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Clinical communication in inflammatory bowel disease: A systematic literature review protocol

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ABSTRACT

Introduction

Evidence regarding effective communication between clinicians and patients with inflammatory bowel disease (IBD) is limited. Studies that investigate clinical communication in IBD are much fewer in number than studies that investigate the perceptions of patients and clinicians about communication in clinical encounters. The current review aims to identify, organise and summarise systematically what is currently known about (a) the characteristics of interactions between clinicians that manage IBD and patients with IBD, and (b) how clinical discussion affects health outcomes in IBD.

Methods and analysis

Scopus, PubMed, Embase, Communication Abstracts – EBSCO, Health & Society – Informit, Linguistics and Language Behavior Abstracts (LLBA) – Proquest, and PsycINFO will be systematically searched for studies that investigate the characteristics of IBD clinical interactions during recorded consultations, from earliest available dates within each database to May 2020. A specifically developed quality assessment tool, grounded in linguistic theory, will be used to critically assess the evidence. In addition, a data extraction template will be developed and utilised to provide a description of the characteristics of IBD clinical communication as well as an estimation of its effect on health outcomes in a narrative synthesis.

Ethics and dissemination

Ethics reviews and approval is not required for this systematic review as no primary data will be collected. The results will be published in peer-reviewed journals and presented at academic conferences.

Registration

This protocol has been submitted to PROSPERO on 19 February 2020 and is currently being assessed by the editorial team.

Keywords: inflammatory bowel disease, communication, clinical communication, clinical encounter, systematic review

STRENGTHS AND LIMITATIONS OF THIS STUDY

Strengths

- This systematic review is the very first to identify, assess, and summarise evidence resulting from investigations of recorded clinical interactions during IBD consultations.
- The review consults a diverse range of databases - including databases with special focus on medicine, health, psychology, communication, and linguistics - to identify eligible studies.
- A broad search strategy is developed to maximise the inclusion of eligible studies.
- The review uses a specifically developed quality assessment tool, grounded in linguistic theory, to critically assess the evidence.

Limitation

- It is expected that the findings will not be integrated to produce cumulative evidence due to the anticipated diverse range of included studies in terms of context and theoretical underpinnings.

1. INTRODUCTION

Inflammatory bowel disease (IBD) is a chronic inflammatory condition of the gastrointestinal tract mainly presenting in two forms: Crohn's disease (CD) and ulcerative colitis (UC). IBD is characterised by intermittent periods of active disease with symptoms including diarrhea, rectal bleeding, urgency, incontinence, chronic abdominal pain, loss of appetite and weight loss, fatigue, joint pain, and skin problems that undermine patients' quality of life and emotional well-being which can affect their personal, social, and professional life. The incidence of IBD is highest amongst those aged between 15 and 29 years [1], exacerbating the economic burden of the disease due to effects on the ability to work of the large young population of patients with IBD.

Due to the chronicity of IBD, patients require ongoing monitoring and long-term maintenance therapy to stay in remission and prevent recurrence of disease activity. Treatment of IBD has become more effective over time due to advances in medical and clinical research and the introduction of more effective drugs. At the same time, it has become more complicated because of the adverse effects that accompany the more effective treatments. As a result, discourses around the role of the patient as a key stakeholder in decision-making have found more recognition and prominence in IBD research [2, 3]. Since the main space in which clinicians and patients negotiate roles and make decisions is their clinical interaction during consultations, understanding the exchange of meaning between clinicians and patients in this space and its existing variations is crucial for understanding the bigger picture of how – and how well – IBD is managed. Such an understanding can help identify ways in which IBD care can improve.

Effects of clinical communication on health outcomes include patient satisfaction, adherence, patient quality of life, disease management, and self-management, as discussed by a number of studies in the IBD-specific literature and by many more studies concerned with other conditions. Ghosh and colleagues argued that in IBD, "good communication between physician and patient is a cornerstone of effective disease management" [4pS245]. The authors suggested that motivational communication may be valuable in IBD care, "where the use of treatments with potentially undesirable side effects must be balanced against the risk of life-long high morbidity from the disease" [4pS247]. Motivational communication is a collaborative approach used to elicit the person's own intrinsic motivation and resources for change [5]. A survey study by Mocciaro and colleagues showed that motivational communication in IBD consultations improved patient satisfaction, and potentially medication adherence and smoking cessation and helped physicians in dealing with patients "moving from "cure" to "care"" [6].

Highlighting the link between clinical communication and patient quality of life and disease management, Mitchell and colleagues argued that discussing the impact of IBD on a patient's daily life during a consultation can produce a better "picture of how patients are affected by their disease and how well their current treatment strategy is working for them" [7p2], and provides a context for considering new treatment options based on patients' expectations of treatment, ability to adapt, and treatment objectives. Furthermore, Kennedy and colleagues pointed out the impact of effective communication on "encouraging and supporting decisions and self-care actions which may enable patients to optimally manage their condition outside of health service settings" [8p567-8].

Whilst there has been advocacy for research on communication in IBD, projects whose "site of engagement/intervention" is the "clinician-patient interface" [9] - i.e. projects that investigate interactions between patients and clinicians, rather than patients' perceptions of clinical communication - are less known. No systematic literature review has been conducted to identify and review such studies. In 2004, Husain and colleagues pointed to "a paucity of data concerning effective communication methods enabling physicians to develop stronger rapport with patients suffering from IBD" [10p444]. Sixteen years later, we still do not know much about the status of IBD communication from research that uses real-life clinician-patient conversation data. The current review aims to ascertain the existing knowledge in this area to inform the field, identify the gaps and areas that require further investigations, and position this literature within current IBD care practice and

research. The main objective is to identify, organise and summarise systematically what is currently known about (a) the characteristics of conversations between clinicians that manage IBD and patients with IBD, and (b) how clinical discussion affects health outcomes in IBD.

2. METHODS

1.1. Eligibility criteria

The review will include studies that investigate the characteristics of the interactions between clinicians that manage IBD patients and patients with IBD during a recorded consultation. These characteristics generally include, but are not limited to, the content of the consultation, patients' and clinicians' experience as represented in their language, the interpersonal meanings exchanged in the consultation, the different rhetorical steps that make up the consultation, and the flow of information in the consultation. Studies based only on self-report of interaction e.g. focus group studies, interviews, surveys, participatory observation with no audio/videorecording will be excluded.

Published peer-reviewed studies in English that used quantitative or qualitative methods (including, but not limited to, discourse analysis, conversation analysis, and content analysis) to analyse recorded real-life interactions between clinicians and patients with IBD (UC or CD) during a consultation will be included in the review. Eligible studies will need to sample patients with IBD and clinicians that manage IBD patients in primary and secondary health care (e.g. general practitioners, IBD specialists, IBD nurses), complementary and alternative medicine (e.g. acupuncturists, traditional Chinese medicine practitioner), or allied health (e.g. dietitian). Studies with a focus on health care providers whose primary treatment includes the interaction itself (e.g. psychotherapists) will be excluded. Studies in which these participant groups are present but IBD is not the focus of the study will also be excluded. Studies will be selected regardless of the type of intervention or exposure as the review will not be focused on a certain type of intervention or exposure. Only journal articles and book chapters published in English are eligible. Peer-reviewed published abstracts, letters to the editor, editorials, and theses will be excluded. However, ineligible sources will be examined to locate corresponding journal articles. Articles published to May 2020 will be included.

2.2. Information sources and search strategy

The review will search for records indexed in:

- Scopus
- PubMed
- Embase
- Communication Abstracts – EBSCO
- Health & Society – Informit
- Linguistics and Language Behavior Abstracts (LLBA) – Proquest
- PsycINFO

In addition, snowball sampling will be employed. Reference lists of eligible articles identified in the online database search as well as the excluded but relevant publications will be consulted. Subject matter experts (those known to the researchers as well as those identified in the database search and snowball sampling) will be contacted via email and consulted to identify any additional literature.

A relatively broad search strategy will be employed due to anticipating limited numbers of studies that explore real-life clinician-patient interactions in IBD and in order to maximise the reach. Table 1 lists the keywords that will be used to search these databases. Keywords referring to the condition or healthcare domain being studied (e.g. IBD) will be used; in conjunction with terms describing the data

type (e.g. consultation and audio-record*). The search strategy will be expressed as the intersection of these two sets of terms.

Table 1 Complete search strategy for all electronic bibliographic databases

		Condition terms (search 1) AND	Data type terms (search 2) AND
Terms that searches below are intended to capture		IBD inflammatory bowel disease ulcerative colitis Crohn's disease	communication interaction clinician-patient doctor-patient clinical encounter consultation audio-record* audio record* video-record* video record*
Database	Search field	Search1	Search 2
PubMed via US National Library of Medicine	Text Word [TW]	1. inflammatory bowel disease OR IBD OR ulcerative colitis OR Crohn's disease	communication OR interaction OR doctor-patient OR clinician-patient OR clinical encounter
		2. inflammatory bowel disease OR IBD OR ulcerative colitis OR Crohn's disease	consultation AND audio record* OR audio-record* OR video record* OR video-record
		Limit searches to: full text AND humans	
Scopus	Title/abstract/ keyword	1. inflammatory bowel disease OR IBD OR ulcerative colitis OR Crohn's disease	communication OR interaction OR doctor-patient OR clinician-patient OR clinical encounter
		2. inflammatory bowel disease OR IBD OR ulcerative colitis OR Crohn's disease	consultation AND audio record* OR audio-record* OR video record* OR video-record
		Limit search 1 to: Article and chapter	
PsychINFO AND EMBASE via Ovid	Text Word [TW]	1. inflammatory bowel disease OR IBD OR ulcerative colitis OR Crohn's disease	communication OR interaction OR doctor-patient OR clinician-patient OR clinical encounter
		2. inflammatory bowel disease OR IBD OR ulcerative colitis OR Crohn's disease	consultation AND audio record* OR audio-record* OR video record* OR video-record
		Limit searches to: full text AND human AND English language	
Communication Abstracts – EBSCO	All text	inflammatory bowel disease OR IBD OR ulcerative colitis OR Crohn's disease	-
Health & Society - Informit	Abstract	inflammatory bowel disease OR IBD OR ulcerative colitis OR Crohn's disease	-
Linguistics and Language Behavior Abstracts (LLBA) - Proquest	Abstract	inflammatory bowel disease OR IBD OR ulcerative colitis OR Crohn's disease	-

2.3. Data management and selection process

Study records obtained from the databases will be exported into Endnote where duplicates will be removed, and screening of titles and abstracts and then full-text records will be performed independently by two reviewers (NK and RK). The reviewers will be over-inclusive with their selections and will include all the studies that appear to meet the inclusion criteria as well as those whose eligibility for inclusion is uncertain. Reviewers will not be blinded to the study authors, institutions or journals of the records they screen.

