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Auricular acupressure to reduce the incidence of adverse reactions to colonoscopic bowel preparation: a randomized controlled trial protocol

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Study protocol

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Abstract

Background: During colonoscopic bowel preparation, intolerance symptoms such as abdominal pain and nausea negatively impact patient compliance and the quality of bowel preparation. Chinese auricular acupressure could alleviate this phenomenon and promote gastrointestinal function. This trial aims to evaluate the efficacy and safety of auricular acupressure for reducing the incidence of adverse reactions during bowel preparation.

Methods: A total of 190 inpatients will be included in this parallel-group randomized controlled trial and will be split equally between the control and intervention groups. The intervention group will receive auricular acupressure during bowel preparation, whereas the control group will receive no additional treatm ent. The total incidence of adverse reactions to bowel preparation is the primary variable, while secondary outcome measures include the incidence and corresponding score of various adverse events, patientwillingness to participate in a future colonoscopy, laxative ingestion time, 100% laxative intake rate, and bowel preparation quality. Analyses will be performed using both intention-to-treat and per-protocol methods. The effects of the intervention will be evaluated by comparing the outcomes between the two arms.

Discussion: This study will provide objective evidenceto evaluate the efficacy and safety of auricular acupressure on the adverse reactionsof bowel preparation providing an important reference for larger trials in the future

Trial registration number: ChiCTR2200061742

Background

Colonoscopy is widely used to diagnose and treat colorectal diseases. Although safe and effective bowel cleansing is an essential requirement for a gut lavage solution, patient acceptability is important and often underestimated because it is closely related to the degree of compliance with the regimen and the quality of bowel cleansing.

Polyethylene glycol (PEG) is the most widely used intestinal cleanser with good efficacy and safety; however, patients are required to orally ingest a large volume of the solution over a short period to adequately cleanse the intestine [1]. This regimen is likely to cause gastrointestinal adverse reactions (ADRs), such as nausea, vomiting, and abdominal distension, the incidence of which accounts for 42%-59.3% in clinical studies [2-4]. Because Asians typically have thinner physiques and a lower gastrointestinal tolerance than people in the West, Chinese guidelines for bowel preparation for colonoscopy (2019, Shanghai) [5] recommend that a 3 L split-dose of PEG is more suitable for Chinese people, rather than the 4 L PEG protocol recommended in Europe and America [6]. It has been shown that the inability to complete the standard volume of PEG in elderly patients is a significant factor influencing the quality of bowel preparation [7]. Therefore, reducing the incidence of ADRs during bowel preparation and improving patient tolerance are important for the success of a colonoscopy.

Auricular acupressure is a non-invasive and well-established strategy in Traditional Chinese Medicine (TCM) and may be a valuable treatment for improving symptoms of gastrointestinal discomfort during colonoscopic bowel preparation. Research has shown that auricular acupressure has advantages in the management of gastrointestinal diseases such as constipation, irritable bowel syndrome [8], and functional abdominal pain disorders [9]. The National Comprehensive Cancer Network acknowledged the efficacy of acupoint stimulation on chemotherapy-induced nausea and vomiting [10], and the consensus of Chinese experts recommended auricular acupressure as a complementary intervention to prevent chemotherapy-induced and perioperative nausea and vomiting [11, 12]. Many researchers have hypothesized that the physiologic basis underlying the success of this therapy is that continuous and reliable stimulation of the outer surface of the ear can relieve the symptoms of distant lesions via neurohumoral mechanisms [13].

To date, no high-quality research has been conducted on the effects of auricular acupressure on the ADRs of colonoscopic bowel preparations. Therefore, this trial is proposed to evaluate the effectiveness of auricular acupressure in reducing bowel preparation ADRs by measuring the incidence of abdominal pain, bloating, nausea, and vomiting; procedure time of drinking PEG; 100% PEG solution intake rate; and other indicators.

