

# Clinical Trial Registration Statement

Name of Journal: World Journal of Gastroenterology

Title: Evaluation of an educational telephone intervention strategy to improve non-screening colonoscopy attendance. A randomized controlled trial

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This study was registered at ClinicalTrials.gov.  
The ClinicalTrials.gov Identifier is: NCT03458377  
URL: <https://clinicaltrials.gov/ct2/show/NCT03458377>

Tabular view of the registration:

Tracking Information	
First Submitted Date ICMJE	February 16, 2018
First Posted Date ICMJE	March 8, 2018
Last Update Posted Date	March 20, 2019
Actual Study Start Date ICMJE	February 20, 2018
Actual Primary Completion Date	September 1, 2018 (Final data collection date for primary outcome measure)
Current Primary Outcome Measures ICMJE (submitted: March 1, 2018)	Colonoscopy non-adherence rate [ Time Frame: At the moment of colonoscopy ] Ratio of patients do not attend the test
Original Primary Outcome Measures ICMJE	<i>Same as current</i>
Change History	<a href="https://clinicaltrials.gov/ct2/show/NCT03458377">Complete list of historical versions of study NCT03458377 on ClinicalTrials.gov Archive Site</a>
Current Secondary Outcome Measures ICMJE (submitted: March 1, 2018)	<ul style="list-style-type: none"><li>• Antiplatelet / anticoagulant rescheduling rate [ Time Frame: At the moment of colonoscopy ]Ratio of patients attend the colonoscopy with poor adjustment of antiplatelet / anticoagulant medication so they need rescheduling of the test<ul style="list-style-type: none"><li>• Anesthetist rescheduling rate [ Time Frame: At the moment of colonoscopy ]Ratio of patients attend the colonoscopy with American Society of Anesthesiologists (ASA) III / IV classification so they need rescheduling of the test under anesthesia</li><li>• Bowel preparation rescheduling rate [ Time Frame: At the moment of colonoscopy ]Ratio of patients attend the colonoscopy with inadequate Boston Bowel Preparation Scale (at least one of the colon segments with less than 2 points) so they need rescheduling of the test</li><li>• Adenoma detection rate [ Time Frame: At the moment of colonoscopy ]Ratio of patients with at least one adenoma in the colon</li><li>• Cecal intubation rate [ Time Frame: At the moment of colonoscopy ]Ratio of successful complete colonoscopies (cecal intubation or in case of previous surgery, ileocolic anastomosis)</li><li>• Satisfaction of the endoscopic procedure [ Time Frame: 30 days after colonoscopy ]Measurement of the overall satisfaction of the colonoscopy with a questionnaire</li></ul></li></ul>

	<p>validated by the American Society for Gastrointestinal Endoscopy (ASGE)</p> <ul style="list-style-type: none"> <li>• Complications related to colonoscopy [ Time Frame: 30 days after colonoscopy ]Telephone interview. The patient will be asked about the appearance of perforation, hemorrhage and abdominal symptoms related to the test</li> <li>• Non-adequation colonoscopy cost of patient preparation for colonoscopy [ Time Frame: From date of randomization until 30 days before colonoscopy ]Cost derived from non-adequation</li> </ul>
<b>Original Secondary Outcome Measures ICMJE</b>	<i>Same as current</i>
<b>Current Other Pre-specified Outcome Measures</b>	<i>Not Provided</i>
<b>Original Other Pre-specified Outcome Measures</b>	<i>Not Provided</i>
<b>Descriptive Information</b>	
<b>Brief Title ICMJE</b>	Telephone Educational Intervention by the Gastrointestinal Endoscopy Nurse. Global Impact on the Quality of Colonoscopy
<b>Official Title ICMJE</b>	Implementation of a Telephone Educational Intervention Performed in Outpatient Patients by the Gastrointestinal Endoscopy Nurse. Study of the Impact on the Pre-procedure, Procedure and Post-procedure Colonoscopy Quality Indicators.
<b>Brief Summary</b>	This study assesses what impact has on colonoscopy quality the implementation of a telephone educational intervention carried out individually on the patient in the days before the test. Half of the study patients will receive the educational intervention and the other half will not.
<b>Detailed Description</b>	<p>A high-quality colonoscopy is an examination in with patients receive an indicated procedure, correct and relevant diagnoses are recognized or excluded, any therapy provided is appropriate, and all steps that minimize risk have been taken. But quality also refers to pre-procedure and post-procedure quality issues such as information, booking, choice, privacy, dignity, aftercare and satisfaction of patients. All those issues can negatively affect the willingness of patients to perform the test and the possibility of preparing adequately. And what is more, it can diminish the quality of the own exploration, the satisfaction of the patients and their adherence to programs of endoscopic follow-up.</p> <p>An action on these colonoscopy non-technical issues with a telephone educational intervention performed by the gastrointestinal endoscopy nurse can positively improve all (pre, intra and post-procedure) colonoscopy quality indicators.</p>
<b>Study Type ICMJE</b>	Interventional
<b>Study Phase ICMJE</b>	Not Applicable
<b>Study Design ICMJE</b>	<p>Allocation: Randomized  Intervention Model: Parallel Assignment  Intervention Model Description:  Reference population: all outpatient referred for the realization of a colonoscopy, regardless of the requesting Service.  Two groups. One of them will receive an complete educational telephone call 7 days before de procedure in addition to the information received from the primary care center on the day of the request for the test. The inclusion in each one of the groups will be done through a randomization sheet.  The intervention includes educational aspects:  Explanation of the importance of making the test. Guidelines for the usual medication of the patient. Definition of fasting, explanation of colon cleansing adjusted to the presence of predictors of poor basic preparation. Explanation of the endoscopic procedure with the elimination of erroneous concepts of the patient with respect to the procedure.</p>

