

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

Corresponding author: Agustín Seoane Urgorri
 Digestive Diseases Department. Endoscopy Unit.
 Hospital del Mar. Parc de Salut Mar.
 Passeig Maritim, 25-29. 08003. Barcelona. Spain.

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	Complete list of historical versions of study NCT03458377 on ClinicalTrials.gov Archive Site
Current Secondary Outcome Measures ICMJE (submitted: March 1, 2018)	<ul style="list-style-type: none"> • 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"> • 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 • 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 • Adenoma detection rate [Time Frame: At the moment of colonoscopy]Ratio of patients with at least one adenoma in the colon • 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) • Satisfaction of the endoscopic procedure [Time Frame: 30 days after colonoscopy]Measurement of the overall satisfaction of the colonoscopy with a questionnaire

	<p>validated by the American Society for Gastrointestinal Endoscopy (ASGE)</p> <ul style="list-style-type: none"> • 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 • 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
Original Secondary Outcome Measures ICMJE	<i>Same as current</i>
Current Other Pre-specified Outcome Measures	<i>Not Provided</i>
Original Other Pre-specified Outcome Measures	<i>Not Provided</i>
Descriptive Information	
Brief Title ICMJE	Telephone Educational Intervention by the Gastrointestinal Endoscopy Nurse. Global Impact on the Quality of Colonoscopy
Official Title ICMJE	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.
Brief Summary	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.
Detailed Description	<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>
Study Type ICMJE	Interventional
Study Phase ICMJE	Not Applicable
Study Design ICMJE	<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. Management of scheduling, destined to improve the adherence of the patient for the test. Masking: Single (Investigator) Masking Description: 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. Primary Purpose: Supportive Care</p>
Condition ICMJE	<ul style="list-style-type: none"> • Colonic Diseases <ul style="list-style-type: none"> • Nurse-Patient Relations • Educational Problems
Intervention ICMJE	<p>Other: Educational telephone call 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. Explanation of norms of action subsequent to the endoscopy. Management of scheduling, destined to improve the adherence of the patient for the test.</p>
Study Arms ICMJE	<ul style="list-style-type: none"> • 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. Intervention: Other: Educational telephone call <ul style="list-style-type: none"> • No Intervention: Non-telephone call group The patient only receives the colonoscopy information from the primary care center on the day of the request for the test.
Publications *	<ul style="list-style-type: none"> • 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. <ul style="list-style-type: none"> • 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. • 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.
* Includes publications given by the data provider as well as publications identified by ClinicalTrials.gov Identifier (NCT Number) in Medline.	
Recruitment Information	
Recruitment Status ICMJE	Completed
Actual Enrollment ICMJE (submitted: March 1, 2018)	1534
Original Estimated Enrollment ICMJE	Same as current
Actual Study Completion Date ICMJE	October 31, 2018
Actual Primary Completion Date	September 1, 2018 (Final data collection date for primary outcome measure)
Eligibility Criteria ICMJE	Inclusion Criteria:

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