Methods/Design

Study design

This parallel, randomized, blank-controlled prospective clinical trial will be conducted at the Guangdong Provincial Hospital of Traditional Chinese Medicine in China. The trial design was in accordance with the Consolidated Standards for Reporting Trials (CONSORT 2010) guidelines and the Interventions for Reporting Standard Acupuncture Controlled Trials (STRICTA) [14]. We will enroll eligible inpatients who will undergo a colonoscopy and randomly allocate them in a 1:1 ratio to the intervention and control groups. The intervention group will receive auricular acupressure during bowel preparation, whereas the control group will not receive any intervention. Gut intolerance will be assessed immediately after bowel preparation. A flowchart of this trial is shown in Figure 1.

Participants

Inclusion criteria

Patients who are willing to participate in the trial and meet the following conditions will be included regardless of sex: those who will undergo a colonoscopy at our institution, those aged 18 to 70 years, and those who sign the informed consent form.

Exclusion criteria

Those who meet any of the following conditions will be excluded: suffering from severe mental disorder; exhibiting serious intestinal diseases; contraindications to colonoscopy; severe liver, kidney, heart, brain, lung dysfunction, or neurological diseases; intolerance to colonoscopy; menstrual cycle, pregnancy, or breastfeeding; allergy to drugs and other ingredients used in the trial; skin lesions at the to-be-treated auricular acupoints; or allergy to ear adhesive.

Recruitment and withdrawal

Eligible inpatients who satisfy the inclusion criteria will be recruited from the Guangdong Provincial Hospital of Traditional Chinese Medicine. All admitted patients who meet the initial eligibility criteria will be asked if they are willing to participate. Participants are permitted to withdraw at any time during the trial for any reason.

Sample size

According to the data from a preliminary study, the incidence of ADRs to bowel preparation was expected to be 60% in the control group and 34% in the intervention group. In line with the 1:1 parallel control principle, the PASS statistical analysis software package was used to calculate the sample size for a double-sided significance level of 0.05 and a power of 90% ($\alpha=0.05$, $\beta=0.1$). Considering an expected 20% loss to follow-up, the sample size was determined to be 190 cases (n=95 in each group).

Randomization and blinding

Excel will be used to generate 190 random numbers with sizes ranging from 0 to 1, and assign sequence numbers based on the order of random numbers from 1 to 190, where odd number corresponds to control group and even number corresponds to ear point group. Make random numbers and sequence numbers into random cards and place them in an opaque envelope seal. A specifically appointed investigator will be responsible for randomization. After informed consent of the participants has been obtained and they have completed the baseline data collection, the allocation personnel will inform the acupuncturists of the allocation assignment.

Owing to the unique features of the intervention, we could only blind the examiners, data collectors, and statisticians but not the interveners or study participants. Before data collection, subjects in the intervention group will be asked to remove the auricular adhesives, which will be checked by the personnel in charge of randomization. During the entire study period, the participants and other researchers are not allowed to disclose the grouping to the endoscopists, data processors, or statisticians. To avoid communication between the two groups, the patients will be sent to separate wards. Thus, bias will be further reduced.

Intervention

Routine bowel preparation scheme

All participants were limited to low-residue foods the day before colonoscopy. All subjects will undergo identical bowel preparation and receive 3 bags of Compound PEG electrolyte powder ( ) (Shenzhen Wanhe pharmaceutical Co. Ltd., China, 68.56 g / bag, H20030827), each containing 1.46 g sodium chloride, 5.68 g anhydrous sodium sulfate, 0.74 g potassium chloride, 1.68 g sodium bicarbonate, and 59 g PEG 4000. Each PEG sachet will be diluted in 1 L of drinking water and consumed within 1 hour. Bowel preparation before colonoscopy will be performed in the morning and afternoon. Subjects scheduled for two different time slots will be instructed to drink 1 L of laxative solution at 8:00 p.m. before the day of colonoscopy. Subjects undergoing colonoscopy in the morning will drink the remaining 2 L from 4:00 to 6:00 a.m. on the day of the examination, whereas subjects undergoing colonoscopy in the afternoon will drink from 10:00 to 12:00 p.m. A bottle of simethicon (Berlin-Chemie AG, Germany; 30 ml/ bottle, HJ20160184) will be added to the last 1 L of the laxative. While taking laxatives, the study participants will be told to move around and massage the abdomen clockwise to promote defecation.

