<tr>
<td>BMI pre</td>
<td>22,88 (4,035)</td>
<td>23.69 (3,998)</td>
<td>0.757</td>
</tr>
<tr>
<td>BMI post</td>
<td>23,37 (4,052)</td>
<td>23,61 (3,984)</td>
<td>0.931</td>
</tr>
<tr>
<td>Physical Activity Pre</td>
<td>1,80 (0,836)</td>
<td>0,80 (0,836)</td>
<td>0.095</td>
</tr>
<tr>
<td>Physical Activity Post</td>
<td>1,50 (1,000)</td>
<td>0,80 (0,836)</td>
<td>0.289</td>
</tr>
<tr>
<td>Alcohol Intake Pre</td>
<td>1,20 (0,836)</td>
<td>1,00 (0,707)</td>
<td>0.694</td>
</tr>
<tr>
<td>Alcohol Intake Post</td>
<td>1,25 (1,258)</td>
<td>1,00 (0,707)</td>
<td>0.716</td>
</tr>
<tr>
<td>Tobacco Intake Pre</td>
<td>1,00 (1,414)</td>
<td>0,20 (0,447)</td>
<td>0.284</td>
</tr>
<tr>
<td>Tobacco Intake Post</td>
<td>1,25 (1,500)</td>
<td>0,20 (0,447)</td>
<td>0.258</td>
</tr>
<tr>
<td>Medication</td>
<td>0,60 (0,547)</td>
<td>0,40 (0,547)</td>
<td>0.580</td>
</tr>
<tr>
<td>Work Activity</td>
<td>1,40 (0,894)</td>
<td>1,00 (0,707)</td>
<td>0.455</td>
</tr>
<tr>
<td>Variable</td>
<td>MEASURING SCALE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------</td>
<td>------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical Activity</td>
<td>Never 1-2 days 3-5 days daily</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol Intake</td>
<td>0 UBE 1-5 UBE 6-10 UBE 11 -17 UBE More than 17 UBE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tobacco Intake</td>
<td>0 Cigarettes/day 1-5 cigarettes/day 6-15 cigarettes/day 16-22 cigarettes/day More than 22 cigarettes/day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Work Activity</td>
<td>Standing Sitting Both</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication</td>
<td>Does not take any medication Yes, takes medication but it has no influence on constipation Yes, takes medication and it has an influence on constipation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 2 shows each group’s means after calculating the difference in pre and post evacuating frequency. Group 1’s mean is 1,75 and group 2’s is 1,4. There is a difference of 0,35 between both groups.

P value is not statistically significant since it is under 0,05.

Table 2. Evacuation frequency Difference

<table>
<thead>
<tr>
<th>INTERVENTION</th>
<th>N</th>
<th>MEAN</th>
<th>ESTANDAR DEVIATION</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency difference</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MLD + Probiotic</td>
<td>4</td>
<td>1,7500</td>
<td>0,50000</td>
<td>0,356</td>
</tr>
<tr>
<td>Probiotics</td>
<td>5</td>
<td>1,4000</td>
<td>0,54772</td>
<td></td>
</tr>
<tr>
<td>Measuring Scale</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-2 times per 1-2 days</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>2 times per week</td>
<td>2</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 time per week</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 3 shows each group’s means after calculating the difference in pre and post evacuating time. Group 1’s mean is 2 and group 2’s is 0,8. There is a difference of 1,2 between both groups.

P value is not statistically significant since it is under 0,05.
Table 3. Evacuation time difference

<table>
<thead>
<tr>
<th>INTERVENTION</th>
<th>N</th>
<th>MEAN</th>
<th>ESTÁNDAR DEVIACIÓN</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time difference</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MLD + Probiotic</td>
<td>4</td>
<td>2,0000</td>
<td>1,41421</td>
<td>0,155</td>
</tr>
<tr>
<td>Probiotics</td>
<td>5</td>
<td>0,8000</td>
<td>0,83666</td>
<td></td>
</tr>
<tr>
<td>Measuring Scale</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than 5</td>
<td>5 - 10</td>
<td>&gt; 10 - 20</td>
<td>&gt; 20 - 30 &gt; 30</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

Table 4 shows each group’s means after calculating the difference difficulty in evacuating pre and post treatment. Group 1’s mean is 1,75 and group 2’s is 1,2. There is a difference of 0,55 between both groups.