Once both reviewers complete the screening of titles and abstracts, they will meet to compare their lists of selected studies and resolve any discrepancies prior to the full-text review. Any unresolved disagreement will be discussed with the whole review team and a collective decision will be made. Reasons for exclusion will also be recorded at this stage. Once agreement is reached, the full text of the selected studies will be uploaded in Endnote and studied independently by the two reviewers for final inclusions. The same discrepancy resolving process will be repeated at this final stage of selection. Reviewers will meet upon finishing the independent selection process to resolve any disagreements and will discuss matters with the whole review team if they cannot reach an agreement.

2.4. Data collection and extraction processes

Selected articles will be carefully studied by the whole team. A data extraction template will be developed based on the questions asked in the review and the information available in the selected studies, and in consultation with the existing health communication and linguistics literature including previous systematic literature reviews of this kind [9, 11-14] and Halliday's theoretical model of the architecture of language, known as systemic functional linguistics [15]. The data extraction template will be accompanied by detailed instructions in Microsoft Excel. It will be piloted by the two reviewers on a sample of included papers to ensure the efficiency of the template and the accuracy and consistency of extractors before the final data extraction which will be performed by NK and checked by the review team.

The review will explore potential trends in this strand of research by comparing the timing of studies (year of research) and the countries in which the studies were conducted. Information on research setting and participant characteristics including age, sex, socio-demographics and ethnicity will be extracted. Stated aims, aims relevant to the review, health outcomes, and stated findings and conclusions will be described for each study. Information on the consultation data including the size of the dataset (corpus size), the actual number of consultation/episodes analysed in the study, the average length of consultations, whether consultations were audio recorded or video recorded, and whether the consultations were one-off or in series will be charted. Furthermore, study design, method of data analysis, and the investigated linguistic features and function(s) of language will be described. Linguistic feature is broadly defined as any semantic, grammatical, or lexical concept such as topic, question (type and quantity), length of consultation, and so on. Function of language equals 'use': what is it that the language is being used for? There are four main functions (or metafunctions) to language: experiential, interpersonal, logical, and textual, which occur simultaneously in any utterance or text [15]. The experiential function allows language users to use language to construe their experience; the interpersonal function allows language users to enact their roles and relationships with each other (e.g. status, intimacy, contact, sharedness between interactants); the logical function concerns how language users create relations between different parts of their talk, and the textual function is what turns a collection of individual words into a coherent text [15, 16].

Table 2 outlines the data items that will be included in the review. Additional items will potentially be added to this list based on the information available in the selected papers.

Table 2 Data items included in the data extraction template

	Item
1	Year of research
2	Country of research
3	Research setting
4	Participants and numbers
5	Participant demographics
6	Stated aims
7	Aims relevant to the review
8	Health outcome
9	Stated findings
10	Stated conclusions
12	Corpus size and number of consultations/episodes analysed in the study Average length of consultations
13	One-off consultation or series
14	Data type (audio or video)
15	Study design (descriptive, correlational, experimental, etc)
16	Method of data analysis (sociolinguistics, conversation analysis, content analysis, etc)
17	Linguistic component/s analysed
18	Linguistic metafunction/s analysed (experiential, logical, interpersonal, and textual)

2.5. Outcomes and prioritisation

A description of the characteristics of conversations between clinicians who manage IBD patients and patients with IBD during a consultation is the main outcome of this review. These characteristics generally identify the content of the consultation, patients' and clinicians' experience as represented in the consultation, the interpersonal relationships between clinician and patient, the different steps involved and the flow of information in the consultation. Another main outcome is an estimation of the effect of IBD clinical discussion on health outcomes (biomedical and psychosocial). Secondary outcomes include a description of the characteristics of the existing consultation data available for scrutiny in the literature, and trends in IBD clinical communication research including mainstream analytic approaches.

2.6. Risk of bias in individual studies

Conventional guidelines for assessing the quality of studies for inclusion in a systematic literature review [17] have limited application to discourse analytic research because this type of research is different from the mainstream qualitative and quantitative health research in terms of its objective and methodology [13]. Rather than using a single set of criteria and ranking studies based on those criteria, following Parry and Land, two broad dimensions will be used to assess each study's value and contribution: (1) the type and amount of data, and (2) the credibility and reliability of the analysis [13]. Credibility is defined as "the confidence that can be placed in the truth of the research findings" [18p121]. To assess the credibility of the studies, Matthiessen's account of the methodological approaches to the analysis of a situation type (e.g. IBD consultation) [19] will be used as a guide. Matthiessen's methodological account [19] is based on Halliday's systemic functional linguistics [20]. Generally, language consists of four layers or strata (context, semantics, grammar and lexis, and phonology) and four main functions (experiential, logical, interpersonal, and textual), as explained above. A comprehensive description of a situation type is time consuming and labour intensive. Matthiessen suggests principled selection of data and data analysis tools to reduce the description bias and increase credibility [19]. To assess the reliability of the studies, information regarding the presence or absence of a second coder will be considered.

Included studies will also be evaluated in terms of the amount of evidence used to support their conclusions and whether the conclusions were biased or evidence-based [21]. Further quality assessment dimensions may be added depending on the included studies. Missing information will not be sought from the authors, neither will unclear aspects of the studies be clarified with them.

Rather, such limitations will be discussed under risk of bias.

2.7. Synthesis

The extracted data will be presented in overview tables for the purpose of summarization and comparison and described in a narrative synthesis. The inclusion criteria in this review allow for including studies from a range of contexts such as IBD specialist consultations, nurse consultations, allied health consultations, and general practice consultations. It is, therefore, expected that the context of the included studies will vary. It is also expected that these studies will be within different research traditions, having different underpinning philosophical assumptions, given the diverse approaches to the analysis of talk in health research, in general. Considering the diversity of contexts and theoretical underpinnings, a narrative synthesis was chosen as the method of synthesizing data.

The narrative synthesis will be based on the results of the data extraction and quality appraisal. Furthermore, following the recommendations of Cochrane Consumers and Communication Review Group [22], the narrative synthesis will also include investigation of the similarities and the differences between the studies based on the study design and information gathered from the data extraction and quality appraisal. Since this is not a meta-synthesis, findings of the included studies will not be integrated, and the data will not be reinterpreted.

3. DISSEMINATION PLANS

Findings of this systematic review will be presented at national and international conferences and published in peer-reviewed journals (open-access if possible).

4. DISCUSSION

Clinician-patient communication is shown to affect biological and functional health outcomes [23-27] and can have economic consequences [28-30]. In IBD, clinical communication is argued to affect patient satisfaction, treatment adherence, patient quality of life, disease management, and self-management, as described in the Introduction section. This systematic review will be the first to review studies that examine clinical communication in IBD using recorded clinician-patient consultation data. It aims to investigate the characteristics of IBD clinical discussions and the effects of these discussions on health outcomes (biomedical and psychosocial). The current protocol outlines the steps and procedures involved in achieving this objective.

Collecting and reviewing evidence from studies that investigate recorded clinical communication in IBD for the first time, consulting a diverse range of databases to identify eligible studies, developing a broad search strategy to maximise inclusion, and using a comprehensive theory of language for appraising the quality of the included studies are arguably among the strengths of this review. Nevertheless, there are limitations as well. Reviews of this kind inevitably include a diverse range of studies in terms of context and theoretical underpinnings and this review will not be an exception. The consequence of this diversity is that findings cannot be integrated to produce cumulative evidence. For this reason, a narrative synthesis approach will be taken where data will be summarised and compared but not statistically integrated. The results of the review can provide clinicians with valuable information to improve the way they communicate with their patients during a consultation. It will also identify the gaps in the literature and the areas that require further investigation for future research.

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6. COMPETING INTERESTS

NK, ARM, and AL have received grant support from Janssen.

RK has received research and educational support from Pfizer, Abbvie, Takeda, and Janssen.

AW has received Honoraria from Takeda, Ferring, Janssen, and Abbvie.

SJC is on advisory boards, has received speaker fees, educational support, research support and /or coordinated education meetings for: AbbVie, Celgene, Ferring, Gilead, Janssen, MSD, Orphan/Aspen, Pfizer, and Takeda.

7. PATIENT AND PUBLIC INVOLVEMENT

Patients or the public were not involved in the design of this systematic review protocol.