Intervention group

The subjects in the intervention group will be treated with auricular acupressure during bowel preparation. Before starting bowel preparation, auricular adhesives will be applied to particular spots on both ears. The product used for auricular acupressure will be Wangbuliuxingzi (Vaccaria seed) auricular adhesive (Hebei Heshi Medical Instrument Co., Ltd., China). The product information is shown in Figure 2. According to the clinical experience of our research group and the effective prescription published previously [16, 17], five acupoints [Cardia (CO3), Stomach (CO4), Large Intestine (CO7), Sympathetic Nerve (AH6), and Subcortex (AT4)] will be selected as the auricular acupoint protocols in this study. The localization of acupoints refers to the nomenclature and location of auricular acupoints [15] stipulated by the World Federation of Acupuncture-Moxibustion Societies (WFAS) in 2013. The anatomical locations are listed in Table 1 and illustrated in Figure 3. Since subjects need to drink a 3-L Split-dose of PEG solution and each 1 L laxative should be drunk within an hour to achieve a better quality of bowel cleansing, they will be asked to self-press the adhesives three times during each 1 L of laxative. Each acupoint should be pressed for at least 1 min per session, and the press should cause a distending and aching sensation within the subject's tolerance. Medical staff will promptly remind and instruct the patient regarding the timing of the laxative.

If the adhesive falls off due to exercise, bathing, or other unexpected conditions, the researcher will reapply the plaster to the original spot. If skin abrasion or swelling occurs at the treated site, the subject must contact the acupuncturist immediately to treat it, which will be recorded in a case report form (CRF).

Control group

The subjects in the control group will not receive any supplementary means for ADR prevention but will receive only a routine bowel preparation scheme.

Colonoscopy procedures

All the colonoscopies will be performed by the same experienced endoscopist. Colon cleanliness will be assessed by the endoscopist and two experienced endoscopy nurses who are not involved in the trial. All three researchers will be blinded to the intervention allocation and will independently judge whether each colon had no staining, minor staining, or residual stool after the operation. The study nurse will register the majority consensus.

Outcome measures

The primary outcome measure will be the total incidence of abdominal pain, bloating, nausea, and vomiting after PEG intake. The secondary outcome measures will be (1) incidence of various ADRs: the proportion of each adverse event; and (2) corresponding score of various adverse events. The Likert scoring method will be used to score the degree of discomfort of the abdominal pain, abdominal distension, and nausea symptoms. For this scale, 0 means no discomfort, while 10 means unable to tolerate due to strong discomfort. Vomiting severity will be scored according to frequency. If the subject vomits once, it will be recorded as 2 points; if the subject vomits more than or equal to 4 times, it will be recorded as 10 points; (3) patients' willingness to have the colonoscopy done again at this facility in the future will also be evaluated (yes or no); (4) procedure time: the procedure time is defined as the time spent drinking PEG (in minutes); (5) 100% PEG solution intake rate: does the patient take a complete laxative as ordered (yes or no); (6) qualified rate of bowel preparation: we use Boston Bowel Preparation Scale (BBPS) to assess efficacy in bowel preparation; the qualified rate of bowel preparation is defined as the ratio of subjects' BBPS score of > 6 [18]; (7) adverse events of auricular acupressure: incidence of allergic reactions such as flushing, rash, exudation, and ulceration at the application site.