	<p>Explanation of norms of action subsequent to the endoscopy.</p> <p>Management of scheduling, destined to improve the adherence of the patient for the test.</p> <p>Masking: Single (Investigator)</p> <p>Masking Description:</p> <p>The endoscope that performs the colonoscopy and the person in charge of collecting the data of colonoscopy complications and the overall satisfaction of the procedure will be blind to the patient group.</p> <p>Primary Purpose: Supportive Care</p>
<b>Condition ICMJE</b>	<ul style="list-style-type: none"> <li>Colonic Diseases <ul style="list-style-type: none"> <li>Nurse-Patient Relations</li> <li>Educational Problems</li> </ul> </li> </ul>
<b>Intervention ICMJE</b>	<p>Other: Educational telephone call</p> <p>Explanation of the importance of making the test. Guidelines for the usual medication of the patient. Definition of fasting, explanation of colon cleansing adjusted to the presence of predictors of poor basic preparation. Explanation of the endoscopic procedure with the elimination of erroneous concepts of the patient with respect to the procedure.</p> <p>Explanation of norms of action subsequent to the endoscopy.</p> <p>Management of scheduling, destined to improve the adherence of the patient for the test.</p>
<b>Study Arms ICMJE</b>	<ul style="list-style-type: none"> <li>Experimental: Telephone call group The patient receives the colonoscopy information from the primary care center on the day of the request for the test and a 20 minute educational telephone call 7 days before de procedure.</li> <li>Intervention: Other: Educational telephone call <ul style="list-style-type: none"> <li>No Intervention: Non-telephone call group</li> </ul> </li> </ul> <p>The patient only receives the colonoscopy information from the primary care center on the day of the request for the test.</p>
<b>Publications *</b>	<ul style="list-style-type: none"> <li><a href="#">Liu X, Luo H, Zhang L, Leung FW, Liu Z, Wang X, Huang R, Hui N, Wu K, Fan D, Pan Y, Guo X. Telephone-based re-education on the day before colonoscopy improves the quality of bowel preparation and the polyp detection rate: a prospective, colonoscopist-blinded, randomised, controlled study. Gut. 2014 Jan;63(1):125-30. doi: 10.1136/gutjnl-2012-304292. Epub 2013 Mar 16.</a></li> <li><a href="#">Sola-vera J, Sáez J, Laveda R, Girona E, García-Sepulcre MF, Cuesta A, Vázquez N, Uceda F, Pérez E, Sillero C. Factors associated with non-attendance at outpatient endoscopy. Scand J Gastroenterol. 2008;43(2):202-6.</a></li> <li><a href="#">Alvarez-Gonzalez MA, Flores-Le Roux JA, Seoane A, Pedro-Botet J, Carot L, Fernandez-Clotet A, Raga A, Pantaleon MA, Barranco L, Bory F, Lorenzo-Zuñiga V. Efficacy of a multifactorial strategy for bowel preparation in diabetic patients undergoing colonoscopy: a randomized trial. Endoscopy. 2016 Nov;48(11):1003-1009. Epub 2016 Aug 4.</a></li> </ul>
<b>* Includes publications given by the data provider as well as publications identified by ClinicalTrials.gov Identifier (NCT Number) in Medline.</b>	
<b>Recruitment Information</b>	
<b>Recruitment Status ICMJE</b>	Completed
<b>Actual Enrollment ICMJE (submitted: March 1, 2018)</b>	1534
<b>Original Estimated Enrollment ICMJE</b>	Same as current
<b>Actual Study Completion Date ICMJE</b>	October 31, 2018
<b>Actual Primary Completion Date</b>	September 1, 2018 (Final data collection date for primary outcome measure)
<b>Eligibility Criteria ICMJE</b>	Inclusion Criteria:

	<ul style="list-style-type: none"> <li>All outpatient referred from the Primary Care Centers to perform a colonoscopy in our Digestive Endoscopy Unit, regardless of the applicant's Service.</li> </ul> <p>Exclusion Criteria:</p> <ul style="list-style-type: none"> <li>Hospital patients, patients who refuse inclusion in the study, patients included in another study, impossibility of carrying out the educational intervention and patients who are unable to obtain informed consent will be excluded from the study.</li> </ul>
<b>Sex/Gender ICMJE</b>	
<b>Ages ICMJE</b>	18 Years and older (Adult, Older Adult)
<b>Accepts Healthy Volunteers ICMJE</b>	No
<b>Contacts ICMJE</b>	<i>Contact information is only displayed when the study is recruiting subjects</i>
<b>Listed Location Countries ICMJE</b>	Spain
<b>Removed Location Countries</b>	
<b>Administrative Information</b>	
<b>NCT Number ICMJE</b>	NCT03458377
<b>Other Study ID Numbers ICMJE</b>	ESTRELLA
<b>Has Data Monitoring Committee</b>	No
<b>U.S. FDA-regulated Product</b>	
<b>IPD Sharing Statement ICMJE</b>	
<b>Responsible Party</b>	Parc de Salut Mar
<b>Study Sponsor ICMJE</b>	Parc de Salut Mar
<b>Collaborators ICMJE</b>	<i>Not Provided</i>
<b>Investigators ICMJE</b>	
<b>PRS Account</b>	Parc de Salut Mar
<b>Verification Date</b>	February 2018