P value is not statistically significant since it is under 0,05.

Table 4. Evacuation difficulty

<table>
<thead>
<tr>
<th>INTERVENTION</th>
<th>N</th>
<th>MEAN</th>
<th>ESTÁNDAR DEVIACIÓN</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difficulty difference</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MLD + Probiotic</td>
<td>4</td>
<td>1,7500</td>
<td>0,95743</td>
<td>0,287</td>
</tr>
<tr>
<td>Probiotics</td>
<td>5</td>
<td>1,2000</td>
<td>0,44721</td>
<td></td>
</tr>
<tr>
<td>Measuring Scale</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

Table 5 shows each group’s means after calculating the difference in the Cleveland Clinic Florida Constipation Score pre and post treatment. Group 1’s mean is 10,25 and group 2’s is 4,6. There is a difference of 5,65 between both groups.

In this analysis the Levene test for equal variances throws a p of 0,039, which tells us that equal variances have not been assumed. When contrasting it with the T student test the value of p is 0,120 which means the result will not be statistically significant.

Table 5. Cleveland Clinic Florida Constipation Score difference

<table>
<thead>
<tr>
<th>INTERVENTION</th>
<th>N</th>
<th>MEAN</th>
<th>ESTÁNDAR DEVIACIÓN</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCF score difference</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MLD + Probiotic</td>
<td>4</td>
<td>10,2500</td>
<td>5,31507</td>
<td>0,120</td>
</tr>
<tr>
<td>Probiotics</td>
<td>5</td>
<td>4,6000</td>
<td>2,07364</td>
<td></td>
</tr>
</tbody>
</table>
In **table 6** we can see when we do the correlation between physical activity and age that there is no statistical significance. This is because participant aggregation was done around central values, no influence was shown between both numeric variables.

**Table 6. Speraman correlation graph**

---

**DISCUSSION**

The main aim of this study was to find out whether the treatment of chronic constipation with probiotic therapy and Dr Vodder’s Method MLD was more effective than treating it solely with probiotic therapy. After analysing the data we can state that this objective has been satisfactorily reached. Although both groups have shown an improvement the one treated with probiotics and Dr Vodder’s MLD has improved a mean 5.65 points
more if compared to the group treated only with probiotics. This difference is based on
the Cleveland Clinic Florida constipation Score.

All the secondary objectives defined for our study have been reached. We have noted a
favourable difference towards the group treated with probiotics and Dr Vodder’s MLD
compared to the group treated only with probiotics regarding evacuation frequency by
0,35 and evacuation difficulty by 0,55. The objective where the difference is bigger is
time taken to evacuate, there was a mean difference of 1,2 between both groups.

For this reason we have proven that treatment of chronic constipation with probiotics
and Dr Vodder’s MLD is more effective than treatment only with probiotics, although
there has been an improvement in both groups.

With the demographic analysis we have seen a bigger difference between the pre and
post intervention values of the variables age, BMI, physical activity and tobacco intake
Regarding age, we found there was a significant difference between both study groups.
Although it has not entailed a limitation in regards to the results of our intervention, we
do think it is a variable that should be taken into consideration for future research
studies since it may influence or prove that one intervention is more efficient in one age
group than another.

In our study there has not been a significant difference between both groups’ BMI, but
on an individual level we observed extreme values. We should bear in mind that the
higher the BMI value the chance of improvement is smaller. The same way that happens
with the age variable, if further research project are done the influence of this variable
should be taken into account.

In our research project there was a higher physical activity frequency in the group who
received Dr Vodder’s MLD and probiotics than in the other group, although this has not
altered the final results. For future research projects the fact that physical activity has a
positive effect on improving the severity of constipation processes should be taken into account.

In this case there was a higher mean tobacco intake level in the group who received Dr Vodder’s MLD and probiotics than in the other group who received probiotics only. It could be a variable that should be taken into account as it may possibly have an effect in the results for future research studies. However it has not altered the final results in our research due to the small sample size.

