Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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The impact of the coronavirus (COVID-19) pandemic on individuals with gastrointestinal disorders: A protocol of an international collaborative study

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ABSTRACT

Objective: The COVID-19 pandemic has had a significant impact on mental health across the globe. People living with a chronic gastrointestinal (GI) disorder might be particularly at risk of mental health complications given higher rates of comorbid anxiety and depression compared to the healthy population. As GI disorders affect up to 40% of the population worldwide, this international collaborative study seeks to evaluate the extent of the impact of the COVID-19 pandemic on GI symptoms specifically and more generally on the well-being of those living with chronic GI conditions.

Methods: A longitudinal survey with three time points (baseline, 6-month, and 12-month) will be conducted online. Adult participants with GI disorders from multiple countries will be recruited via patient associations, social media advertising, utilizing snowball sampling. Participants will be invited to complete a battery of questionnaires including demographic and health parameters, and measures of gastrointestinal symptoms, fear of

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COVID-19, perceived impact of COVID-19, illness perceptions, coping, depression, anxiety, stress, catastrophizing, and quality of life, using validated measures where available. Statistical analyses will include univariate descriptive models, multivariate models utilizing regression, mediation, and moderation, and latent growth models.

Conclusions: This project may present novel information to the field of psychogastroenterology and may provide crucial information regarding the areas of impact for individuals with GI disorders during and following the pandemic. Further, this information can guide healthcare providers and patient associations on how to target support related to the pandemic mental health sequelae for these patients.

1. Introduction

Worldwide estimates indicate that up to 40% of people are affected by some form of gastrointestinal (GI) disorder, with functional gastrointestinal disorders (e.g., irritable bowel syndrome (IBS)), the most common and occurring in 25% to 30% of people [1,2]. Although less prevalent, inflammatory bowel disease (IBD) (e.g., Crohn's disease and ulcerative colitis) affect close to 7 million individuals globally, with the highest prevalence in North America and Europe [3–5], and coeliac disease affects around 1.4% of people globally [6]. GI disorders are debilitating, costly [7,8], and responsible for more than a quarter million deaths each year in the United States alone [9].

The coronavirus (COVID-19) pandemic has had a pervasive impact on human society with approximately 90 million people infected and 1.9 million deaths recorded to date and rising [10]. Presently there is little information to assess the infection risk that COVID-19 might pose to people living with a GI disorders. In a recent consensus article [11], pre-existing digestive diseases, such as IBD, were identified as raising concern due to the nature of certain treatment approaches, including biologics and immunosuppressants, that are thought to increase the risk of complications from a COVID-19 infection. Recent studies show that use of corticosteroids, but not tumour necrosis factor (TNF) antagonists, increase risk for adverse COVID-19 outcomes [12].

Many countries around the world have implemented community level restrictions, such as self-isolation procedures to reduce the spread of the virus and pressure on healthcare services. There is already evidence that implementation of these measures, along with the uncertainty of living with a new pathogen, has had a significant impact on the mental health of the general population [13–16].

Although patients with chronic gastrointestinal (GI) disorders are already at higher risk of experiencing mental health problems such as anxiety and depression [17–20], these risks may be further exacerbated by barriers to healthcare provision as a result of the current measures to contain the virus, including reduced access to doctors, procedures such as endoscopy, and medications [21–23]. Further, the inclusion of chronic diseases (and certain therapeutics) [24] in the list of COVID-19 at-risk groups is likely to increase concerns and a sense of vulnerability in those affected by these diseases. In a recent study, a very high proportion of people living with IBD (85%) reported a fear of contracting the virus [25], resulting in leaving their homes less frequently than before the pandemic for daily tasks, such as going to the supermarket, or routine appointments for fear of infection [26]. Another study investigating the mental health of people with IBD showed that significant numbers of patients present with high levels of anxiety (up to 50%) and depression symptoms (up to 20%) due in part to isolation and fear of infection [27]. A study in patients with IBS and functional dyspepsia (FD) showed that about 12% reported an increase in symptoms, with mental health partly driving this increase [28]. Even from this limited data it appears the pandemic increases stress and fears, which drives behaviours that isolate patients and worsen mental health, which in turn can increase GI symptoms and likely impair quality of life (QoL).