REFERENCES

1. Johnston, R.D. and R.F.A. Logan, *What is the peak age for onset of IBD?* Inflammatory Bowel Diseases, 2008. **14**(suppl_2): p. S4-S5.
2. Siegel, C.A., et al., *Gastroenterologists' Views of Shared Decision Making for Patients with Inflammatory Bowel Disease.* Digestive Diseases and Sciences, 2015. **60**(9): p. 2636-2645.
3. Drescher, H., et al., *Treat-to-Target Approach in Inflammatory Bowel Disease: The Role of Advanced Practice Providers.* The Journal for Nurse Practitioners, 2019. **15**(9): p. 676-681.
4. Ghosh, S., et al., *What do changes in inflammatory bowel disease management mean for our patients?* J Crohns Colitis, 2012. **6 Suppl 2**: p. S243-9.
5. Miller, W. and S. Rollnick, *Motivational Interviewing, Second Edition : Preparing People for Change*. 2002, New York, UNITED STATES: Guilford Publications.
6. Mocciaro, F., et al., *Motivational interviewing in inflammatory bowel disease patients: a useful tool for outpatient counselling.* Dig Liver Dis, 2014. **46**(10): p. 893-7.
7. Mitchell, R., et al., *Talking about life and IBD: A paradigm for improving patient-physician communication.* Journal of Crohn's and Colitis, 2009. **3**(1): p. 1-3.
8. Kennedy, A., L. Gask, and A. Rogers, *Training professionals to engage with and promote self-management.* Health Educ Res, 2005. **20**(5): p. 567-78.
9. Moore, A.R., *Language and medicine*, in *The Cambridge Handbook of Systemic Functional Linguistics*, G. Thompson, et al., Editors. 2019, Cambridge University Press: Cambridge. p. 651-688.
10. Husain, A. and G. Triadafilopoulos, *Communicating with patients with inflammatory bowel disease.* Inflamm Bowel Dis, 2004. **10**(4): p. 444-50; discussion 451.
11. Kindell, J., et al., *Everyday conversation in dementia: a review of the literature to inform research and practice.* Int J Lang Commun Disord, 2017. **52**(4): p. 392-406.
12. Parry, R.H., V. Land, and J. Seymour, *Communicating face-to-face about sensitive future matters including end of life: a systematic review of evidence from fine-grained observational research.* PROSPERO, 2011. **CRD42011001626**.
13. Parry, R.H. and V. Land, *Systematically reviewing and synthesizing evidence from conversation analytic and related discursive research to inform healthcare communication practice and policy: an illustrated guide.* BMC Med Res Methodol, 2013. **13**: p. 69.
14. Stortenbeker, I., et al., *A review on linguistic and interactional aspects in consultations about medically unexplained symptoms.* PROSPERO, 2018. **CRD42018095405**
15. Halliday, M.A.K., *Part A*, in *Language, Context, and Text: Aspects of Language in a Social-Semiotic Perspective*, M.A.K. Halliday and R. Hasan, Editors. 1985/89, OUP/Deakin University Press: Oxford/Geelong.
16. Halliday, M.A.K., *On Language and Linguistics, Volume 3 of the Collected works of M.A.K. Halliday*, ed. J.J. Webster. 2003, London & New York: Continiuum.
17. Higgins, J.P.T., et al., *The Cochrane Collaboration's tool for assessing risk of bias in randomised trials.* BMJ, 2011. **343**: p. d5928.

18. Korstjens, I. and A. Moser, *Series: Practical guidance to qualitative research. Part 4: Trustworthiness and publishing.* Eur J Gen Pract, 2018. **24**(1): p. 120-124.
19. Matthiessen, C.M.I.M., *Register in the round: Diversity in a unified theory of register analysis*, in *Register Analysis: Theory and Practice*, M. Ghadessy, Editor. 1993, Pinter: London. p. 221–292.
20. Halliday, M.A.K. and C.M.I.M. Matthiessen, *Halliday's introduction to functional grammar*. 2014, London & New York: Routledge.
21. Aromataris, E. and Z. Munn, eds. *Joanna Briggs Institute Reviewer's Manual*. 2017, The Joanna Briggs Institute.
22. Ryan, R. and Cochrane Consumers and Communication Review Group, *Cochrane Consumers and Communication Review Group: data synthesis and analysis.* June 2013.
23. Lee, W., et al., *The mediatory role of medication adherence in improving patients' medication experience through patient-physician communication among older hypertensive patients.* Patient Prefer Adherence, 2017. **11**: p. 1119-1126.
24. Heisler, M., et al., *The relative importance of physician communication, participatory decision making, and patient understanding in diabetes self-management.* J Gen Intern Med, 2002. **17**(4): p. 243-52.
25. Street, R.L., Jr., et al., *How does communication heal? Pathways linking clinician-patient communication to health outcomes.* Patient Educ Couns, 2009. **74**(3): p. 295-301.
26. Safran, D.G., et al., *Linking primary care performance to outcomes of care.* J Fam Pract, 1998. **47**(3): p. 213-20.
27. Zachariae, R., et al., *Association of perceived physician communication style with patient satisfaction, distress, cancer-related self-efficacy, and perceived control over the disease.* Br J Cancer, 2003. **88**(5): p. 658-65.
28. Linedale, E.C., et al., *Uncertain Diagnostic Language Affects Further Studies, Endoscopies, and Repeat Consultations for Patients With Functional Gastrointestinal Disorders.* Clinical Gastroenterology and Hepatology, 2016. **14**(12): p. 1735-1741.e1.
29. Hurtig, R.R., R.M. Alper, and B. Berkowitz, *The cost of not addressing the communication barriers faced by hospitalized patients.* Perspectives of the ASHA special interest groups, 2018. **3**(12): p. 99-112.
30. Vermeir, P., et al., *Communication in healthcare: a narrative review of the literature and practical recommendations.* International journal of clinical practice, 2015. **69**(11): p. 1257-1267.

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Clinical communication in inflammatory bowel disease: A systematic literature review protocol

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ABSTRACT

Introduction

Evidence regarding effective communication between clinicians and patients with inflammatory bowel disease (IBD) is limited. Studies that investigate clinical communication in IBD are much fewer in number than studies that investigate the perceptions of patients and clinicians about communication in clinical encounters. The current review aims to identify, organise and summarise systematically what is currently known about (a) the characteristics of interactions between clinicians that manage IBD and patients with IBD, and (b) how clinical discussion affects health outcomes in IBD.

Methods and analysis

Scopus, PubMed, Embase, Communication Abstracts – EBSCO, Health & Society – Informit, Linguistics and Language Behavior Abstracts (LLBA) – Proquest, and PsycINFO will be systematically searched for studies that investigate the characteristics of IBD clinical interactions during recorded consultations, from earliest available dates within each database to May 2020. A specifically developed quality assessment tool, grounded in linguistic theory, will be used to critically assess the evidence. In addition, a data extraction template will be developed and utilised to provide a description of the characteristics of IBD clinical communication as well as an estimation of its effect on health outcomes in a narrative synthesis.

Ethics and dissemination

Ethics reviews and approval is not required for this systematic review as no primary data will be collected. The results will be published in peer-reviewed journals and presented at academic conferences.

Registration

This systematic review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 28 April 2020 (registration number: CRD42020169657).

Keywords: inflammatory bowel disease, communication, clinical communication, clinical encounter, systematic review

STRENGTHS AND LIMITATIONS OF THIS STUDY

Strengths

- This systematic review will be the very first to identify, assess, and summarise evidence resulting from investigations of recorded clinical interactions during IBD consultations.
- The review will consult a diverse range of databases - including databases with special focus on medicine, health, psychology, communication, and linguistics - to identify eligible studies.
- The review will use a specifically developed quality assessment tool, grounded in linguistic theory, to critically assess the evidence.

Limitation

- It is expected that the findings will not be integrated to produce cumulative evidence due to the anticipated diverse range of included studies in terms of context and theoretical underpinnings.
- Due to funding limitations, this systematic review will be restricted to publications in English language only and, thus, may not represent all the available evidence.

1. INTRODUCTION

Inflammatory bowel disease (IBD) is a chronic inflammatory condition of the gastrointestinal tract mainly presenting in two forms: Crohn's disease (CD) and ulcerative colitis (UC). IBD is characterised by intermittent periods of active disease with symptoms including diarrhea, rectal bleeding, urgency, incontinence, chronic abdominal pain, loss of appetite and weight loss, fatigue, joint pain, and skin problems that undermine patients' quality of life and emotional well-being which can affect their personal, social, and professional life. The incidence of IBD is highest amongst those aged between 15 and 29 years [1], exacerbating the economic burden of the disease due to effects on the ability to work of the large young population of patients with IBD.

Due to the chronicity of IBD, patients require ongoing monitoring and long-term maintenance therapy to stay in remission and prevent recurrence of disease activity. Treatment of IBD has become more effective over time due to advances in medical and clinical research and the introduction of more effective drugs. At the same time, it has become more complicated because of the adverse effects that accompany the more effective treatments. As a result, discourses around the role of the patient as a key stakeholder in decision-making have found more recognition and prominence in IBD research [2, 3]. Since the main space in which clinicians and patients negotiate roles and make decisions is their clinical interaction during consultations, understanding the exchange of meaning between clinicians and patients in this space and its existing variations is crucial for understanding the bigger picture of how – and how well – IBD is managed. Such an understanding can help identify ways in which IBD care can improve.

Effects of clinical communication on health outcomes include patient satisfaction, adherence, patient quality of life, disease management, and self-management, as discussed by a number of studies in the IBD-specific literature and by many more studies concerned with other conditions. Ghosh and colleagues argued that in IBD, "good communication between physician and patient is a cornerstone of effective disease management" [4, p. S245]. The authors suggested that motivational communication may be valuable in IBD care, "where the use of treatments with potentially undesirable side effects must be balanced against the risk of life-long high morbidity from the disease" [4, p. S247]. Motivational communication is a collaborative approach used to elicit the person's own intrinsic motivation and resources for change [5]. A survey study by Mocciaro and colleagues showed that motivational communication in IBD consultations improved patient satisfaction, and potentially medication adherence and smoking cessation and helped physicians in dealing with patients "moving from "cure" to "care"" [6].

Highlighting the link between clinical communication and patient quality of life and disease management, Mitchell and colleagues argued that discussing the impact of IBD on a patient's daily life during a consultation can produce a better "picture of how patients are affected by their disease and how well their current treatment strategy is working for them" [7, p. 2], and provides a context for considering new treatment options based on patients' expectations of treatment, ability to adapt, and treatment objectives. Furthermore, Kennedy and colleagues pointed out the impact of effective communication on "encouraging and supporting decisions and self-care actions which may enable patients to optimally manage their condition outside of health service settings" [8, p. 567-8].

