STUDY PROTOCOL

A realist review protocol of the role and contribution of the advanced nurse practitioner (ANP) in gastroenterology nursing [version 1; peer review: awaiting peer review]

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Abstract

Background: The role and contribution of advanced nurse practitioners (ANP) has been well researched and found to be of great value for improving quality patient care and enhancing patient outcomes through education and health promotion. However, the role and the contribution of the ANP to gastroenterology nursing have not been evaluated either nationally or internationally. A review to determine the role and contribution of the ANP in gastroenterology nursing will inform on the contribution of the role and whether the role makes a difference to patient outcomes and cost effectiveness of patient care.

Objective: This review aims to investigate the nursing role and contribution of the advanced nurse practitioner in gastroenterology. Furthermore, improved understanding of the underlying causal mechanisms explaining how the ANP role in gastroenterology nursing works, will provide a deeper understanding of how, why, for whom and in what contexts the role and contribution of the ANP to gastroenterology nursing are most successful.

Methods: A realist review will consolidate evidence on how, when why and where the ANP role in gastroenterology works or fails through identifying programme theories underlying to the role's introduction. The following steps will be operationalised; locating existing theories, searching the literature, documenting literature selection, engaging in data extraction and synthesis and refining programme theory. As an iterative approach, review cycles will uncover explanatory and contingent theories through context-mechanism-outcome configurations (CMOCc). Due to the variation in context and mechanisms, different outcomes will be likely across different clinical settings although similar patterns may be identified.

Conclusions: Due to the theory-oriented approach of realist reviews, the pragmatic consequences of the review, will lend itself to deeper understanding of how the role and contribution of the ANP in gastroenterology nursing works in practice.
Keywords
Advanced nurse Practitioner, Nurse Endoscopist, Role Evaluation, Contribution, Gastroenterology Nursing, Realist, Review

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Introduction
The role of the ANP in gastroenterology nursing embodied an alternative model of care to meet global health needs coupled with the demand to circumvent costly health care. Applying advanced nurse practitioners to non-traditional nursing roles may stimulate care provision which is more responsive to patient and service user needs. Task shifting of specialised procedural activity from the medical to the nursing domain demanded a unique technical skill set, but more importantly, requires complex change due to the underlying assumptions made by all involved. These underlying assumptions relate to ideas about the role in so far as role was the exclusive responsibility of medical staff in the past. As such, task shifting goes beyond the mere division of tasks, urging clear role responsibilities and boundaries to guide ANP’s towards journeying beyond traditional scope of practices. For example, in the case of the ANP in gastroenterology nursing, protocol-driven activities and supervision by the gastroenterology physician is advancing task shifting to role expansion. The latter involves the transfer of previous specific task-oriented technical skill sets from medical staff to an ANP.

Internationally, the strategic intent of the role of the advanced nurse practitioner (ANP) in gastroenterology nursing, developed from the demand of colorectal cancer screening programmes (Chapman & Cooper, 2009; Verschuur et al., 2007; Winawer et al., 1997). The ANP role in gastroenterology was further rationalised to undertake technical tasks and responsibilities, traditionally fulfilled by physicians in the USA and UK (Harris & Redshaw, 1998; Helliier et al., 1995) with training programmes at advanced practice level commencing in the early 1990’s (Norton, 2012). Currently, the role of ANP’s in gastroenterology is well established in countries such as the UK, the Netherlands and Canada (Norton et al., 2009; Verschuur et al., 2007; Wright, 2000), as well as Ireland and Australia (Duffield et al., 2017; Reid et al., 2009). ANPs in gastroenterology are registered nurses with a Master’s Degree qualification and who completed the equivalent of a three-year period performing endoscopy as part of an advanced practice nursing role (Duffield et al., 2017). Form a national perspective, the MSc in Advanced Practice (Nursing) (ANP) Gastroenterology, is completed within a two year academic programme and consist of two research modules, three prescribing modules and four specialist advanced practice modules (University College Dublin School of Nursing Midwifery and Health Systems, 2021).