Safety assessment

Allergic reactions such as skin flushing, rash, exudation, and ulceration may occur during the treatment evaluation period. If an allergic reaction occurs, acupoint acupressure on the ear will be immediately stopped. Auricular acupressure-related adverse effects shall be recorded and addressed immediately.

Data collection

All baseline data for each participant will be collected before the start of the intervention. Baseline data will include sex, body mass index (BMI), past medical history, medication history, recent defecation, history of colorectal surgery, indications for colonoscopy, and gastrointestinal disorders before bowel preparation. To facilitate researchers in observing and recording various indicators, each subject's information will be recorded in the CRF, and codes and abbreviations will be used instead of names to protect privacy. Data in the CRF form will be independently entered and checked by two third-party data managers unrelated to the test to confirm authenticity, accuracy, and integrity. The participants' medical records (study medical records, CRF, colonoscopy results, etc.) will be stored in the hospital. No public report of the results of this study will disclose the participants' personal identities.

Quality control

To ensure the quality of this study, the trial underwent several changes and revisions by relevant digestive disease specialists, acupuncture experts, professional statisticians, and research methodologists. Strict inclusion and exclusion criteria were established. To maintain objectivity, we will ensure that the data collector statisticians and endoscopists will be blinded. All the researchers, particularly the auricular acupressure operators, completed our training, thereby ensuring consistent treatment practices and uniformity in the terminology used for communication with the subjects. The CRF will be meticulously completed in accordance with the CRF guidelines and checked by third-party data administrators unrelated to the trial to ensure the scientific accuracy of the data. If suspicious data is found, the researcher should be contacted and verified, and the data administrator will modify, confirm and enter the data according to the researcher's reply. All quality control documents shall be complete and filed as required.

Statistical analysis

SPSS (version 25.0) will be used for data processing. The measurement data will be expressed as means ± standard deviation or median (interquartile interval), and the counting data will be described by the number of cases (percentage). Data will be analyzed using the principle of intention-to-treat. That is, regardless of whether the subjects receive the treatment of the assigned group, they will be included in the allocated group for the statistical analysis of the curative effect. Efficacy and safety measures will be analyzed in accordance with “per-protocol”, whereby we will include all subjects who completed the entire trial and followed the protocol requirements. Fisher’s exact test or Pearson’s chi-square test will be used for trial group comparisons of the incidence of ADRs. Differences in quantitative data such as age, BMI, the score of various adverse events, and procedure time will be compared between the experimental and control groups using the t-test for comparison of two samples and the rank-sum test for non-normal distribution or unevenness of variance. All tests of effects will be conducted at a two-sided alpha level of 0.05.

Patient and public involvement

The patients will not be involved in the design or conduct of the study. However, patients who showed symptoms of bowel preparation intolerance in our clinical department were consulted before the trial design, and the selected auricular acupoints, treatment frequency, and duration of this trial were summarized based on our clinical experience and patient feedback.

Ethics statement

This study was approved by the Institutional Ethics Committee of the Guangdong Provincial Hospital of Traditional Chinese Medicine on 1st May 2022 (approval no. YF2022-093). Informed consent forms were developed in compliance with the Declaration of Helsinki (revised in 2013) [15] (supplementary 1). All qualified participants will be informed of the details of the study and required to sign written informed consent forms before participating. The results will be published in a peer-reviewed publication and presented at conferences.