Whilst there has been advocacy for research on communication in IBD, projects whose "site of engagement/intervention" is the "clinician-patient interface" [9] - i.e. projects that investigate interactions between patients and clinicians, rather than patients' perceptions of clinical communication - are less known. No systematic literature review has been conducted to identify and review such studies. In 2004, Husain and colleagues pointed to "a paucity of data concerning effective communication methods enabling physicians to develop stronger rapport with patients suffering from IBD" [10, p. 444]. Sixteen years later, we still do not know much about the status of IBD communication from research that uses real-life clinician-patient conversation data. The current review aims to ascertain the existing knowledge in this area to inform the field, identify the gaps and areas that require further investigations, and position this literature within current IBD care practice and research. The main objective is to identify, organise and summarise systematically what is

currently known about (a) the characteristics of conversations between clinicians that manage IBD and patients with IBD, and (b) how clinical discussion affects health outcomes in IBD.

2. METHODS

1.1. Eligibility criteria

The review will include studies that investigate the characteristics of the interactions between clinicians that manage IBD patients and patients with IBD and/or their parent/guardian during a recorded consultation. These characteristics generally include, but are not limited to, the content of the consultation, patients' and clinicians' experience as represented in their language, the interpersonal meanings exchanged in the consultation, the different rhetorical steps that make up the consultation, and the flow of information in the consultation. Studies based only on self-report of interaction e.g. focus group studies, interviews, surveys, participatory observation with no audio/videorecording will be excluded.

Published peer-reviewed studies in English that used quantitative or qualitative methods (including, but not limited to, discourse analysis, conversation analysis, and content analysis) to analyse recorded real-life interactions between clinicians and patients with IBD (UC or CD) during a consultation will be included in the review. Eligible studies will need to sample patients with IBD and clinicians that manage IBD patients in primary and secondary health care (e.g. general practitioners, IBD specialists, IBD nurses), complementary and alternative medicine (e.g. acupuncturists, traditional Chinese medicine practitioner), or allied health (e.g. dietitian). Studies with a focus on health care providers whose primary treatment includes the interaction itself (e.g. psychotherapists) will be excluded. Studies in which these participant groups are present but IBD is not the focus of the study will also be excluded. Studies will be selected regardless of the type of intervention or exposure as the review will not be focused on a certain type of intervention or exposure. Only journal articles and book chapters published in English are eligible. Peer-reviewed published abstracts, letters to the editor, editorials, and theses will be excluded. However, ineligible sources will be examined to locate corresponding journal articles. Articles published to May 2020 will be included.

2.2. Information sources and search strategy

The review will search for records indexed in:

- Scopus
- PubMed
- Embase
- Communication Abstracts – EBSCO
- Health & Society – Informit
- Linguistics and Language Behavior Abstracts (LLBA) – Proquest
- PsycINFO

In addition, snowball sampling will be employed. Reference lists of eligible articles identified in the online database search as well as the excluded but relevant publications will be consulted. Subject matter experts (those known to the researchers as well as those identified in the database search and snowball sampling) will be contacted via email and consulted to identify any additional literature.

A relatively broad search strategy will be employed due to anticipating limited numbers of studies that explore real-life clinician-patient interactions in IBD and in order to maximise the reach. Table 1 lists the keywords that will be used to search these databases. Keywords referring to the condition or healthcare domain being studied (e.g. IBD) will be used; in conjunction with terms describing the data

type (e.g. consultation and audio-record*). The search strategy will be expressed as the intersection of these two sets of terms.

Table 1 Complete search strategy for all electronic bibliographic databases

		Condition terms (search 1) AND	Data type terms (search 2) AND
Terms that searches below are intended to capture		IBD inflammatory bowel disease ulcerative colitis Crohn's disease	communication interaction clinician-patient doctor-patient clinical encounter consultation audio-record* audio record* video-record* video record*
Database	Search field	Search1	Search 2
PubMed via US National Library of Medicine	Text Word [TW]	1. inflammatory bowel disease OR IBD OR ulcerative colitis OR Crohn's disease	communication OR interaction OR doctor-patient OR clinician-patient OR clinical encounter
		2. inflammatory bowel disease OR IBD OR ulcerative colitis OR Crohn's disease	consultation AND audio record* OR audio-record* OR video record* OR video-record
		Limit searches to: full text AND humans	
Scopus	Title/abstract/ keyword	1. inflammatory bowel disease OR IBD OR ulcerative colitis OR Crohn's disease	communication OR interaction OR doctor-patient OR clinician-patient OR clinical encounter
		2. inflammatory bowel disease OR IBD OR ulcerative colitis OR Crohn's disease	consultation AND audio record* OR audio-record* OR video record* OR video-record
		Limit search 1 to: Article and chapter	
PsychINFO AND EMBASE via Ovid	Text Word [TW]	1. inflammatory bowel disease OR IBD OR ulcerative colitis OR Crohn's disease	communication OR interaction OR doctor-patient OR clinician-patient OR clinical encounter
		2. inflammatory bowel disease OR IBD OR ulcerative colitis OR Crohn's disease	consultation AND audio record* OR audio-record* OR video record* OR video-record
		Limit searches to: full text AND human AND English language	
Communication Abstracts – EBSCO	All text	inflammatory bowel disease OR IBD OR ulcerative colitis OR Crohn's disease	-
Health & Society - Informit	Abstract	inflammatory bowel disease OR IBD OR ulcerative colitis OR Crohn's disease	-
Linguistics and Language Behavior Abstracts (LLBA) - Proquest	Abstract	inflammatory bowel disease OR IBD OR ulcerative colitis OR Crohn's disease	-

2.3. Data management and selection process

Study records obtained from the databases will be exported into Endnote where duplicates will be removed, and screening of titles and abstracts and then full-text records will be performed independently by three reviewers (NK, RK, and AL). The reviewers will be over-inclusive with their selections and will include all the studies that appear to meet the inclusion criteria as well as those whose eligibility for inclusion is uncertain. Reviewers will not be blinded to the study authors, institutions or journals of the records they screen.

Once the reviewers complete the screening of titles and abstracts, they will meet to compare their lists of selected studies and resolve any discrepancies prior to the full-text review. Any unresolved disagreement will be discussed with the whole review team and a collective decision will be made. Reasons for exclusion will also be recorded at this stage. Once agreement is reached, the full text of the selected studies will be uploaded in Endnote and studied independently by the reviewers for final inclusions. The same discrepancy resolving process will be repeated at this final stage of selection. Reviewers will meet upon finishing the independent selection process to resolve any disagreements and will discuss matters with the whole review team if they cannot reach an agreement.

2.4. Data collection and extraction processes

Selected articles will be carefully studied by the whole team. A data extraction template will be developed based on the questions asked in the review and the information available in the selected studies, and in consultation with the existing health communication and linguistics literature including previous systematic literature reviews of this kind [9, 11-14] and Halliday's theoretical model of the architecture of language, known as systemic functional linguistics [15]. The data extraction template will be accompanied by detailed instructions in Microsoft Excel. It will be piloted by two reviewers on a sample of included papers to ensure the efficiency of the template and the accuracy and consistency of extractors before the final data extraction which will be performed by NK and checked by the review team.

The review will explore potential trends in this strand of research by comparing the timing of studies (year of research), the countries in which the studies were conducted, and the type of consultation under scrutiny (e.g., IBD nurse consultations, IBD specialist consultations, etc.). Information will be extracted on research setting, participant characteristics including their role (e.g., patient, parent, nurse, gastroenterologist, etc.), socio-demographics, and the status of patient participants (e.g., pregnant, pre-conception, post-surgery, in transition to adult care, etc.), as well as disease characteristics including type of IBD (UC, CD, or IBD unclassified), disease activity, disease phenotype, and extraintestinal manifestations. Stated aims, aims relevant to the review (e.g., investigation of whether/how the clinicians talk about treatment options including their benefits and side-effects, patient's quality of life, or goals of care; description of clinician-patient relationship as construed in talk; etc.), study design, health outcomes and measures, and stated findings and conclusions will be described for each study. Information on the consultation data including the size of the dataset (corpus size), the actual number of consultation/episodes analysed in the study, the average length of consultations, whether consultations were audio recorded or video recorded, and whether the consultations were one-off or in series will be charted. Furthermore, the method of linguistic data analysis and the investigated linguistic features will be described. A linguistic feature is broadly defined as any semantic, grammatical, or lexical concept such as topic, question (type and quantity), length of consultation, and so on.

Table 2 outlines the data items that will be included in the review. Additional items will potentially be added to this list based on the information available in the selected papers.

Table 2 Data items included in the data extraction template

Participant characteristics
Participants and numbers
Participant socio-demographics

Additional health status information
Disease characteristics
Type of IBD
Disease activity
Disease phenotype
Extraintestinal manifestation
Study characteristics
Year of research
Country of research
Research setting and type of consultation
Stated aims
Aims relevant to the review
Study design
Outcomes and measures
Stated findings
Stated conclusions
Consultation data and analysis characteristics
Corpus size and number of consultations/episodes analysed in the study
Average length of consultations
One-off consultation or series
Data type (audio or video)
Method of linguistic data analysis (sociolinguistics, conversation analysis, content analysis, etc.)
Linguistic component/s analysed

2.5. Outcomes and prioritisation

A description of the characteristics of conversations between clinicians who manage IBD patients and patients with IBD (and/or their parent/guardian) during a consultation is the main outcome of this review. These characteristics generally identify the content of the consultation, patients' and clinicians' experience as represented in the consultation, the interpersonal relationships between clinician and patient, the different steps involved and the flow of information in the consultation. Another main outcome is an estimation of the effect of IBD clinical discussion on health outcomes (biomedical and psychosocial). Secondary outcomes include a description of the characteristics of the existing consultation data available for scrutiny in the literature, and trends in IBD clinical communication research including mainstream analytic approaches.