Within an Irish context, St. James Hospital in Dublin was the first to have an ANP candidate in gastroenterology nursing in 2004. The endoscopy procedural performance practicum took place in Ireland and the UK, alongside a two-year Masters Degree general nursing programme. The ANP candidate was appointed as the first registered ANP in gastroenterology nursing in 2007. The 2009 publication of the Health Information and Quality Assurance (HIQA) Report (Health Information and Quality Authority, 2009), outlining human resource requirements for a national colorectal cancer screening programme, officially recognised the role of the ANP in gastroenterology at national level. The subsequent introduction of the national colorectal screening programme in 2012, BowelScreen stimulated the specific development and implementation of the ANP role in gastroenterology nursing. At that time and it continues today, colorectal cancer accounted for the second highest cause of cancer deaths among the Irish population and approximately fifty percent of patients diagnosed with this aggressive illness, died as direct result (Irish Cancer Society, 2018; National Cancer Screening Service, 2012). Equally, endoscopy screening remains the preferred and essential intervention method for early diagnosis and treatment of bowel cancer and improved prognosis (Fang et al., 2014; Mendivil et al., 2019). Initially, the role of the ANP in gastroenterology nursing was largely associated with the performance of flexible sigmoidoscopy, but more recently has evolved to include diagnostic and therapeutic, upper and lower procedures (Baumgardner et al., 2017; Department of Nursing, 2020; Vance, 2005; Woods et al., 2006). Diagnostic procedures currently performed include gastroscopy, colonoscopy, and sigmoidoscopy while therapeutic procedures include polypectomy, biopsy, and stenting are undertaken. Although ANP endoscopy performance in Ireland is restricted to a supervisory function of the gastroenterology physician, within the international context, the ANP in gastroenterology can diagnose and treat several conditions as an independent practitioner (Department of Nursing, 2020). These include conditions such as esophagitis, duodenitis and gastric or duodenal ulcers.

Background
Pauing of ‘aerosol-generating’ endoscopy procedures, due to its associated high risk of transmission (Repici et al., 2020; Tse et al., 2020), positioned gastrointestinal endoscopy at the forefront of clinical demand and adaptive clinical practices. Delayed diagnosis, particularly of patients who received positive screening results and awaiting diagnostic endoscopy confirmation (Burch, 2020), coupled with increases in elective waiting lists and waiting times for endoscopy procedures, may result in health decline and ultimate succumbing to illness. Previous empirical studies associated with the role of the ANP in gastroenterology, focused largely on procedural safety and effectiveness of the role (Baumgardner et al., 2017; Bossa et al., 2006; Massl et al., 2014; Smale et al., 2003). Early randomised control trials (RCTs) concluded that experienced ANPs in gastroenterology can perform screening flexible sigmoidoscopy as safely and effectively as gastroenterologists (Schoenfeld et al., 1999). Other RCTs centered on the effectiveness of gastroenterology ANPs through determining the frequency of missed polyps (Schoenfeld et al., 1999), and the impact and diagnosis associated with caecal intubation and complication rates (Dwarakanath et al., 2004). These authors also outlined that well-trained ANPs in gastroenterology perform colonoscopy safely with noticed improvements in throughput and waiting times of patients treated by the ANP and found no statistically significant difference in clinical effectiveness for diagnostic endoscopy between doctors and ANPs (Dwarakanath et al., 2004). Two further RCTs focused on the ANP’s ability to perform accurate upper diagnostic endoscopy (Meaden et al., 2006), when compared with medical staff. In 2006, a large multi-organisational study in the UK found that the
ANP in gastroenterology perform endoscopy effective, more thorough than their medical counterparts and has the potential to become more cost-effective with increased experience (Williams et al., 2006). The gastroenterology ANP’s were more thorough in their examination of the esophagus and stomach, received significantly higher satisfaction rates post endoscopy by patients, and although doctor-led endoscopy was proven to have better outcomes in terms of patient preference at one year post-procedural, it came at a higher cost (Williams et al., 2006). Studies which investigated the role of the ANP in gastroenterology were dominated by the biomedical aspects of the role through comparisons of the ANP role with medical counterparts, such as gastroenterology physicians and physician assistants (Bossa et al., 2006; Dreamic et al., 2018; Massl et al., 2014). A very recent evaluation of the nurse endoscopist role in Australia concluded that a nurse endoscopist model of care is a safe and acceptable model to introduce (Cusack et al., 2018).