Discussions

PEG-related abdominal pain, bloating, nausea, and vomiting are common during bowel preparation prior to endoscopy. Many attempts have been made to reduce ADRs caused by intestinal preparations, including reducing the dose of oral solutions, applying a defoamer, improving the taste of laxatives, and general nursing of intestinal preparations. Low-volume PEG combined with adjunctive laxatives, such as ascorbic acid [19], sodium phosphate [20], and the compound sodium picosulfate [21], has been shown to not be inferior to full-dose PEG in terms of colonic preparation quality and patient tolerance. However, vomiting, bloating, and abdominal pain still affect a substantial number of patients who receive sodium phosphate as an adjunct for colonic preparation [4]. Sodium phosphate may also cause a water-electrolyte imbalance, acute phosphate nephropathy, and renal function damage [22]. Additionally, sodium picosulfate has been reported to induce inflammatory changes in the intestinal mucosa [23]. These challenges limit the clinical application of adjunctive laxatives. The application of an antifoaming agent can mitigate the effect of foam on the digestive tract mucosa and lesions. A meta-analysis (six randomized controlled trials [RCTs], 5630 participants) showed that simethicone decreased bloating and improved patient tolerance to standard bowel preparation [24]. Soft drink beverages, including orange juice, pineapple juice, and Coca-Cola, have been proven to improve patient acceptability and compliance with bowel preparation for colonoscopy in most instances; however, there is no evidence that they can lessen the likelihood of negative consequences [25, 26]. Walking and abdominal massage are empirical methods used to reduce symptoms such as nausea, vomiting, and bloating after laxative administration, but exhibit limited efficacy.

Auricular acupressure is a method of using magnetic beads and cowherb seeds to stimulate auricular acupoints to prevent and treat diseases under the guidance of TCM and acupuncture moxibustion theories [13, 27]. This method continuously stimulates acupoints with minimal pain and no adverse effects. Clinical evidence has shown that auricular acupressure has clear benefits in improving gastrointestinal motility and decreasing visceral sensitivity. A meta-analysis published in 2014 (17 RCTs, 1673 patients) concluded that auriculotherapy, a generally safe technique, may be useful for managing constipation [17]. Another meta-analysis that assessed 17 RCTs (1536 patients) found that auricular acupressure combined with an antiemetic enhanced the relief efficiency of overall chemotherapy-induced nausea and vomiting and played an important role in reducing delayed nausea and vomiting [16]. A previous study has shown that a 4-week auricular acupressure treatment can reduce the frequency of diarrhea and abdominal pain in female patients with irritable bowel syndrome [8]. This trial will objectively evaluate the prevention and control effects of ADRs related to bowel preparation by evaluating the incidence, corresponding score of various adverse events, patient willingness, procedure time, 100% PEG solution intake rate, and qualified rate of bowel preparation. This will contribute clinical evidence for future efforts to find easy and effective ways to lessen the negative effects of colonoscopic bowel preparation.

In TCM, the ear is connected directly or indirectly to the 12 meridians and viscera, and ear stimulation can restore the balance between qi and blood and affect the function of certain parts of the body [28, 29]. Similarly, the inverted fetal map proposed by Dr. Nogier in 1957 gave rise to the hypothesis of biological holography, which argues that each functioning and relatively independent portion of an organism is analogous to embryological tissue and includes all information regarding the entire organism [30]. In view of the above, Chinese scholars proposed that observing the position, size, thickness, shape, and color of auricles is helpful in evaluating the functional status of viscera. By stimulating different points on the ear, a range of disorders, such as chronic or acute pain, sleep disturbance, abdominal pain, diarrhea, nausea, dizziness, disorders of the endocrine glands and urinary system, and obesity, can be treated using this method. In this auricular acupoint prescription, stomach (CO4) and large intestine (CO7) are organs related to bowel preparation, and stimulating these points can promote gastrointestinal peristalsis and reduce abdominal distension. Cardia (CO3) is an effective acupuncture point to limit vomiting based on experience. Subcortex (AT4) can adjust the function of the digestive system and relieve nausea and vomiting caused by the nerve reflex action. Finally, sympathetic nerve (AH6) can soothe the mind, regulate autonomic nerve dysfunction, and have a strong visceral analgesic and spasmodic effect.