After developing our research project, we have not found any studies on the effect of the combined Dr Vodder MLD and probiotics on the treatment of chronic constipation with which to compare the results of our study with. However, the results obtained with the groups with the probiotics exclusive treatment can be compared. In a 2011 research study by Liu Louis Wing Cheong, he carried out a systematic revision to evaluate the use of different probiotics stems for the treatment of chronic constipation, comparing the different effectiveness of them for constipation treatment\(^\text{31}\). This author analysed several probiotic strains amongst which was *Lactobacillus plantarum* which has been used in our probiotic intervention.

As a final conclusion to our study, we can say that both groups have been found to be effective, but more so in the group reinforced by Dr Vodder’s MLD. However the results are not statistically significant since in none of the cases the p value was smaller than 0.05, the probable cause is the small simple size. Further research studies are needed with a bigger sample size in order for the results to be able to be extrapolated to the general population.
Food supplement with probiotic. *Lactobacillus plantarum 299v*. Beneficial for the maintenance of intestinal function.

**INGREDIENTS**

- Starch, potato (*Solanum tuberosum* L.)
- Capsule Components: Hydroxypropylmethylcellulose; Probiotic *Lactobacillus plantarum 299v* *
- Anti-caking agents: magnesium stearate.
- Contain soy.
  * Each capsule provides 10,000 million live bacteria.

**WHO IS PROTRANSITUS LP AIMED AT?**

*Protransitus LP* is aimed at those with a sensitive gut that prevents the proper maintenance of intestinal function. These intestinal disorders usually manifest with intestinal discomfort feeling: bloating, heaviness, gas, changes in bowel habits,...

There is great ignorance about the origin of these disorders, although there have been proposed several factors that may be involved. Including psychological factors (stress, anxiety...), dietary factors, hormonal factors...

They alter the balance of intestinal flora and may affect gut motility and cause this feeling of discomfort that can be highly disabling, and even get to seriously affect quality of life: social, professional...

**WHAT IS PROTRANSITUS LP?**

*Protransitus LP* is a dietary supplement that contains a specific probiotic strain, *Lactobacillus plantarum 299v*, which can reduce these feelings of intestinal discomfort as published scientific studies (1, 2), together with an additional action to balance the intestinal flora.

The human gut is colonized by living bacteria from more than 400 different species, which form the intestinal flora. Cohabiting benign and harmful bacteria, although normally a balance between protecting both from the aggression of other microorganisms is established. However, poor diet, stress or the presence of certain diseases may favor the growth of harmful bacteria. One way to strengthen the functioning of the bacterial flora is by ingesting live microorganisms that have a positive
effect on health. These organisms are known as probiotics.

HOW TO USE PROTRANSITUS LP?

We recommend taking 1 or 2 capsules LP Protransitus daily, preferably before breakfast, for 4 weeks, repeating the decision if necessary.

- Do not exceed the stated recommended daily dose.
- Food supplements should not be used as substitutes for a balanced diet.
- Do not administer to children under 3 years.

WHAT lifestyle modifications SHOULD BE CONSIDERED?

- Take a varied diet.
- Avoid heavy meals, with many spices or too much fat.
- Avoid foods that you have detected to trigger the intestinal discomfort.
- Avoid eating in a hurry and respect the timing of meals.
- Drink at least 1.5 litres of water a day.
- Enjoy a relaxing time.
- Practice some form of regular physical activity.

PRESENTATION

- Each box contains 30 capsules.
- Each box contains 10 capsules.

CONSERVATION

- Store in a dry place away from heat sources.
- Keep out of reach of children.