Currently, a total of seventeen ANPs and six candidate ANPs (cANPs) in gastroenterology nursing, practice alongside 80 gastroenterologists (approximate) in the public healthcare service in Ireland. There is an increased demand for the role because the COVID-19 threat contributed to the postpone and suspension of non-critical and elective endoscopy procedures, including national bowel screening programmes (National Screening Service, 2020; The Irish Society of Gastroenterology, 2020). Table 1 provide an outline of the geographical location of the ANPs and cANPs in gastroenterology nursing and the gastroenterologists practising in Ireland.

To coincide with the theory-driven approach of a realist review through evidence synthesis, the current empirical evidence on the known contributors of advanced nurse practitioners to nursing will firstly be synthesized and opportunities to draw comparisons to the contribution of the gastroenterology advanced nurse practitioner to nursing, formulated. The outcome of an initial preliminary search of the literature, revealed limited international information relevant to the role and the contribution of the ANP in gastroenterology nursing and it highlighted significant endoscopy-specific, clinical implications for affected patient cohorts.

Rationale for using a realist review
A realist review will highlight the underlying assumptions that the introduction of the role of the ANP in gastroenterology made within the international healthcare social world. Indeed, the strength of a realist review rests in the fact that it seeks to explain how and why an intervention such as the introduction of the ANP role in gastroenterology nursing may be successful or not (Pawson et al., 2005). Moving beyond a mere evaluation of intervention effectiveness of the ANP role, towards a deeper explanatory evaluation, further underlines the realist approaches’ success in the application to healthcare (Ford et al., 2015; Pawson et al., 2004). Additionally, this review will contribute to existing literature and current understanding through the application of a realist review approach, not previously implemented to advanced nurse practitioner role evaluation, which can ultimately improve patient outcomes.

Realist review methodology
Realism as philosophical perspective is underpinned by critical realism with a paradigm position between positivism and constructivism / interpretivism (Pawson & Tilley, 1997). Realism postulates that understanding of the social reality can only be achieved through a systematic examination of underlying mechanisms, the contexts in which interventions are introduced in and the outcomes generated. Critical realism tenets allow for both qualitative and quantitative approaches to be adopted (Clark et al., 2008), and promote the acknowledgement of complexity and the nature of the research question to determine methodological choice (Clark et al., 2008). Complex healthcare interventions, such as the introduction of the ANP role in gastroenterology, are viewed as operating within the personal, interpersonal, and social arenas outside of the intervention and realism seeks to better understand how these social interactions influence intervention success (Connelly, 2007; Pawson et al., 2005). Forming part of the realist approach, realist review are defined as ‘a theory-driven interpretative approach to the synthesis of evidence’ (Brennan et al., 2014).

| Hospital Groups                  | ANP | cANP | Gastroenterologists (Approximate) |
|----------------------------------|-----|------|-----------------------------------|
| Ireland East Hospital Group      | 3   | 3    | 18                                |
| RCSI Hospital Group              | 3   | 3    | 14                                |
| Dublin Midlands Hospital Group   | 1   | 1    | 12                                |
| University Limerick Hospital Group | 3   |      | 10                                |
| South/Southwest Hospital Group   | 4   |      | 12                                |
|Saolta Hospital Group            | 3   | 2    | 14                                |
|**Total**                        |17   |6     |80                                |
A preliminary background