2.6. Risk of bias in individual studies

Conventional guidelines for assessing the quality of studies for inclusion in a systematic literature review [16] have limited application to discourse analytic research because this type of research is different from the mainstream qualitative and quantitative health research in terms of its objective and methodology [13]. Rather than using a single set of criteria and ranking studies based on those criteria, following Parry and Land, two broad dimensions will be used to assess each study's value and contribution: (1) the type and amount of data, and (2) the credibility and reliability of the analysis [13]. Credibility is defined as "the confidence that can be placed in the truth of the research findings" [17, p. 121]. To assess the credibility of the studies, Matthiessen's account of the methodological approaches to the analysis of a situation type (e.g. IBD consultation) [18] will be used as a guide. Matthiessen's methodological account [18] is based on Halliday's systemic functional linguistics [19]. Generally, language consists of four layers or strata (context, semantics, grammar and lexis, and phonology) and four main functions (experiential, logical, interpersonal, and textual). Function of language equals 'use': what is it that the language is being used for? The four main functions (or metafunctions) of language occur simultaneously in any utterance or text [15]. The experiential function allows language users to use language to construe their experience; the interpersonal function allows language users to enact their roles and relationships with each other (e.g. status, intimacy, contact, sharedness between interactants); the logical function concerns how language users create relations between different parts of their talk, and the textual function is what turns a

collection of individual words into a coherent text [15, 20]. A comprehensive description of a situation type is time consuming and labour intensive. Matthiessen suggests principled selection of data and data analysis tools to reduce the description bias and increase credibility [18]. To assess the reliability of the studies, information regarding the presence or absence of a second coder and the use of a unit of analysis will be considered.

Included studies will also be evaluated in terms of the amount of evidence used to support their conclusions and whether the conclusions were biased or evidence-based [21]. Further quality assessment dimensions may be added depending on the included studies. Missing information will not be sought from the authors, neither will unclear aspects of the studies be clarified with them. Rather, such limitations will be discussed under risk of bias.

2.7. Synthesis

The extracted data will be presented in overview tables for the purpose of summarization and comparison and described in a narrative synthesis. The inclusion criteria in this review allow for including studies from a range of contexts such as IBD specialist consultations, nurse consultations, allied health consultations, and general practice consultations. It is, therefore, expected that the context of the included studies will vary. It is also expected that these studies will be within different research traditions, having different underpinning philosophical assumptions, given the diverse approaches to the analysis of talk in health research, in general. Considering the diversity of contexts and theoretical underpinnings, a narrative synthesis was chosen as the method of synthesizing data.

The narrative synthesis will be based on the results of the data extraction and quality appraisal. Furthermore, following the recommendations of Cochrane Consumers and Communication Review Group [22], the narrative synthesis will also include investigation of the similarities and the differences between the studies based on the study design and information gathered from the data extraction and quality appraisal. Since this is not a meta-synthesis, findings of the included studies will not be integrated, and the data will not be reinterpreted.

2.8. Patient and public involvement

There has been no contribution from patients or the public to the design of this systematic review protocol.

3. DISSEMINATION PLANS

Findings of this systematic review will be presented at national and international conferences and published in peer-reviewed journals (open-access if possible). In the event of protocol amendments, the date of each amendment will be accompanied by a description of the change and the rationale.

4. DISCUSSION

Clinician-patient communication is shown to affect biological and functional health outcomes [23-27] and can have economic consequences [28-30]. In IBD, clinical communication is argued to affect patient satisfaction, treatment adherence, patient quality of life, disease management, and self-management, as described in the Introduction section. This systematic review will be the first to review studies that examine clinical communication in IBD using recorded clinician-patient consultation data. It aims to investigate the characteristics of IBD clinical discussions and the effects of these discussions on health outcomes (biomedical and psychosocial). The current protocol outlines the steps and procedures involved in achieving this objective.

Collecting and reviewing evidence from studies that investigate recorded clinical communication in IBD for the first time, consulting a diverse range of databases to identify eligible studies, developing a

broad search strategy to maximise inclusion, and using a comprehensive theory of language for appraising the quality of the included studies are arguably among the strengths of this review. Nevertheless, there are limitations as well. Reviews of this kind inevitably include a diverse range of studies in terms of context and theoretical underpinnings and this review will not be an exception. The consequence of this diversity is that findings cannot be integrated to produce cumulative evidence. For this reason, a narrative synthesis approach will be taken where data will be summarised and compared but not statistically integrated. In addition, because of funding limitations, this review will be restricted to publications in English language only and, thus, may not represent all the available evidence. Nevertheless, the results of the review can provide clinicians with valuable information to improve the way they communicate with their patients during a consultation. It will also identify the gaps in the literature and the areas that require further investigation for future research.

5. FUNDING

The authors received no specific funding for this work.

6. COMPETING INTERESTS

NK, ARM, and AL have received grant support from Janssen.

RK has received research and educational support from Pfizer, Abbvie, Takeda, and Janssen.

AW has received Honoraria from Takeda, Ferring, Janssen, and Abbvie.

SJC has received honoraria, speaker fees, educational support, and/or research support from: AbbVie, Celgene, Ferring, Gilead, Janssen, MSD, Novartis, Orphan/Aspen, Pfizer, Shire and Takeda.

7. CONTRIBUTORSHIP STATEMENT

NK, ARM, and AL conceived the idea of this systematic review project. NK developed the protocol and prepared the first draft of this manuscript with feedback from ARM, AL, SJC, RK, and AW on the design of the protocol and the manuscript.

REFERENCES

1. Johnston, R.D. and R.F.A. Logan, *What is the peak age for onset of IBD?* Inflammatory Bowel Diseases, 2008. **14**(suppl_2): p. S4-S5.
2. Siegel, C.A., et al., *Gastroenterologists' Views of Shared Decision Making for Patients with Inflammatory Bowel Disease.* Digestive Diseases and Sciences, 2015. **60**(9): p. 2636-2645.
3. Drescher, H., et al., *Treat-to-Target Approach in Inflammatory Bowel Disease: The Role of Advanced Practice Providers.* The Journal for Nurse Practitioners, 2019. **15**(9): p. 676-681.
4. Ghosh, S., et al., *What do changes in inflammatory bowel disease management mean for our patients?* J Crohns Colitis, 2012. **6 Suppl 2**: p. S243-9.
5. Miller, W. and S. Rollnick, *Motivational Interviewing, Second Edition : Preparing People for Change*. 2002, New York, UNITED STATES: Guilford Publications.
6. Mocciaro, F., et al., *Motivational interviewing in inflammatory bowel disease patients: a useful tool for outpatient counselling.* Dig Liver Dis, 2014. **46**(10): p. 893-7.
7. Mitchell, R., et al., *Talking about life and IBD: A paradigm for improving patient-physician communication.* Journal of Crohn's and Colitis, 2009. **3**(1): p. 1-3.
8. Kennedy, A., L. Gask, and A. Rogers, *Training professionals to engage with and promote self-management.* Health Educ Res, 2005. **20**(5): p. 567-78.

9. Moore, A.R., *Language and medicine*, in *The Cambridge Handbook of Systemic Functional Linguistics*, G. Thompson, et al., Editors. 2019, Cambridge University Press: Cambridge. p. 651-688.
10. Husain, A. and G. Triadafilopoulos, *Communicating with patients with inflammatory bowel disease.* Inflamm Bowel Dis, 2004. **10**(4): p. 444-50; discussion 451.
11. Kindell, J., et al., *Everyday conversation in dementia: a review of the literature to inform research and practice.* Int J Lang Commun Disord, 2017. **52**(4): p. 392-406.
12. Parry, R.H., V. Land, and J. Seymour, *Communicating face-to-face about sensitive future matters including end of life: a systematic review of evidence from fine-grained observational research* PROSPERO 2011. **CRD42011001626**.
13. Parry, R.H. and V. Land, *Systematically reviewing and synthesizing evidence from conversation analytic and related discursive research to inform healthcare communication practice and policy: an illustrated guide.* BMC Med Res Methodol, 2013. **13**: p. 69.
14. Stortenbeker, I., et al., *A review on linguistic and interactional aspects in consultations about medically unexplained symptoms.* PROSPERO, 2018. **CRD42018095405**
15. Halliday, M.A.K., *Part A*, in *Language, Context, and Text: Aspects of Language in a Social-Semiotic Perspective*, M.A.K. Halliday and R. Hasan, Editors. 1985/89, OUP/Deakin University Press: Oxford/Geelong.
16. Higgins, J.P.T., et al., *The Cochrane Collaboration's tool for assessing risk of bias in randomised trials.* BMJ, 2011. **343**: p. d5928.
17. Korstjens, I. and A. Moser, *Series: Practical guidance to qualitative research. Part 4: Trustworthiness and publishing.* Eur J Gen Pract, 2018. **24**(1): p. 120-124.
18. Matthiessen, C.M.I.M., *Register in the round: Diversity in a unified theory of register analysis*, in *Register Analysis: Theory and Practice*, M. Ghadessy, Editor. 1993, Pinter: London. p. 221–292.
19. Halliday, M.A.K. and C.M.I.M. Matthiessen, *Halliday's introduction to functional grammar*. 2014, London & New York: Routledge.
20. Halliday, M.A.K., *On Language and Linguistics, Volume 3 of the Collected works of M.A.K. Halliday*, ed. J.J. Webster. 2003, London & New York: Continiuum.
21. Aromataris, E. and Z. Munn, eds. *Joanna Briggs Institute Reviewer's Manual*. 2017, The Joanna Briggs Institute.
22. Ryan, R. and Cochrane Consumers and Communication Review Group, *Cochrane Consumers and Communication Review Group: data synthesis and analysis.* June 2013.
23. Lee, W., et al., *The mediatory role of medication adherence in improving patients' medication experience through patient-physician communication among older hypertensive patients.* Patient Prefer Adherence, 2017. **11**: p. 1119-1126.
24. Heisler, M., et al., *The relative importance of physician communication, participatory decision making, and patient understanding in diabetes self-management.* J Gen Intern Med, 2002. **17**(4): p. 243-52.
25. Street, R.L., Jr., et al., *How does communication heal? Pathways linking clinician-patient communication to health outcomes.* Patient Educ Couns, 2009. **74**(3): p. 295-301.
26. Safran, D.G., et al., *Linking primary care performance to outcomes of care.* J Fam Pract, 1998. **47**(3): p. 213-20.
27. Zachariae, R., et al., *Association of perceived physician communication style with patient satisfaction, distress, cancer-related self-efficacy, and perceived control over the disease.* Br J Cancer, 2003. **88**(5): p. 658-65.
28. Linedale, E.C., et al., *Uncertain Diagnostic Language Affects Further Studies, Endoscopies, and Repeat Consultations for Patients With Functional Gastrointestinal Disorders.* Clinical Gastroenterology and Hepatology, 2016. **14**(12): p. 1735-1741.e1.