LABORATORIES Salvat, SA C / Gall 30-36 08950-Esplugues de Llobregat Barcelona - Spain

Annex II. Cleveland Clinic Florida Constipation Scoring System

**Cleveland Clinic Florida Constipation Scoring System**

(Agachan et al., 1996)

<table>
<thead>
<tr>
<th>Frequency of Bowel Movements</th>
<th>Time: Minutes in Lavatory per Attempt</th>
</tr>
</thead>
<tbody>
<tr>
<td>0  1-2 times per 1-2 days</td>
<td>0  Less than 5</td>
</tr>
<tr>
<td>1  2 times per week</td>
<td>1  5-10</td>
</tr>
<tr>
<td>2  Once per week</td>
<td>2  &gt; 10-20</td>
</tr>
<tr>
<td>3  Less than once per week</td>
<td>3  &gt; 20-30</td>
</tr>
<tr>
<td>4  Less than once per week</td>
<td>4  &gt; 30</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Difficulty: Painful Evacuation Effort</th>
</tr>
</thead>
<tbody>
<tr>
<td>0  Never</td>
</tr>
<tr>
<td>1  Rarely</td>
</tr>
<tr>
<td>2  Sometimes</td>
</tr>
<tr>
<td>3  Usually</td>
</tr>
<tr>
<td>4  Always</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Assistance: Type of Assistance</th>
</tr>
</thead>
<tbody>
<tr>
<td>0  Without assistance</td>
</tr>
<tr>
<td>1  Stimulative laxatives</td>
</tr>
<tr>
<td>2  Digital assistance or enema</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Completeness: Feeling Incomplete Evacuation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0  Never</td>
</tr>
<tr>
<td>1  Rarely</td>
</tr>
<tr>
<td>2  Sometimes</td>
</tr>
<tr>
<td>3  Usually</td>
</tr>
<tr>
<td>4  Always</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pain: Abdominal Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>0  Never</td>
</tr>
<tr>
<td>1  Rarely</td>
</tr>
<tr>
<td>2  Sometimes</td>
</tr>
<tr>
<td>3  Usually</td>
</tr>
<tr>
<td>4  Always</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Failure: Unsuccessful Attempts for Evacuation per 24 Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>0  Never</td>
</tr>
<tr>
<td>1  1-3</td>
</tr>
<tr>
<td>2  &gt; 3-6</td>
</tr>
<tr>
<td>3  &gt; 6-9</td>
</tr>
<tr>
<td>4  &gt; 9</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>History: Duration of Constipation (Years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0  0</td>
</tr>
<tr>
<td>1  1-5</td>
</tr>
<tr>
<td>2  &gt; 5-10</td>
</tr>
<tr>
<td>3  &gt; 10-20</td>
</tr>
<tr>
<td>4  &gt; 20</td>
</tr>
</tbody>
</table>

Final Score:

Minimum Score: 0
Maximum Score: 30

0: Normal
15: Light Constipation
30: Severe Constipation
Annex III. Informed Consent.

INFORMED CONSENT

Title of the Study:

• Effectiveness of lymphatic drainage therapy with Dr Vodder’s method and probiotic therapy vs. probiotic therapy in constipation treatment. A pilot study

Research Team:

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• Sara Álvarez Harris
• Yolanda Robledo Do Nascimento

Place of Development of the Study:

• It is a multicenter study with patients from
  o Almería.
  o Málaga.
  o Huelva.
  o Madrid.

You have been invited to participate in this clinical research study. Before you decide whether you chose to participate or not, you must know and understand each of the following epigraphs. This process is called informed consent. Please feel free to ask any questions regarding any aspect that may help you clarify any doubts that may arise.

Once you have understood and if you then decide to take part in the project, you will be asked to sign this consent form, you will be given a signed and dated copy of it.

STUDY JUSTIFICATION.

With this study we want to test the efficiency of different constipation treatment techniques.

AIM OF THE STUDY.

You are being invited to partake in a research study that has the following aims:

• To modify some of your daily living habits in order to allow you to have a better defecating process.
• To increase faeces evacuation frequency.
BENEFITS OF THE STUDY.

With this study we intend to obtain an improvement in the evacuation frequency of constipated people.

STUDY PROCEDURES.

There will be two different procedures applied to two different groups:

- In the case of being included in group 1:
  - Probiotic intake.
  - Manual Lymph Drainage,

- In the case of being included in group 2:
  - Probiotic intake.

ASSOCIATED RISKS OF THE STUDY

Manual Lymph Drainage does not have any associated negative risks, however certain side effects may appear such as:

- Increased flux, during menstruation, and/or a modification of the start date of the menstrual cycle.
- During Manual Lymph Drainage there may be a central blood pressure decrease.