Wong, Pawson & Tilley, 2004

Rycroft-Malone, Wong

Ford, Coleman

international literature (published studies), that will generate
to conduct a realist review that involves a synthesis of the
texts for each key

Methods

Review aims

To conduct a realist review that involves a synthesis of the

programme theories to determine an understanding of the role

and contribution of the ANP in gastroenterology. The review

will furthermore unpack the mechanisms of how a com-

cplex intervention (the role of the ANP in gastroenterology)

works in specific contexts within clinical settings. It will also

highlight areas for improvement.

Review questions

1. What does the role and contribution of the ANP in
gastroenterology involve?

2. What positive or negative outcomes such as qual-

ity assurance, polyp detection rates, procedural safety

and effectiveness and patient satisfaction have been

reported of the role and contribution of the ANP in
gastroenterology?

3. What are the contexts that determine whether the mech-

anisms produce positive or negative outcomes and why?

4. How satisfied are patients receiving care from an ANP

in gastroenterology?

Objectives

1. To conduct a realist review to understand the role and

contribution of the ANP in gastroenterology nursing

2. To develop programme theory on the role and

contribution of the ANP in gastroenterology nursing

3. To draw on the findings of the review to guide a Realist

Evaluation study of the role and contribution of the ANP

in gastroenterology nursing

Review design

The review design will involve an eight-step approach, col-

lated form a six-step review guide (Weetman et al., 2017), a

project protocol outline (Ford et al., 2015) and a designed project

diagram (Wong et al., 2015). The Realist review will be com-

pleted over a three-month period commencing end of October

2021. A PRISMA-P checklist will be completed and the

review will be informed and reported in accordance with the

RAMESES (Realist And Meta-narrative Evidence Synthesis:

Evolving Standards) (Wong et al., 2016).

Step 1: Locating existing theories. A preliminary background

search strategy will be developed and will comprise of five

search strings, indicating key words and index terms associated

with each of the significant domains of the role and contribu-

tion of the ANP. This strategy will be essential for the develop-

ment of the second more comprehensive search strategy. Table 2

outlines the initial preliminary search strings for each key

area. The documents sourced will be interrogated for theo-

ries such as the role’s intervention strategies and the effect of

the role on patient outcomes, as it relates to the role and con-

tributions of the ANP in gastroenterology nursing. This will

lead to the development of initial programme theories. Due to

the iterative nature of the realist review, the initial programme

theories will be further developed and refined throughout
### Table 2. Initial Preliminary Search Strings for Key Areas.

| Key Area 1: An analysis of ANP roles and contributions in gastroenterology nursing taking into account the outcomes and impact of practice in relation to quality of care, across a broad range of clinical contexts, access to screening services and the cost effectiveness of the role |
|---|
| **P** (nurs* AND (pract* OR consult* OR special* OR physician*) OR "Nurse Practitioners"[Mesh]) AND ((endosc* OR gastro*) OR ("Endoscopy/nursing"[Mesh])) |
| **I** role* OR dut* OR job* OR responsib* OR funct* OR fulfil* OR enact* OR part* OR task* OR "Nurse's Role"[Mesh] OR "Primary Nursing"[Mesh] |
| **O** qualit* OR impact* OR outcome* OR effect* OR efficient OR improve* OR assess* OR access* OR clinical OR context* OR "clinical context*" OR screen* OR service* OR "Patient Outcome Assessment"[Mesh] OR "Outcome and Process Assessment, Health Care"[Mesh] OR "Early Diagnosis"[Mesh] OR "Outcome Assessment, Health Care"[Mesh] OR "cost effectiveness" OR cost* OR economic OR "economic evaluation" OR "Cost-Benefit Analysis/economics"[Mesh] |