29. Hurtig, R.R., R.M. Alper, and B. Berkowitz, *The cost of not addressing the communication barriers faced by hospitalized patients.* Perspectives of the ASHA special interest groups, 2018. **3**(12): p. 99-112.
30. Vermeir, P., et al., *Communication in healthcare: a narrative review of the literature and practical recommendations.* International journal of clinical practice, 2015. **69**(11): p. 1257-1267.

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	✓
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	✓
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	✓
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	✓
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	✓
Support:			
Sources	5a	Indicate sources of financial or other support for the review	✓
Sponsor	5b	Provide name for the review funder and/or sponsor	N/A
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	N/A
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	✓
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	✓
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	✓
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	✓
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	✓
Study records:			

Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	✓
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	✓
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	✓
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	✓
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	✓
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	✓
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	N/A
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	N/A
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	N/A
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	✓
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	N/A
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	N/A

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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Clinical communication in inflammatory bowel disease: A systematic literature review protocol

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ABSTRACT

Introduction

Evidence regarding effective communication between clinicians and patients with inflammatory bowel disease (IBD) is limited. Studies that investigate clinical communication in IBD are much fewer in number than studies that investigate the perceptions of patients and clinicians about communication in clinical encounters. The current review aims to identify, organise and summarise systematically what is currently known about (a) the characteristics of interactions between clinicians that manage IBD and patients with IBD, and (b) how clinical discussion affects health outcomes in IBD.

Methods and analysis

Scopus, PubMed, Embase, Communication Abstracts – EBSCO, Health & Society – Informit, Linguistics and Language Behavior Abstracts (LLBA) – Proquest, and PsycINFO will be systematically searched for studies that investigate the characteristics of IBD clinical interactions during recorded consultations, from earliest available dates within each database to May 2020. A specifically developed quality assessment tool, grounded in linguistic theory, will be used to critically assess the evidence. In addition, a data extraction template will be developed and utilised to provide a description of the characteristics of IBD clinical communication as well as an estimation of its effect on health outcomes in a narrative synthesis.

Ethics and dissemination

Ethics reviews and approval is not required for this systematic review as no primary data will be collected. The results will be published in peer-reviewed journals and presented at academic conferences.

Registration

This systematic review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 28 April 2020 (registration number: CRD42020169657).

Keywords: inflammatory bowel disease, communication, clinical communication, clinical encounter, systematic review

STRENGTHS AND LIMITATIONS OF THIS STUDY

Strengths

- This systematic review will be the very first to identify, assess, and summarise evidence resulting from investigations of recorded clinical interactions during IBD consultations.
- The review will consult a diverse range of databases - including databases with special focus on medicine, health, psychology, communication, and linguistics - to identify eligible studies.
- The review will use a specifically developed quality assessment tool, grounded in linguistic theory, to critically assess the evidence.

Limitation

- It is expected that the findings will not be integrated to produce cumulative evidence due to the anticipated diverse range of included studies in terms of context and theoretical underpinnings.
- Due to funding limitations, this systematic review will be restricted to publications in English language only and, thus, may not represent all the available evidence.

1. INTRODUCTION

Inflammatory bowel disease (IBD) is a chronic inflammatory condition of the gastrointestinal tract mainly presenting in two forms: Crohn's disease (CD) and ulcerative colitis (UC). IBD is characterised by intermittent periods of active disease with symptoms including diarrhea, rectal bleeding, urgency, incontinence, chronic abdominal pain, loss of appetite and weight loss, fatigue, joint pain, and skin problems that undermine patients' quality of life and emotional well-being which can affect their personal, social, and professional life. The incidence of IBD is highest amongst those aged between 15 and 29 years (1), exacerbating the economic burden of the disease due to effects on the ability to work of the large young population of patients with IBD.

Due to the chronicity of IBD, patients require ongoing monitoring and long-term maintenance therapy to stay in remission and prevent recurrence of disease activity. Treatment of IBD has become more effective over time due to advances in medical and clinical research and the introduction of more effective drugs. At the same time, it has become more complicated because of the complex risk-benefit profile of the more effective treatments. As a result, discourses around the role of the patient as a key stakeholder in decision-making have found more recognition and prominence in IBD research (2, 3). Since the main space in which clinicians and patients negotiate roles and make decisions is their clinical interaction during consultations, understanding the exchange of meaning between clinicians and patients in this space and its existing variations is crucial for understanding the bigger picture of how – and how well – IBD is managed. Such an understanding can help identify ways in which IBD care can improve.

Effects of clinical communication on health outcomes include patient satisfaction, adherence, patient quality of life, disease management, and self-management, as discussed by a number of studies in the IBD-specific literature and by many more studies concerned with other conditions. Ghosh and colleagues argued that in IBD, "good communication between physician and patient is a cornerstone of effective disease management" (4, p. S245). The authors suggested that motivational communication may be valuable in IBD care, "where the use of treatments with potentially undesirable side effects must be balanced against the risk of life-long high morbidity from the disease" (4, p. S247). Motivational communication is a collaborative approach used to elicit the person's own intrinsic motivation and resources for change (5). A survey study by Mocciaro and colleagues showed that motivational communication in IBD consultations improved patient satisfaction, and potentially medication adherence and smoking cessation and helped physicians in dealing with patients "moving from "cure" to "care"" (6).

Highlighting the link between clinical communication and patient quality of life and disease management, Mitchell and colleagues argued that discussing the impact of IBD on a patient's daily life during a consultation can produce a better "picture of how patients are affected by their disease and how well their current treatment strategy is working for them" (7, p. 2), and provides a context for considering new treatment options based on patients' expectations of treatment, ability to adapt, and treatment objectives. Furthermore, Kennedy and colleagues pointed out the impact of effective communication on "encouraging and supporting decisions and self-care actions which may enable patients to optimally manage their condition outside of health service settings" (8, p. 567-8).

Whilst there has been advocacy for research on communication in IBD, projects whose "site of engagement/intervention" is the "clinician-patient interface" (9) - i.e. projects that investigate interactions between patients and clinicians, rather than patients' perceptions of clinical communication - are less known. No systematic literature review has been conducted to identify and review such studies. In 2004, Husain and colleagues pointed to "a paucity of data concerning effective communication methods enabling physicians to develop stronger rapport with patients suffering from IBD" (10, p. 444). Sixteen years later, we still do not know much about the status of IBD communication from research that uses real-life clinician-patient conversation data. The current review aims to ascertain the existing knowledge in this area to inform the field, identify the gaps and areas that require further investigations, and position this literature within current IBD care practice and research. The main objective is to identify, organise and summarise systematically what is

currently known about (a) the characteristics of conversations between clinicians that manage IBD and patients with IBD, and (b) how clinical discussion affects health outcomes in IBD.

2. METHODS

The development of this study protocol was in accordance to the Preferred Reporting Items for Systematic Reviews and Meta-analyses Protocol (PRISMA-P) (11, 12). A copy of the completed PRISMA-P 2015 checklist is presented in appendix A. This study protocol is registered with the International Registration of Systematic reviews (PROSPERO) (registration number: CRD42020169657).

2.1. Eligibility criteria

The review will include studies that investigate the characteristics of the interactions between clinicians that manage IBD patients and patients with IBD and/or their parent/guardian during a recorded consultation. These characteristics generally include, but are not limited to, the content of the consultation, patients' and clinicians' experience as represented in their language, the interpersonal meanings exchanged in the consultation, the different rhetorical steps that make up the consultation, and the flow of information in the consultation. Studies based only on self-report of interaction e.g. focus group studies, interviews, surveys, participatory observation with no audio/videorecording will be excluded.

Published peer-reviewed studies in English that used quantitative or qualitative methods (including, but not limited to, discourse analysis, conversation analysis, and content analysis) to analyse recorded real-life interactions between clinicians and patients with IBD (UC or CD) during a consultation will be included in the review. Eligible studies will need to sample patients with IBD and clinicians that manage IBD patients in primary and secondary health care (e.g. general practitioners, IBD specialists, IBD nurses), complementary and alternative medicine (e.g. acupuncturists, traditional Chinese medicine practitioner), or allied health (e.g. dietitian). Studies with a focus on health care providers whose primary treatment includes the interaction itself (e.g. psychotherapists) will be excluded. Studies in which these participant groups are present but IBD is not the focus of the study will also be excluded. Studies will be selected regardless of the type of intervention or exposure as the review will not be focused on a certain type of intervention or exposure. Only journal articles and book chapters published in English are eligible. Peer-reviewed published abstracts, letters to the editor, editorials, and theses will be excluded. However, ineligible sources will be examined to locate corresponding journal articles. Articles published to May 2020 will be included.