CLARIFICATIONS.

- Your decision of partaking in the study is completely voluntary.
- There will be no negative consequences for you in the case of not accepting the invitation.
- If you do decide to take part in the study you are free to abandon it at any point if you so wish, even if the researcher in charge does not ask you to do so – you are free to give the reasons behind your decision or not, which will be fully accepted in any case.
- This study will not involve any cost on your side.
- You will not be paid for your participation.
- During the study you are welcome to ask the researcher in charge for up to date information on the study.
- All the information obtained in this study for the participant’s correct identification will be treated with the uttermost confidentiality by the research team.
- If you consider you have no further doubts or questions regarding your participation in this study, you may, if you so wish, sign the Informed Consent Letter which is part of the present document.
INFORMED CONSENT.

I, ________________________________ have read and understood the previous information and my questions have been answered satisfactorily. I have been informed and I understand that the data derived from this study may be published or diffused for scientific purposes. I agree to participate in this research study. I will receive a copy of this informed consent form signed and dated.

________________________________________________
Participant/ legal representative’s signature        Date

This part is to be filled in by the researcher (or his/her representative):

I have hereof explained to Mr(s).___________________ the nature and purpose of this research; I have explained the risks and benefits derived from taking part in the study. I have answered the questions that have arisen as far as possible and I have asked if there be any further questions. I accept that I have read and know the corresponding regulation on research on human beings and abide by it. Once the questions and answers session was concluded the present document was signed.

____________________________
Research team signature        Date        Telephone number
Annex IV. Initial Questionnaire.

### Patient number:

#### Initial Questionnaire

- **Age**: [ ]
- **Weight**: [ ]
- **Height**: [ ]
- **BMI (weight/height^2)**: [ ]

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Tobacco Intake</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probiotics</td>
<td>0 cigarettes/day</td>
</tr>
<tr>
<td>Probiotics + MLD</td>
<td>1 to 5 cigarettes/day</td>
</tr>
<tr>
<td></td>
<td>6 to 15 cigarettes/day</td>
</tr>
<tr>
<td></td>
<td>15 to 22 cigarettes/day</td>
</tr>
<tr>
<td></td>
<td>More than 22 Cigarettes/day</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Physical Activity</th>
<th>Alcohol Intake (weekly)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never</td>
<td>0 UBE</td>
</tr>
<tr>
<td>1-2 days/week</td>
<td>1 to 5 UBE</td>
</tr>
<tr>
<td>3-5 days/week</td>
<td>6 to 10 UBE</td>
</tr>
<tr>
<td>Daily</td>
<td>11 to 17 UBE</td>
</tr>
<tr>
<td></td>
<td>More than 17 UBE</td>
</tr>
</tbody>
</table>

#### Work Activity

- Standing
- Sitting
- Both

#### Medication

- Does not take any medication.
- Yes, takes medication, but it DOESN’T have any influence on constipation
- Yes, takes medication and it has an influence on constipation

* 1 glass of wine = 1 UBE
* 1 bottle of beer = 1 UBE
* 1 tall glass liquor = 2 UBE
Annex V. Final Questionnaire

**FINAL QUESTIONNAIRE**

- Weight
- Height
- BMI (weight/height²)

### Physical Activity
- Never
- 1-2 days/week
- 3-5 days/week
- Daily

### Tobacco Intake
- 0 cigarettes/day
- 1 to 5 cigarettes/day
- 6 to 15 cigarettes/day
- 15 to 22 cigarettes/day
- More than 22 cigarettes/day

### Alcohol Intake (weekly)
- 0 UBE
- 1 to 5 UBE
- 6 to 10 UBE
- 11 to 17 UBE
- More than 17 UBE

*1 glass of wine = 1 UBE
*1 bottle of beer = 1 UBE
*1 tall glass liquor = 2 UBE*
BIBLIOGRAPHY


31. Liu Louis Wing Cheong LW. Chronic constipation: current treatment options.. Canadian journal of gastroenterology = Journal canadien de gastroenterologie. 2011. 25 Suppl B p 22B-28B