| Key Area 2: The unique technical skills-set of ANPs in gastroenterology nursing |
|---|
| **P** (nurs* AND (pract* OR consult* OR special* OR physician*) OR "Nurse Practitioners"[Mesh]) AND ((endosc* OR gastro*) OR ("Endoscopy/nursing"[Mesh])) |
| **I** skill* OR enabl* OR facilitate* |

| Key Area 3: Framing the role of the ANP within a nursing context and acknowledging that the nursing role is also part of supporting medical gastrointestinal procedures. |
|---|
| **P** (nurs* AND (pract* OR consult* OR special* OR physician*) OR "Nurse Practitioners"[Mesh]) AND ((endosc* OR gastro*) OR ("Endoscopy/nursing"[Mesh])) |
| **I** "Model of Care" OR nurs* OR medic* OR model* OR domain* OR realm* OR sphere* OR bubble* OR "Models of Practice" OR practice* OR framework* OR "Discipline of Nursing" OR "Practice Patterns" OR "Models, Nursing"[Mesh] OR "Models, Educational"[Mesh] OR "Shared Governance, Nursing"[Mesh] OR "Nursing"[Mesh] OR "nursing" [Subheading] OR "Practice Patterns, Nurses"[Mesh] OR "Practice Patterns, Physicians"[Mesh] |
| **C** interdependent* OR relationship* OR physician endoscop* OR medical endoscop* OR gastroenterolo* OR consult* endoscop* OR "Model of Care" OR nurs* OR medic* OR model* OR "Practice Patterns, Physicians"[Mesh] AND "Physician-Nurse Relations"[Mesh] OR "Physician Assistants"[Mesh] |
| **O** "Role definition" OR boundar* OR "Scope of nurse Practice" OR "Service Needs" OR "Role Models OR 'Nurse's Role'[Mesh]" OR need* OR demand* OR "Health Services Accessibility" OR access* |

| Key Area 4: Current and potential competence requirements of the ANP role in gastroenterology nursing mapped against the Nursing and Midwifery Board of Ireland NMBI standards |
|---|
| **P** (nurs* AND (pract* OR consult* OR special* OR physician*) OR "Nurse Practitioners"[Mesh]) AND ((endosc* OR gastro*) OR ("Endoscopy/nursing"[Mesh])) |
| **I** competenc* OR requirement* OR capability* OR skill* OR ability* OR capacity* OR expertise* OR knowledge* OR "Professional Competence"[Mesh] |
| **O** "Role definition" OR boundar* OR "Scope of Nurse Practice" OR "Advanced Practice (Nursing) Standards and Requirements" OR nursing standard* OR standard* OR quality OR "quality of care" OR nursing excellence OR "professional standard*" OR "standard* for excellence) OR "standard* of nursing practice*" |
the review process. A comprehensive search will commence once the initial programme theories has been developed.

**Step 2: Searching the literature.** A comprehensive three-step approach to searching the literature will be adopted. The search strategy was discussed with a subject librarian and will be tested for comprehensiveness and accuracy. Standard Boolean operators will be utilised to combine search terms, with truncation markers and MeSH headings included. Databases will be searched with strategies adopted for the navigation of each database. Search results will be exported to Endnote 20, and imported to Covidence to achieve transparency, replication and improved systematic management of the literature (Covidence, 2018).

1. An initial preliminary search of MEDLINE and CINAHL will be undertaken to identify the key words, subject headings, alternate terminology associated with the topic area and studies deemed to be eligible will be included if they addressed one of these areas:

   **Key Area 1:** An analysis of ANP roles and contributions in gastroenterology nursing, considering the outcomes and impact of practice in relation to quality of care, across a broad range of clinical contexts, access to screening services and the cost effectiveness of the role.

   **Key Area 2:** The unique technical skills-set of ANPs in gastroenterology nursing.

   **Key Area 3:** Framing the role of the ANP within a nursing context and acknowledging that the nursing role is also part of supporting medical gastrointestinal procedures.