The epiphenomenon linking GI conditions with mental health and wellbeing (the brain-gut connection) is well known. Symptoms of anxiety appear in at least 25% of patients and symptoms of depression in at least 20% of patients with GI presentations, with the most consistent evidence available for IBS, FD, and IBD [29]. Several studies have shown that intolerance of uncertainty is a key variable in the development of anxiety and depressive disorders [30]. Evidence also highlights the effect of unpredictability of GI symptom episodes on patient's mental health, in particular symptoms of depression and/or anxiety [31]. Furthermore, various psychological processes such as catastrophizing (a form of cognitive distortion that prompts people to jump to the worst possible conclusion, usually with very limited information or objective reason to despair) [32–34], somatization (the tendency to experience and communicate multiple somatic symptoms and to seek medical help for them) [35–37], and experiential avoidance (attempts to avoid internal experiences of feelings, even though doing so can create harm in the long run) [38–40] have been shown to modulate the relationship between symptoms and outcomes of mental wellbeing and QoL. COVID19 has increased uncertainty and unpredictability for many. In addition, positive coping strategies such as social support connection have been reduced during the pandemic. Therefore, in the current worldwide situation, in which uncertainty and social isolation are commonplace, people with GI disorders are likely at risk of developing or experiencing an exacerbation of anxiety or depression symptomatology. This, in turn, may lead to a relapse of their GI symptoms and reduction in QoL [41,42].

Determining the impact of the COVID-19 pandemic and its associated restrictions on mental health and QoL of patients with GI disorders will inform the care needs of these individuals. Through a longitudinal design, this study seeks to investigate how demographic, situational, and psychological variables might be contributing to the adjustment of people living with a GI disorder to the current pandemic. The current protocol was designed by a leading international consortium of researchers and practitioners specializing in gastroenterology and psychogastroenterology [43]. It is anticipated that this investigation will significantly contribute to identifying the challenges faced and to developing strategies to minimise the impact of the COVID-19 pandemic on individuals living with a GI disorder.

We broadly aim to:

(1) Explore perceived differences in GI symptoms, psychological state (i.e., symptoms of anxiety, depression, stress), and QoL, as well as potential psychological moderators such as illness perceptions, catastrophizing, coping styles, acceptance, fear of COVID, across COVID-19 pandemic stages: a) Pre-COVID-19 (based on recall from November 2019); b) baseline - initial COVID-19 waves (June–October 2020); c) 6 months post initial data collection phase (March 2021); d) 12-months post initial data collection phase (October 2021).
(2) Explore how the COVID-19 pandemic has influenced disease management for aspects such as access to family physician and specialist, medication access, medication adherence, and activities associated with promoting or maintaining health, such as exercise and diet.
(3) Explore how psychological processes of coping, catastrophizing, illness perceptions, and experiential avoidance mediate the relationship between gastrointestinal symptoms and, mental wellbeing and QoL through time (baseline, 6-month and 12-month follow-up).

2. Methods

2.1. Ethics approval

This protocol has been approved by the Swinburne University of Technology Human Research Ethics Committee in May 2020 (Ref: 20202978-4430). Further local approvals were obtained from participating countries when required. The project started recruiting in June 2020 and will complete recruitment by December 2021.

2.2. Design

This study will use a longitudinal design with three time points for data collection. Time 1 (Baseline) will be collecting data between June and October 2020. Baseline data collection had a delay in relation to the start of the pandemic due to the considerable difficulties in organizing a multinational study under the circumstances, and due to some delays in obtaining the necessary ethical approvals. Two subsequent data collection waves will take place 6 months and 12 months after the baseline data collection.

2.3. Participants and recruitment

Inclusion criteria include, being 18 years and older, having a self-reported clinical diagnosis by a healthcare provider of any chronic GI disorder, ability to consent, and ability to communicate in English. As for exclusion criteria, no country specific limitations are considered to participation with the exception of those not fluent in English being unable to participate.