Basic research currently suggests that the mechanisms by which auricular therapy regulates gastrointestinal dysfunction are linked to vagus nerve modulation and humoral regulation. (1) Neural regulatory mechanism: The auricular branches of the vagus nerve (ABVN) are the most significant sensory nerves in the ear because their function affects the concha and most portions of the auditory canal [31]. ABVN supplies fibers to the nucleus of the solitary tract, which regulates organ function by mediating gastrointestinal, gag, cough, and respiratory reflexes [32]. ABVN stimulation is believed to regulate the vagus nerve autonomic nervous system because of the complex connections between the brain and viscera [33]. Auricular vagal nerve stimulation can improve sympathovagal imbalance, as confirmed by rat models of constipation and dyspepsia that received auricular acupressure intervention [33, 34]. Sun [35] observed that acupuncture points on the ears effectively promoted the rehabilitation of gastrointestinal function following gastric cancer surgery. This effect was not as noticeable in patients who underwent proximal or whole gastrectomy as in those who underwent distal gastrectomy. He believed that the first two surgical techniques eliminated a portion of the Cajal interstitial cells, reducing gastric slow wave motion during fasting and interfering with signal transmission between "nerve and muscle." (2) Humoral regulation mechanism: Two-way modulation of gastrointestinal motility-related hormone secretion can be achieved by pressing the auricular acupoints. According to one study, the serum motilin concentration in patients undergoing laparoscopic surgery increased during and after the operation [36], suggesting that this could be one of the mechanisms causing nausea and vomiting following laparoscopic surgery. In these patients, auricular acupressure reduced the incidence of nausea and vomiting, and promoted the recovery of gastrointestinal function [37]. However, in patients with dyspepsia, auricular acupressure had a completely different effect. For example, Pan [38] discovered that combining auricular acupressure with Western medicine for the treatment of functional dyspepsia can successfully lower serum nitric oxide

production and improve symptoms. In patients with gastric cancer after surgery, auricular acupressure can effectively increase the content of plasma vasoactive intestinal peptide [39], promote the release of endogenous opioids and other neurotransmitters in patients undergoing gynecological open surgery, and produce anti-nausea, anti-vomiting, and analgesic effects [37].

The lack of a sham intervention to blind the trial participants is a limitation of this study. This is due to the lack of a suitable sham intervention to counteract the placebo effect because stimulation of the auricle rather than acupoint locations would also cause a physiological response [40]. A recent study [9] speculates that using a transdermal electrical device to probe dormant acupuncture points unrelated to gut function may provide an ideal sham auricular acupressure intervention. Further verification will be conducted in future studies.

In conclusion, this study presents a rigorous design for determining the ability of auricular acupressure to reduce the incidence of ADRs during colonoscopic bowel preparation. The results of this trial will help assess the feasibility of the protocol and inform the development of larger trials.

Trial status Patient recruitment began in October 2022 and is expected to be completed by the end of 2023.

Abbreviations

PEG; Polyethylene glycol

ADRs; Adverse reactions

TCM; Traditional Chinese Medicine

CRF; Case report form

BMI; Body mass index

RCT; Randomized controlled trial

ABVN; Auricular branches of the vagus nerve

Declarations

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Authors' Contributions: This protocol was first conceived by JZ, with critical contributions from other authors. JZ and HY wrote the first draft of the protocol and submitted it to ChiCTR. HY and GR helped to design and edit the manuscript. HZ, BZ, and XH provided clinical advice and revised the manuscript

critically. All the authors contributed constructive comments to the manuscript and approved its final version. CZ and XH are the guarantors of publication and are fully responsible for this paper.

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Table

Table 1 Location of the auricular acupoints

Acupoint	Location
Cardia (CO_3)	In the concha inferior to the posterior 1/ 3rd of the helix crus.
Stomach (CO_4)	At the end of the helix crus.
Large Intestine (CO_7)	At the anterior 1/ 3rd of the region between the helix crus and Line AB.
Sympathetic Nerve (AH_6)	At the juncture of the end of the inferior antihelix crus and the medial edge of the helix.
Subcortex (AT_4)	On the medial side of the antitragus.