   **Key Area 4:** Current and potential competence requirements of the ANP role in gastroenterology nursing mapped against the Nursing and Midwifery Board of Ireland NMBI standards

**Key Area 5:** Define the contribution of the ANP role in gastroenterology to nursing practice according to the four pillars of the advanced practice framework for generic advanced practitioners (clinical practice, leadership and management, education and research).

2. A comprehensive search of the following databases will be conducted: Cumulative Index to the Nursing and Allied Health Literature (CINAHL), PubMed (MEDLINE), EMBASE, PsychINFO and published or unpublished dissertations. The search will include the descriptive, discursive, and empirical literature. Where appropriate, grey literature (i.e., materials not indexed by major databases), will be included such as policy documents, reports, and regulatory frameworks. Standard Boolean operators AND, OR, NOT will be used to combine search terms. Search strategies will be adopted for each database as appropriate.

3. A manual review of the reference list of identified reports polices and studies will be conducted.

4. The PICO Framework will be applied to structure the key words used in the search strategy. In the PICO framework:

   **(P)**– Population refers to the sample of subjects. Here, the ‘P’ refers to the ANP in gastroenterology nursing or other titles such as advanced nurse practitioner, advanced practice nurse, nurse practitioner, nurse physician, nurse consultant, nurse endoscopist, endoscopist, colonoscopist, advanced practitioner, and non-physician endoscopist.

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### Table: PICO Framework

| **P** | **I** | **O** |
|-------|-------|-------|
| (nurs* AND (pract* OR consult* OR special* OR physician*)) OR "Nurse Practitioners"[Mesh]) AND ((endosc* OR gastro*) OR "Endoscopy/nursing"[Mesh]) | contribution* OR donation* OR gift* OR donativ* OR engagement* OR promotion OR development* OR role* OR dut* OR job* OR responsib* OR funct* OR fulfill* OR enact* OR part* OR task* OR "Nurse's Role"[Mesh] OR "Primary Nursing"[Mesh] OR "International Council of Nurses"[Mesh] OR "Endoscopy, Gastrointestinal"[Mesh] OR "Endoscopy"[Mesh] OR "Capsule Endoscopy"[Mesh]) | "practice guideline" OR "practice guidelines as topic"[MeSH Terms] OR "clinical practice guideline"[All Fields] OR "clinical practice" OR "direct clinical practice" OR "clinical leadership" OR leadership role OR "leadership and collaborative practice" OR professional competence OR "organization and administration"[MeSH Terms] OR "disease management"[MeSH Terms] OR management [Text Word] autonomous* OR independent OR requirement* OR capability* OR "evidence-based practice*" OR advance* OR "educational development*" OR "education and learning" OR educat* OR educat* requirement* OR ("Nursing Education Research/ education"[Majr] OR "Nursing Education Research/legislation and jurisprudence"[Majr]) OR ("Research in Nursing/standards"[Majr]) OR "research activit*" OR "research and evidence-based practice" |
(I) Intervention refers to the treatment/intervention that will be provided which is the ‘the role and contribution of the ANP in Gastroenterology nursing.’

(C) Comparison identifies a reference group for comparison. In the current study the C’ includes comparison such as previous work that has evaluated a range of health professional roles impacting on patient outcomes in general and specifically in the gastroenterology nursing context. Also, comparisons with physician assistants, advanced practitioners, performing endoscopy procedures and physician endoscopists are relevant.

(O) Outcome represents what results are to be measured to examine the effectiveness of the intervention. The ‘O’ in the current context refers to the evaluations undertaken in terms of different types, methodologies and or assessments used. If previous evaluation tools were used – these will be described and furthermore critiqued.