Participants are free to withdraw at any point during the study without specifying their reasons. No aspect of participant health care will be affected by their decision to withdraw from the study. Dropout/attrition will be recorded for the purposes of establishing representativeness of the sample.

Participants will be recruited online via GI-specific patient organisations around the world (e.g., national coeliac or Crohn's and colitis patient groups in the USA, UK, Australia, Portugal etc.…) and via social media (e.g., Facebook, GI specific Reddit sub-threads). At present, recruitment for the Time 1 period of the study has been closed. Participants will report what their GI disorder is and what medications they use. The medications will be grouped into categories for analysis. At the time of the writing of this manuscript a total of 831 participants completed the questionnaires for baseline. Sample size was guided by the Bentler and Chou [44] recommendation of a minimum of 5–10 cases per free parameter. Using the upper bracket limit (i.e., 10) and the SEM model containing 12 free parameters. The minimum sample size would be 120 and the sample of 831 participants surpassed this requirement. Follow-up data collection is in progress.

2.4. Measures

All measures will be administered at all time points.

Demographics – age, sex, marital status, number of dependents, country, living arrangements ("Who do you live with?"), residence (e.g., private rental, own house), level of education, living setting (e.g., metropolitan, rural), employment pre and post COVID-19 pandemic (e.g., full-time employed, part-time student), healthcare worker (Yes/No), healthcare insurance (Yes/No).

Lifestyle behaviours – smoking (number of cigarettes per/day), alcohol (alcohol units per week), exercise (number of times you exercised for more than 15 min per week). All items are answered "pre-COVID" and "in the last week".

GI-related questions – diagnosis, stoma (Yes/No), illness activity (in the past month), diet (any specific diet for GI disorder), co-morbidities, prescribed medication, over the counter medication.

Gastrointestinal Symptom Rating Scale (GSRS) [45] - This 15-item scale asks about symptoms of reflux, abdominal pain, indigestion, diarrhoea, and constipation. Symptoms are rated on a seven-point Likert scale ranging from absence of troublesome symptoms to very troublesome symptoms. All items are answered "pre-COVID" and "in the last week". The total score ranges from 15 to 105, with higher scores consistent with more severe symptoms. Reliability for the GSRS is good in the current sample; $\alpha = 0.91$.

The Brief Illness Perception Questionnaire (Brief IPQ) [46]. Brief IPQ is a widely used and reliable measure of illness perception [47]. This eight-item scale asks the respondents to select the number on a scale from 0 to 10 that best corresponds to their views regarding living with their illness (e.g., how concerned are you about your illness?). Lower scores correspond to an absence or less impact (e.g., 0 = no concern), whereas higher scores indicate significant impact (e.g., 10 = extremely concerned). In the present study, we adapted the Brief IPQ to the COVID context, utilizing two IPQ subscales: GI-specific (IPQ-GI, 8 items) and COVID-19-specific (IPQ-COVID, 5 items). In the first subscale (IPQ-GI), to ensure that the scale assessed GI-specific perceptions, the word "illness" was replaced with "gastrointestinal condition", for example "How much control do you feel you have over your illness?" became "How much control do you feel you have over your gastrointestinal condition?" The 8-item scale has a strong reliability ($\alpha = 0.83$). A second version of this scale (IPQ-COVID) was used to assess perceptions relating to COVID-19. For each of the original items, the word "your illness" was replaced with "COVID-19", for example "How much control do you feel you have over your illness?" became "How much control do you feel you have over COVID-19?". After three items (4, 5, 7) were discarded based on Cronbach alpha, the reliability was good ($\alpha = 0.75$). IPQ-GI and IPQ-COVID totals were created by averaging items, with higher scores indicating poorer illness perceptions, or poorer perceptions relating to COVID-19, respectively.