2.2. Information sources and search strategy

The review will search for records indexed in:

- Scopus
- PubMed
- Embase
- Communication Abstracts – EBSCO
- Health & Society – Informit
- Linguistics and Language Behavior Abstracts (LLBA) – Proquest
- PsycINFO

In addition, snowball sampling will be employed. Reference lists of eligible articles identified in the online database search as well as the excluded but relevant publications will be consulted. Subject matter experts (those known to the researchers as well as those identified in the database search and snowball sampling) will be contacted via email and consulted to identify any additional literature.

A relatively broad search strategy will be employed due to anticipating limited numbers of studies that explore real-life clinician-patient interactions in IBD and in order to maximise the reach. Table 1 lists the keywords that will be used to search these databases. Keywords referring to the condition or healthcare domain being studied (e.g. IBD) will be used; in conjunction with terms describing the data type (e.g. consultation and audio-record*). The search strategy will be expressed as the intersection of these two sets of terms.

Table 1 Complete search strategy for all electronic bibliographic databases

		Condition terms (search 1) AND	Data type terms (search 2) AND
Terms that searches below are intended to capture		IBD inflammatory bowel disease ulcerative colitis Crohn's disease	communication interaction clinician-patient doctor-patient clinical encounter consultation audio-record* audio record* video-record* video record*
Database	Search field	Search1	Search 2
PubMed via US National Library of Medicine	Text Word [TW]	1. inflammatory bowel disease OR IBD OR ulcerative colitis OR Crohn's disease	communication OR interaction OR doctor-patient OR clinician-patient OR clinical encounter
		2. inflammatory bowel disease OR IBD OR ulcerative colitis OR Crohn's disease	consultation AND audio record* OR audio-record* OR video record* OR video-record
		Limit searches to: full text AND humans	
Scopus	Title/abstract/ keyword	1. inflammatory bowel disease OR IBD OR ulcerative colitis OR Crohn's disease	communication OR interaction OR doctor-patient OR clinician-patient OR clinical encounter
		2. inflammatory bowel disease OR IBD OR ulcerative colitis OR Crohn's disease	consultation AND audio record* OR audio-record* OR video record* OR video-record
		Limit search 1 to: Article and chapter	
PsychINFO AND EMBASE via Ovid	Text Word [TW]	1. inflammatory bowel disease OR IBD OR ulcerative colitis OR Crohn's disease	communication OR interaction OR doctor-patient OR clinician-patient OR clinical encounter
		2. inflammatory bowel disease OR IBD OR ulcerative colitis OR Crohn's disease	consultation AND audio record* OR audio-record* OR video record* OR video-record
		Limit searches to: full text AND human AND English language	
Communication Abstracts – EBSCO	All text	inflammatory bowel disease OR IBD OR ulcerative colitis OR Crohn's disease	-
Health & Society - Informit	Abstract	inflammatory bowel disease OR IBD OR ulcerative colitis OR Crohn's disease	-

Linguistics and Language Behavior Abstracts (LLBA) - Proquest	Abstract	inflammatory bowel disease OR IBD OR ulcerative colitis OR Crohn's disease	-

2.3. Data management and selection process

Study records obtained from the databases will be exported into Endnote where duplicates will be removed, and screening of titles and abstracts and then full-text records will be performed independently by three reviewers (NK, RK, and AL). The reviewers will be over-inclusive with their selections and will include all the studies that appear to meet the inclusion criteria as well as those whose eligibility for inclusion is uncertain. Reviewers will not be blinded to the study authors, institutions or journals of the records they screen.

Once the reviewers complete the screening of titles and abstracts, they will meet to compare their lists of selected studies and resolve any discrepancies prior to the full-text review. Any unresolved disagreement will be discussed with the whole review team and a collective decision will be made. Reasons for exclusion will also be recorded at this stage. Once agreement is reached, the full text of the selected studies will be uploaded in Endnote and studied independently by the reviewers for final inclusions. The same discrepancy resolving process will be repeated at this final stage of selection. Reviewers will meet upon finishing the independent selection process to resolve any disagreements and will discuss matters with the whole review team if they cannot reach an agreement.

2.4. Data collection and extraction processes

Selected articles will be carefully studied by the whole team. A data extraction template will be developed based on the questions asked in the review and the information available in the selected studies, and in consultation with the existing health communication and linguistics literature including previous systematic literature reviews of this kind (9, 13-16) and Halliday's theoretical model of the architecture of language, known as systemic functional linguistics (17). The data extraction template will be accompanied by detailed instructions in Microsoft Excel. It will be piloted by two reviewers on a sample of included papers to ensure the efficiency of the template and the accuracy and consistency of extractors before the final data extraction which will be performed by NK and checked by the review team.

The review will explore potential trends in this strand of research by comparing the timing of studies (year of research), the countries in which the studies were conducted, and the type of consultation under scrutiny (e.g., IBD nurse consultations, IBD specialist consultations, etc.). Information will be extracted on research setting, participant characteristics including their role (e.g., patient, parent, nurse, gastroenterologist, etc.), socio-demographics, and the status of patient participants (e.g., pregnant, pre-conception, post-surgery, in transition to adult care, etc.), as well as disease characteristics including type of IBD (UC, CD, or IBD unclassified), disease activity, disease phenotype, and extraintestinal manifestations. Stated aims, aims relevant to the review (e.g., investigation of whether/how the clinicians talk about treatment options including their benefits and side-effects, patient's quality of life, or goals of care; description of clinician-patient relationship as construed in talk; etc.), study design, health outcomes and measures, and stated findings and conclusions will be described for each study. Information on the consultation data including the size of the dataset (corpus size), the actual number of consultation/episodes analysed in the study, the average length of consultations, whether consultations were audio recorded or video recorded, and whether the consultations were one-off or in series will be charted. Furthermore, the method of linguistic data analysis and the investigated linguistic features will be described. A linguistic feature is broadly defined as any semantic, grammatical, or lexical concept such as topic, question (type and quantity), length of consultation, and so on.

Table 2 outlines the data items that will be included in the review. Additional items will potentially be added to this list based on the information available in the selected papers.

Table 2 Data items included in the data extraction template

Participant characteristics
Participants and numbers
Participant socio-demographics
Additional health status information
Disease characteristics
Type of IBD
Disease activity
Disease phenotype
Extraintestinal manifestation
Study characteristics
Year of research
Country of research
Research setting and type of consultation
Stated aims
Aims relevant to the review
Study design
Outcomes and measures
Stated findings
Stated conclusions
Consultation data and analysis characteristics
Corpus size and number of consultations/episodes analysed in the study
Average length of consultations
One-off consultation or series
Data type (audio or video)
Method of linguistic data analysis (sociolinguistics, conversation analysis, content analysis, etc.)
Linguistic component/s analysed

2.5. Outcomes and prioritisation

A description of the characteristics of conversations between clinicians who manage IBD patients and patients with IBD (and/or their parent/guardian) during a consultation is the main outcome of this review. These characteristics generally identify the content of the consultation, patients' and clinicians' experience as represented in the consultation, the interpersonal relationships between clinician and patient, the different steps involved and the flow of information in the consultation. Another main outcome is an estimation of the effect of IBD clinical discussion on health outcomes (biomedical and psychosocial). Secondary outcomes include a description of the characteristics of the existing consultation data available for scrutiny in the literature, and trends in IBD clinical communication research including mainstream analytic approaches.

2.6. Risk of bias in individual studies

Conventional guidelines for assessing the quality of studies for inclusion in a systematic literature review (18) have limited application to discourse analytic research because this type of research is different from the mainstream qualitative and quantitative health research in terms of its objective and methodology (15). Rather than using a single set of criteria and ranking studies based on those criteria, following Parry and Land, two broad dimensions will be used to assess each study's value and contribution: (1) the type and amount of data, and (2) the credibility and reliability of the analysis (15). Credibility is defined as "the confidence that can be placed in the truth of the research findings" (19, p. 121). To assess the credibility of the studies, Matthiessen's account of the methodological approaches to the analysis of a situation type (e.g. IBD consultation) (20) will be used as a guide. Matthiessen's methodological account (20) is based on Halliday's systemic functional linguistics (21). Generally, language consists of four layers or strata (context, semantics, grammar and lexis, and phonology) and four main functions (experiential, logical, interpersonal, and textual). Function of language equals 'use': what is it that the language is being used for? The four main functions (or

metafunctions) of language occur simultaneously in any utterance or text (17). The experiential function allows language users to use language to construe their experience; the interpersonal function allows language users to enact their roles and relationships with each other (e.g. status, intimacy, contact, sharedness between interactants); the logical function concerns how language users create relations between different parts of their talk, and the textual function is what turns a collection of individual words into a coherent text (17, 22). A comprehensive description of a situation type is time consuming and labour intensive. Matthiessen suggests principled selection of data and data analysis tools to reduce the description bias and increase credibility Matthiessen (20). To assess the reliability of the studies, information regarding the presence or absence of a second coder and the use of a unit of analysis will be considered.

Included studies will also be evaluated in terms of the amount of evidence used to support their conclusions and whether the conclusions were biased or evidence-based (23). Further quality assessment dimensions may be added depending on the included studies. Missing information will not be sought from the authors, neither will unclear aspects of the studies be clarified with them. Rather, such limitations will be discussed under risk of bias.

2.7. Synthesis

The extracted data will be presented in overview tables for the purpose of summarization and comparison and described in a narrative synthesis. The inclusion criteria in this review allow for including studies from a range of contexts such as IBD specialist consultations, nurse consultations, allied health consultations, and general practice consultations. It is, therefore, expected that the context of the included studies will vary. It is also expected that these studies will be within different research traditions, having different underpinning philosophical assumptions, given the diverse approaches to the analysis of talk in health research, in general. Considering the diversity of contexts and theoretical underpinnings, a narrative synthesis was chosen as the method of synthesizing data.

The narrative synthesis will be based on the results of the data extraction and quality appraisal. Furthermore, following the recommendations of Cochrane Consumers and Communication Review Group (24), the narrative synthesis will also include investigation of the similarities and the differences between the studies based on the study design and information gathered from the data extraction and quality appraisal. Since this is not a meta-synthesis, findings of the included studies will not be integrated, and the data will not be reinterpreted.