**Step 3: Document selection.** An initial predefined inclusion and exclusion criteria will be applied, favouring both qualitative and quantitative primary research which refers to the nursing role of the ANP in gastroenterology. Table 3 outlines the full inclusion and exclusion criteria with a rationale. A screening process of all study titles and abstracts by two independent reviewers (MB and MC), applying the predefined inclusion and exclusion criteria will guide the document selection process. All searches will be exported to Endnote 20 and search results will be imported to the software programme Covidence, to track the inclusion and exclusion of documents, supported by justifications. Once completed, full text studies will be screened by the same reviewers (MB and MC) independently. Any discrepancies that may emerge relating to the inclusion and exclusion of studies will be resolved by a third reviewer (LO’C). A PRISMA-P flow chart will be populated following completion of the document selection process to provide greater understanding of the core concepts and key areas reported on within the review process. The PRISMA-P flow chart will be made available in the Extended Data section.

**Quality appraisal**

The Crowe Critical Appraisal Tool (CCAT) will be utilised by two independent reviewers (MB and MC) and each study will be mapped in accordance with the CCAT Form (v1.4) (Conchra Research & Technology, 2015). All CCAT Forms will be compared by both reviewers (MB and MC) before agreement for inclusion is reached. The CCAT is recognised as an objective assessment instrument (Crowe et al., 2011), and was successfully applied by the authors during a previous rapid realist review (RRR) (O’Connor et al., 2021).

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**Table 3. Inclusion and Exclusion Criteria to Inform Study Selection.**

| Criteria               | Inclusion                                      | Exclusion                                      | Rationale                                                                                                                                 |
|------------------------|------------------------------------------------|------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| **Time Period**        | 1970 – 2021                                    | Outside selected time period                   | ANPs in gastroenterology nursing were first introduced in the USA in the late 1960’s                                                    |
| **Language**           | English                                        | Any other language                             | Reviewers are English speaking only                                                                                                       |
| **Main Focus**         | The role and contribution of the ANP to gastroenterology nursing | Technical and biomedical aspects of the role | The focus of the review is on the nursing role                                                                                              |
| **Comparison studies**| Between ANPs and physicians/physician assistants, if the nursing role of the ANP was identified or defined specifically | Between studies which exclude the role and contribution of the ANP in gastroenterology | The nursing role of the ANP in gastroenterology will be examined                                                                         |
| **Studies**            | With adult participants over 18 years of age    | With participants under 18 years of age       | Paediatric gastroenterology is viewed as a specialty discipline, performed by specialised teams                                             |
| **ANPs in gastroenterology nursing** | Registered nurses working in gastroenterology nursing without an ANP qualification or CANP status | Registered nurses without an ANP qualification or CANP status falls outside the scope of this review |                                                                                                                                              |
| **ANP in gastroenterology nursing performing nursing endoscopy** | ANP gastroenterology specialising in Irritable Bowel Syndrome/Disease | ANP specialising in Irritable Bowel Syndrome/Disease falls outside the scope of this review |                                                                                                                                              |
| **Study Types**        | Peer reviewed, primary research studies         | All other studies                              | ANP in gastroenterology is expanding and prominent in several countries                                                                |
| **Geographical Location** | All international locations                   | None                                           |                                                                                                                                              |
**Step 4: Data extraction.** An electronic data extraction form (Figure 2), designed in accordance with realist review methodology and utilised during a previous RRR, will be utilised as tested instrument. Data will be extracted by one reviewer (MB) and checked by a second reviewer (MC). The Data Extraction Form will be made available in the Extended Data section. Figure 1 outlines the Main Headings of the Data Extraction Form to be used with a descriptive account.

**Step 5: Validation of findings.** To ensure the Realist review’s relevance to the clinical practice context, and expert panel will validate the review findings.