COVID-19 pandemic related questions - Likelihood of contact at work, likelihood of contact other than work, isolation type, local COVID-19 situation, current restrictions, current flu like symptoms (Yes/No), COVID-19 infection (Yes/No; how diagnosed; how long diagnosed), hospitalization due to COVID-19 (Yes/No), still COVID-19 symptomatic (Yes/No).

COVID-19 pandemic Impact – In this 11 item measure, created specifically for this study, participants are asked to rate using a four-point Likert scale (1-"No problem at all" to 4- "Serious problem"; with a "Not applicable" option also available) how much the COVID-19 pandemic has impacted: Illness management, access to family physician appointments, access to GI specialist appointments, access to other specialities appointments, access to medications, access to social support, access to toilet paper, access to food, adherence to diet, adherence to medication, access to non-medical treatments. Internal consistency for the COVID-19 Impact Scale in the current sample is good (Cronbach $\alpha = 0.89$).

The Fear Relating to COVID-19 Scale (GI) [29] – Derived from the Fear of AIDS scale [48], the Fear Relating to COVID-19 Scale is a nine-item measure validated for the IBD population [27]. Respondents indicate the level of fear/concern they are experiencing regarding different situations (e.g., contracting COVID-19, having contact with health professionals). For the present study, five GI specific items were added regarding: 1) whether COVID-19 will worsen the GI disorder; 2) whether COVID-19 will affect access to medical care; 3) whether COVID-19 will affect the management of the GI disorder; 4) whether the GI disorder will increase the risk of contracting COVID-19; and 5) whether having a GI disorder will increase the risk of death from COVID-19. All items are rated on a five-point scale from 1 (no fear) to 5 (very much fear) and higher scores indicate greater fear/concern about COVID-19. The measure presents two factors: General Fear of COVID-19 and GI specific Fear of COVID-19, both with acceptable internal reliability in the current sample ($\alpha = 0.93$, and $\alpha = 0.88$ respectively).

Brief COPE Inventory [49] - The Brief COPE consists of 28 items answered on a four-point Likert scale ranging from "I haven't been doing

this at all" to "I have been doing this a lot". Items include several coping statements such as: "I've been getting emotional support from others". A total of 14 subscales (coping strategies) are calculated by summing scores including: self-distraction, active coping, denial, substance use, use of emotional support, use of instrumental support, behavioural disengagement, venting, positive reframing, planning, humour, acceptance, religion, and self-blame. The Brief COPE has been translated in several languages and used across multiple disease conditions and lower scores are associated with worse disease outcomes, including for GI diseases [50]. Internal consistency for the Brief COPE Inventory in the current sample is good (Cronbach $\alpha = 0.89$).

Somatic Symptom Scale–8 (SSS-8) [51] – The SSS-8 is an abbreviated eight-item version of the PHQ-15 questionnaire [52] that assesses somatic symptom burden across GI, pain, fatigue, and cardiopulmonary aspects. Items such as "In the past 7 days, how much have you been bothered by back pain?" are rated on five-point Likert scale ranging from "not at all" to "very much". Items are summed to obtain a total somatic burden score. Internal consistency for the SSS-8 in the current sample is good (Cronbach $\alpha = 0.81$).

Catastrophizing subscale of the Coping Strategies Questionnaire (CSQ-CAT) [53] - The coping strategies questionnaire (CSQ) [54] is a measure of pain coping strategies used by patients. There are seven subscales, however, only the catastrophizing subscale was included in the current study. Items such as "It is terrible, and I feel it's never going to get any better." are answered on a 0–6 scale with anchors of "Never do that" to "Always do that". Scores are summed to obtain a catastrophizing total score. Internal consistency for the CSQ-CAT in the current sample is good (Cronbach $\alpha = 0.88$).

Acceptance and Action Questionnaire-II (AAQ-II) [55] - The AAQ-II is a seven-item measure aiming to evaluate experiential avoidance, i.e. attempts to avoid internal experiences of feelings, even though doing so can create harm in the long run. Ratings are from 1 ("Never true") to 7 ("Always true"), and higher scores correspond to higher levels of experiential avoidance. Internal consistency for the AAQ-II in the current sample is good (Cronbach $\alpha = 0.94$).