Figures

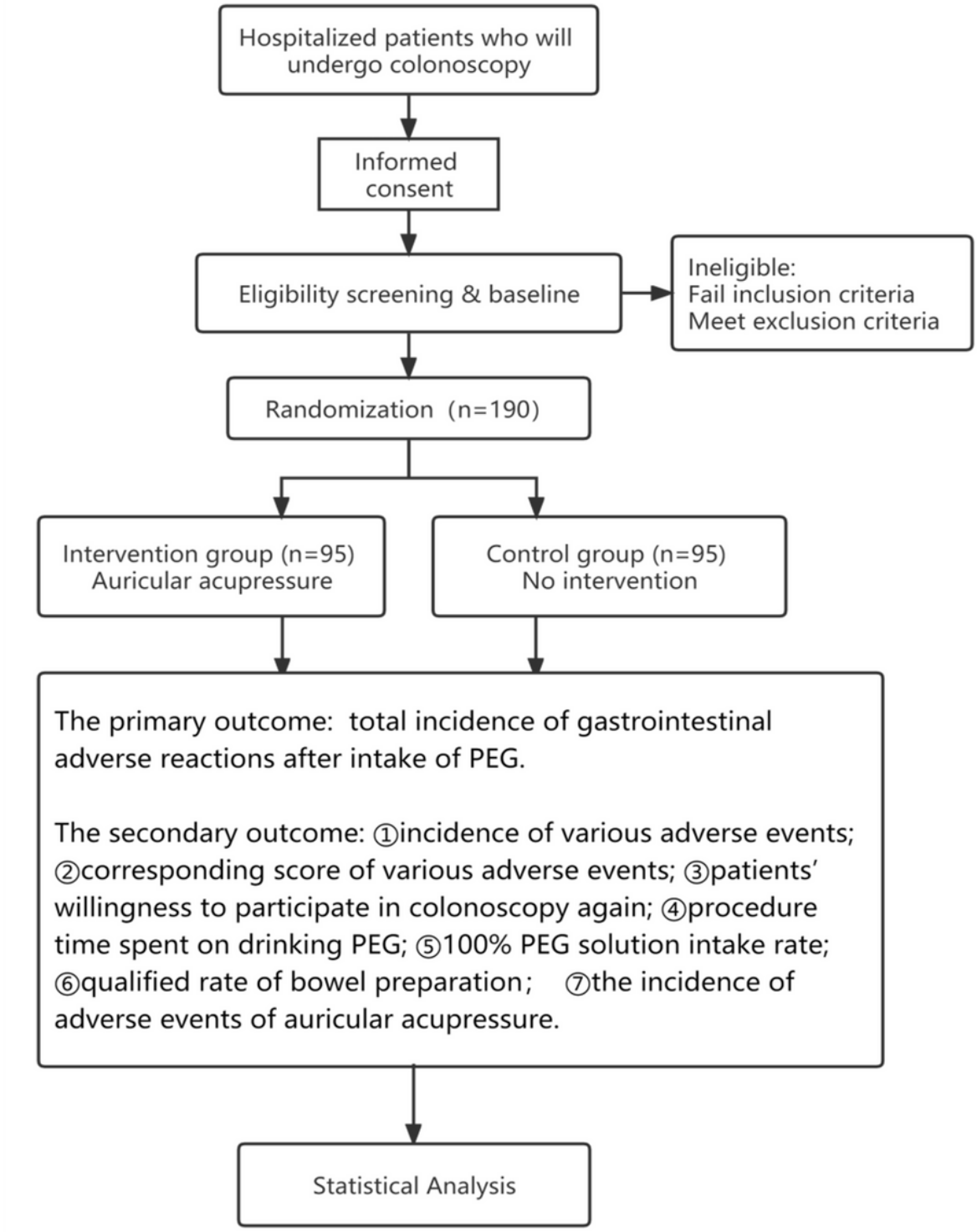


Figure 1

Flow chart of the study

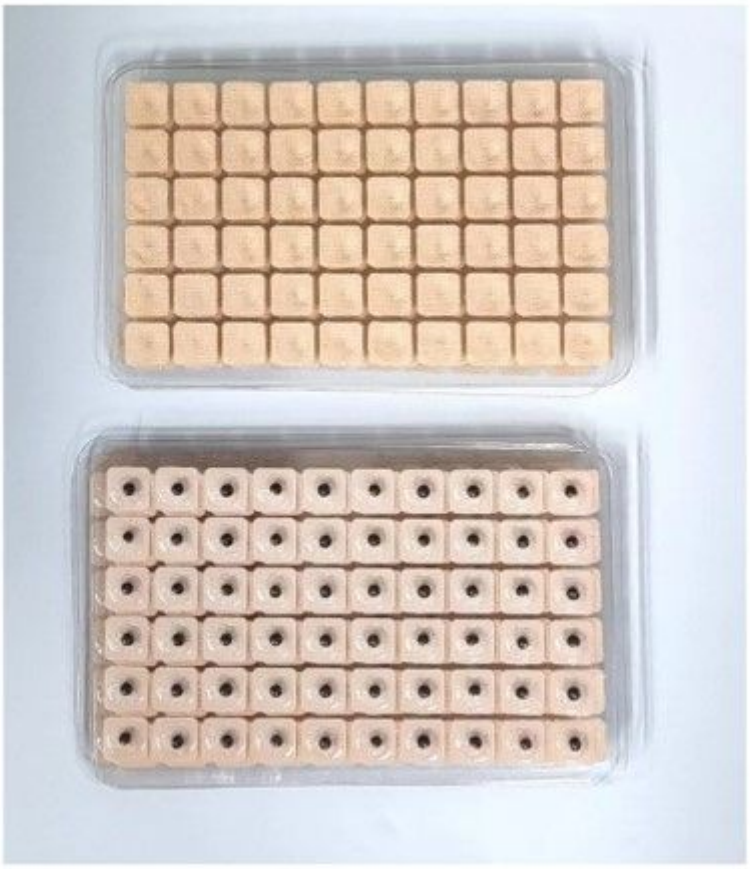


Figure 2

Auricular adhesives

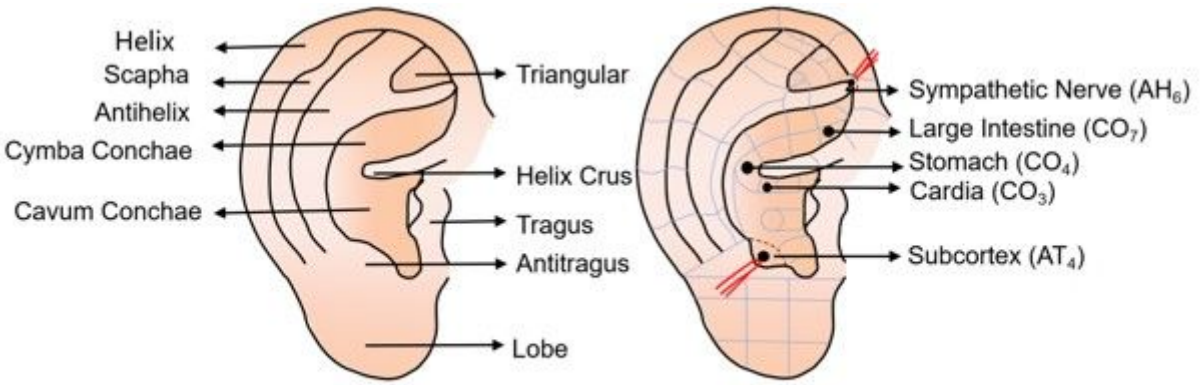


Figure 3

Anatomical locations of the auricular acupoints

Supplementary Files

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- Additionalfile1.pdf
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