2.8. Patient and public involvement

There has been no contribution from patients or the public to the design of this systematic review protocol.

3. ETHICS AND DISSEMINATION

No human subject participants will be involved. Therefore, ethical approval will not be required. Findings of this systematic review will be presented at national and international conferences and published in peer-reviewed journals (open-access if possible). In the event of protocol amendments, the date of each amendment will be accompanied by a description of the change and the rationale.

4. DISCUSSION

Clinician-patient communication is shown to affect biological and functional health outcomes (25-29) and can have economic consequences (30-32). In IBD, clinical communication is argued to affect patient satisfaction, treatment adherence, patient quality of life, disease management, and self-management, as described in the Introduction section. This systematic review will be the first to

review studies that examine clinical communication in IBD using recorded clinician-patient consultation data. It aims to investigate the characteristics of IBD clinical discussions and the effects of these discussions on health outcomes (biomedical and psychosocial). The current protocol outlines the steps and procedures involved in achieving this objective.

Collecting and reviewing evidence from studies that investigate recorded clinical communication in IBD for the first time, consulting a diverse range of databases to identify eligible studies, developing a broad search strategy to maximise inclusion, and using a comprehensive theory of language for appraising the quality of the included studies are arguably among the strengths of this review. Nevertheless, there are limitations as well. Reviews of this kind inevitably include a diverse range of studies in terms of context and theoretical underpinnings and this review will not be an exception. The consequence of this diversity is that findings cannot be integrated to produce cumulative evidence. For this reason, a narrative synthesis approach will be taken where data will be summarised and compared but not statistically integrated. In addition, because of funding limitations, this review will be restricted to publications in English language only and, thus, may not represent all the available evidence. Nevertheless, the results of the review can provide clinicians with valuable information to improve the way they communicate with their patients during a consultation. It will also identify the gaps in the literature and the areas that require further investigation for future research.

5. FUNDING

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6. COMPETING INTERESTS

NK, ARM, and AL have received grant support from Janssen.

RK has received research and educational support from Pfizer, Abbvie, Takeda, and Janssen.

AW has received Honoraria from Takeda, Ferring, Janssen, and Abbvie.

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7. CONTRIBUTORSHIP STATEMENT

NK, ARM, and AL conceived the idea of this systematic review project. NK developed the protocol and prepared the first draft of this manuscript with feedback from ARM, AL, SJC, RK, and AW on the design of the protocol and the manuscript.

REFERENCES

1. Johnston RD, Logan RFA. What is the peak age for onset of IBD? Inflammatory Bowel Diseases. 2008;14(suppl_2):S4-S5.
2. Siegel CA, Lofland JH, Naim A, Gollins J, Walls DM, Rudder LE, et al. Gastroenterologists' Views of Shared Decision Making for Patients with Inflammatory Bowel Disease. Digestive Diseases and Sciences. 2015;60(9):2636-45.
3. Drescher H, Lissoos T, Hajisafari E, Evans ER. Treat-to-Target Approach in Inflammatory Bowel Disease: The Role of Advanced Practice Providers. The Journal for Nurse Practitioners. 2019;15(9):676-81.

4. Ghosh S, D'Haens G, Feagan BG, Silverberg MS, Szigethy EM. What do changes in inflammatory bowel disease management mean for our patients? Journal of Crohn's & colitis. 2012;6 Suppl 2:S243-9.
5. Miller W, Rollnick S. Motivational Interviewing, Second Edition : Preparing People for Change. New York, UNITED STATES: Guilford Publications; 2002.
6. Mocciaro F, Di Mitri R, Russo G, Leone S, Quercia V. Motivational interviewing in inflammatory bowel disease patients: a useful tool for outpatient counselling. Digestive and liver disease : official journal of the Italian Society of Gastroenterology and the Italian Association for the Study of the Liver. 2014;46(10):893-7.
7. Mitchell R, Kremer A, Westwood N, Younge L, Ghosh S. Talking about life and IBD: A paradigm for improving patient-physician communication. J Crohn's Colitis. 2009;3(1):1-3.
8. Kennedy A, Gask L, Rogers A. Training professionals to engage with and promote self-management. Health education research. 2005;20(5):567-78.
9. Moore AR. Language and medicine. In: Thompson G, Bowcher WL, Fontaine L, Schönthal D, editors. The Cambridge Handbook of Systemic Functional Linguistics. Cambridge: Cambridge University Press; 2019. p. 651-88.
10. Husain A, Triadafilopoulos G. Communicating with patients with inflammatory bowel disease. Inflamm Bowel Dis. 2004;10(4):444-50; discussion 51.
11. Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. Systematic Reviews. 2015;4(1):1.
12. Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ : British Medical Journal. 2015;349:g7647.
13. Kindell J, Keady J, Sage K, Wilkinson R. Everyday conversation in dementia: a review of the literature to inform research and practice. International journal of language & communication disorders. 2017;52(4):392-406.
14. Parry RH, Land V, Seymour J. Communicating face-to-face about sensitive future matters including end of life: a systematic review of evidence from fine-grained observational research PROSPERO 2011;CRD42011001626.
15. Parry RH, Land V. Systematically reviewing and synthesizing evidence from conversation analytic and related discursive research to inform healthcare communication practice and policy: an illustrated guide. BMC medical research methodology. 2013;13:69.
16. Stortenbeker I, Stommel W, van Dulmen S, Lucassen P, Das E, olde Hartman T. A review on linguistic and interactional aspects in consultations about medically unexplained symptoms. . PROSPERO. 2018;CRD42018095405
17. Halliday MAK. Part A. In: Halliday MAK, Hasan R, editors. Language, Context, and Text: Aspects of Language in a Social-Semiotic Perspective. Oxford/Geelong: OUP/Deakin University Press; 1985/89.
18. Higgins JPT, Altman DG, Gøtzsche PC, Jüni P, Moher D, Oxman AD, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. BMJ. 2011;343:d5928.
19. Korstjens I, Moser A. Series: Practical guidance to qualitative research. Part 4: Trustworthiness and publishing. The European journal of general practice. 2018;24(1):120-4.
20. Matthiessen CMIM. Register in the round: Diversity in a unified theory of register analysis. In: Ghadessy M, editor. Register Analysis: Theory and Practice. London: Pinter; 1993. p. 221–92.
21. Halliday MAK, Matthiessen CMIM. Halliday's introduction to functional grammar. London & New York: Routledge; 2014.
22. Halliday MAK. On Language and Linguistics, Volume 3 of the Collected works of M.A.K. Halliday. Webster JJ, editor. London & New York: Continiuum; 2003.

23. Aromataris E, Munn Z, editors. Joanna Briggs Institute Reviewer's Manual: The Joanna Briggs Institute; 2017.
24. Ryan R, Cochrane Consumers and Communication Review Group. Cochrane Consumers and Communication Review Group: data synthesis and analysis. June 2013.
25. Lee W, Noh Y, Kang H, Hong SH. The mediatory role of medication adherence in improving patients' medication experience through patient-physician communication among older hypertensive patients. Patient preference and adherence. 2017;11:1119-26.
26. Heisler M, Bouknight RR, Hayward RA, Smith DM, Kerr EA. The relative importance of physician communication, participatory decision making, and patient understanding in diabetes self-management. Journal of general internal medicine. 2002;17(4):243-52.
27. Street RL, Jr., Makoul G, Arora NK, Epstein RM. How does communication heal? Pathways linking clinician-patient communication to health outcomes. Patient education and counseling. 2009;74(3):295-301.
28. Safran DG, Taira DA, Rogers WH, Kosinski M, Ware JE, Tarlov AR. Linking primary care performance to outcomes of care. The Journal of family practice. 1998;47(3):213-20.
29. Zachariae R, Pedersen CG, Jensen AB, Ehrnrooth E, Rossen PB, von der Maase H. Association of perceived physician communication style with patient satisfaction, distress, cancer-related self-efficacy, and perceived control over the disease. British journal of cancer. 2003;88(5):658-65.
30. Linedale EC, Chur-Hansen A, Mikocka-Walus A, Gibson PR, Andrews JM. Uncertain Diagnostic Language Affects Further Studies, Endoscopies, and Repeat Consultations for Patients With Functional Gastrointestinal Disorders. Clinical Gastroenterology and Hepatology. 2016;14(12):1735-41.e1.
31. Hurtig RR, Alper RM, Berkowitz B. The cost of not addressing the communication barriers faced by hospitalized patients. Perspect ASHA Spec Interest Groups. 2018;3(12):99-112.
32. Vermeir P, Vandijck D, Degroote S, Peleman R, Verhaeghe R, Mortier E, et al. Communication in healthcare: a narrative review of the literature and practical recommendations. Int J Clin Pract. 2015;69(11):1257-67.

Appendix A: PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item		Page
ADMINISTRATIVE INFORMATION				
Title:				
Identification	1a	Identify the report as a protocol of a systematic review	✓	Title, Abstract
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	N/A	
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	✓	Abstract, p. 4
Authors:				
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	✓	p. 1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	✓	p. 9
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	✓	p. 8
Support:				
Sources	5a	Indicate sources of financial or other support for the review	✓	p. 9
Sponsor	5b	Provide name for the review funder and/or sponsor	N/A	
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	N/A	
INTRODUCTION				
Rationale	6	Describe the rationale for the review in the context of what is already known	✓	p. 3
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	✓	pp. 3-4
METHODS				
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	✓	p. 4
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	✓	pp. 4-5
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	✓	p. 5

Study records:				
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	✓	p. 6
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	✓	p. 6
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	✓	p. 6
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	✓	pp. 6-7
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	✓	p. 7
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	✓	pp. 7-8
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	N/A	
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	N/A	
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	N/A	
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	✓	p. 8
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	N/A	
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	N/A	

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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