Psychosocial wellbeing questions - Previous mental health (MH) issues (Yes/No), previous contact with a mental health professional (MHP) (Yes/No), current MH issues (Yes/No), current contact with MHP (Yes/No), what kind of MHP, duration of contact with MHP, how often meetings with MHP, willingness to see an MHP, MH medication, what MH condition, MH problems Pre-COVID (Yes/No), MH problems post-COVID (Yes/No).

Depression, Anxiety and Stress Scale, (DASS-21) [56] - The 21-item version of the DASS measures symptoms of depression, anxiety and stress, with questions rated on a four-point Likert scale, ranging from 0 (did not apply to me at all) to 3 (applied to me very much or most of the time). The DASS-21 produces one total score and 3 subscale scores for depression, anxiety and stress with higher scores indicating higher levels of distress. The DASS-21 has been shown to possess adequate construct validity and reliability to measure the dimensions of depression, anxiety and stress separately and of distress overall. All items are answered "pre-COVID" and "in the past two weeks". Internal consistency for the DASS-21 in the current sample is good (Cronbach $\alpha = 0.95$).

EUROHIS-QOL [57] – Derived from the WHOQOL [58], this 8-item measure assesses general quality of life in Health domains (items 1 and 2) as well as Physical (Items 3 and 5), Environmental (Items 4 and 8), Psychological (Item 6) and Social (Item 7) domains. Items are scored on a 5-point Likert scale with descriptors varying by domain. The sum of all items gives a total score for quality of life. All items are answered "pre-COVID" and "in the last week". Internal consistency for the EUROHIS-QOL in the current sample is good (Cronbach $\alpha = 0.86$).

2.5. Procedure

To maximize recruitment and generalisability, researchers posted invitations to individuals living with a GI condition via social media (e.g., Facebook, Twitter), and GI-relevant websites (e.g., www.Mindovergut.com). In addition, peer-based GI associations in multiple countries were contacted and asked to post the study information to facilitate recruitment. Participants who chose to take part in this project clicked on a link to the survey (www.gicovid19study.com), which opened with a participant information sheet. This page explained the purpose of the study and research background, what participation would involve, the individual's rights and interests in relation to privacy, confidentiality, voluntary participation and freedom to withdraw from the study without providing reasons, outcomes of the research, and who to contact if they have any concerns or complaints. Consent was indicated through the respondent's choice to proceed. At the start of the questionnaire participants created a unique ID for matching purposes for the subsequent data collection time points. The questionnaire presentation was done in the order described in the measures section. The questionnaire took approximately 40 min to complete (all efforts were made to use the shortest possible versions of the measures of interest whilst retaining good validity and reliability). After completing the baseline questionnaire, participants were directed to a separate independent Qualtrics questionnaire and invited to provide their email address so that we could connect for 6- and 12-month follow up. At 6 and 12 months, participants of the baseline questionnaire who provided their email address will be invited to complete the respective online surveys. Responses will be matched by the unique ID created by each participant. At completion of the questionnaires, participants will be provided with a debriefing statement, which further explains the purpose of the research and information on relevant support options listed on the study website to alleviate distress resulting from participation, in the unlikely event that this occurs. At the conclusion of the study, the Qualtrics page will be deactivated, and data will be downloaded and stored on a secure server.

2.6. Statistical analyses

This study will generate several research questions that will be addressed in different publications. Overall, and in line with the aims of the overarching study, statistical analyses will include univariate descriptive models to provide information regarding the experience of people with a chronic GI disorder throughout the COVID-19 pandemic. Multilevel multivariate models (e.g., group comparisons, regression, mediation, moderation) will be used to investigate the influence of demographics, GI- and COVID-19 pandemic-related experiences, and psychological processes on indicators of wellbeing. Finally, longitudinal analyses (e.g., latent growth models) will address the impact of the COVID-19 pandemic on participants over time.