**Step 6: Data synthesis.** Data synthesis is tasked to refine programme theory and should address four dimensions, such as theory integrity, adjudication of competing theories, consideration of theories in comparative clinical settings and drawing comparisons of the ‘official’ theory with actual clinical practice (Pawson, 2002; Pawson et al., 2005). Based on the principles of Realist Evaluation (Pawson & Tilley, 1997), a data synthesis approach was developed for application: Organisation of extracted data into evidence tables; theming by individual reviewers; comparison of reviewers’ themes for a specific study and formulation of chains of inference from the identified themes; linking of the chains of inference and tracking and linking included studies and finally hypothesis formulation (Rycroft-Malone et al., 2012). Thematic analysis will be utilised to analyse the findings from each included study (Braun & Clarke, 2021), and context-mechanism-outcome configurations (CMOc) will be identified. The software package NVivo 12 will be utilised to assist data analysis post thematic coding and all included studies will be imported to the web-based application.

**Step 7: Refining programme theory.** Programme theories will be refined and tested, and it is anticipated that programme theories will inform how underlying mechanisms are triggered within specific care settings, resulting in certain outcomes pertaining to the role and contribution of the ANP in gastroenterology. Theory saturation which takes the form of no new significant findings emerging will be ensured through the iterative nature of the realist review process (Rycroft-Malone et al., 2012).

**Step 8: Dissemination of findings.** Through the publication of the realist review, the findings will be disseminated and will guide a Realist Evaluation study of the role and contribution of the ANP in gastroenterology which will be conducted.

**Ethics**
The realist review will not require ethical approval.

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**Figure 1. Review Design.**
| Study ID: | Reviewer: |
|----------|-----------|
| Study Characteristics | Date of review: |
| Author(s) and Year of Publication | Description |
| Date published |
| Study Title | Title of study/article |
| Country of Origin and Healthcare Setting | Where study was conducted |
| What type of setting? |
| Discipline of the author | Nursing or Medical |
| Aims and Purpose | What wanted to be achieved |
| Study Design | Specify design |
| Number of Clinical Setting(s) | Single site or Multi-institutional sites |
| Type of Participants and Sample Size | Study Participants |
| Intervention (e.g. educational programme; new role) | Description of intervention and control |
| Context (relates to the conditions in which the role of the ANP in gastroenterology was introduced) | Facilitative or hindering to a mechanism |
| Mechanisms (the process of how people interpreted and acted upon the introduction of the role of the ANP in gastroenterology) | Generative force resulting in an outcome. May manifest as a reason/response/reaction |
| Outcome (the intended and unintended consequences of the role implementation) | What occurred – intended or unintended |
| Findings | Overall findings |
| Additional Comments | Any other relevant details |

**Figure 2.** Data Extraction Form.

**Study status**
This realist review protocol was submitted for peer review and publication and will commence end of December 2021 and last for one year, until December 2022.

**Discussion and conclusion**
This review protocol outlines the latest evidence-based practice for the conduct of a realist review in a systematic manner (Ford et al., 2015; Pawson & Tilley, 2004; Pawson et al., 2005;...
The study DOI is: https://doi.org/10.6084/m9.figshare.16820515. v1

No data are associated with this article.

Extended data
Figshare Repository: A Data Management Plan (DMP) will be uploaded to Figshare with all relevant figures, tables, and extended data. The data presented in this study are openly available in the Figshare Repository at: https://figshare.com/articles/thesis/A_Realist_Review_Protocol_of_the_Role_and_Contribution_of_the_Advanced_Nurse_Practitioner_ANP_in_Gastroenterology_Nursing/16820515

This protocol contains the following extended data:
Figure 1: Realist Review Design
Figure 2: Data Extraction Form
Table 1: Geographical Location and Total Number of ANPs, cANPs and Gastroenterologists in Ireland
Table 2: Initial Preliminary Search Strings for Key Areas
Table 3: Inclusion and Exclusion Criteria to Inform Study Selection

Reporting guidelines (if applicable)
The Realist Review will be informed by the RAMESES (Realist And Meta-narrative Evidence Synthesis: Evolving Standards) project (Wong et al., 2016).

Author contributions
Marlize Barnard
Roles: Conceptualization, Data Curation, Formal Analysis, Investigation, Methodology, Project Administration, Resources, Software, Writing – Review & Editing

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