3. Discussion

The COVID-19 global pandemic has had an unprecedented impact on the health and wellbeing of people around the world. Government-mandated lockdowns implemented to safeguard public health have severely disrupted people's daily routines across the globe, interfering with common activities such as work, education, access to medical services and grocery products, travel, and leisure activities, as well as threatening financial and food security. Furthermore, basic human behaviours such as social interactions (e.g., shaking hands, hugging, meeting) have been re-interpreted as aversive and potentially deadly occurrences. As a result of these changes, there has been an increase in mental health problems in the general population worldwide [16], with concern about even greater impact on those with chronic GI disorders who already have a heightened vulnerability for mental health concerns [17,18].

To date, there is little known about how the COVID-19 pandemic has affected the mental health and wellbeing of those living with a chronic GI disorder. Considering the high prevalence of GI disorders globally, it is timely to assess the potential direct and indirect effects in order to prepare for and guide care needs during and post-pandemic. Preliminary

work with individuals who have IBD and IBS has highlighted the impact of fear of contracting the virus on daily activities such as going to the supermarket or attending regular doctor's appointments [25,26]. The impact on the mental health (anxiety and depression) of people living with IBD has also been significantly associated with isolation and fear of infection [27]. However, more evidence is needed for other GI populations, and the factors underlying mental health outcomes need to be further explored. We expect to see the afore mentioned trends reflected in the current study and to further elucidate some of the potential mechanisms that contribute to the worsening of mental health in GI populations during the pandemic. For example, we expect that those most affected by isolation measures, or shortages of access to products and medical care, to be significantly more psychologically distressed. We also expect that known and hypothesized mediators/moderators (e.g., catastrophizing, illness perceptions, experiential avoidance) of the relationship between GI symptoms and psychological distress to be significant. Finally, we expect these mediating/moderating effects to hold through time. With the likelihood of a foreseeable continued disruption, identifying factors that could mitigate or modulate the potential negative effects of lockdown measures and lack of social contact on people's psychological wellbeing becomes paramount to build intervention models that could help promote a greater resilience to such events.

4. Limitations

While the study is highly topical and novel, it unavoidably has limitations. It relies on a convenience sample of English speakers from different countries and with different GI presentations. Therefore, although the varied recruitment sources are likely to aid in reaching relevant participants, a selection bias that will limit conclusions regarding representativity of the sample is possible. It is likely that an under-sampling of populations will occur at country level and socio-economic level mainly due to targeting only those with internet access and who speak English. Similarly, it is likely that some of the people most affected by the pandemic such as frontline workers or people who are financially struggling at the moment will be harder to reach or less amenable to participate. However, since recruitment for research studies at health clinics has become impractical (due to lockdown of clinics/research labs), given the risk of the virus for researchers, and also due to the burden of the pandemic on health practitioners, we opted to conduct the study online and recruit via GI-related groups and social media. Regarding the language barrier, the decision to conduct the study in English only was dictated by the pragmatic issues with the time and effort necessary to translate the whole survey into different languages, therefore increasing the chance that time specific variables such as those related to the first wave of lockdown measures would be lost. In addition, this study was not able to include a measure pre-COVID and instead relied on recall of pre-pandemic levels of gastrointestinal and mental health symptoms and quality of life which could be subjected to retrospective response bias. Further, we are also relying on GI disorder self-identification without a gold-standard health professional's opinion, lab tests, or objective examinations for some medical diagnoses. Due to the current constraints, it would not be feasible to include such gold-standard evaluations, however we are using a general measure of GI symptomatology that will be helpful in gauging the severity of symptoms across conditions. Finally, country specific pandemic measures and COVID-19 incidence rates are likely to differ, therefore depending on the timing of when participants will be answering the survey, different contexts might be at play. However, this study will be collecting data on these variables as potential covariates and, furthermore, given the longitudinal nature of the study, it is more likely that different phases of the pandemic in different countries will be captured.

5. Conclusion

The present study offers a unique opportunity to examine prospectively on an international level, how the COVID-19 pandemic has shaped the lives of those living with GI disorders, specifically focusing on various aspects of mental health and their relationship with GI symptoms and healthcare utilisation. Given the scope of the COVID-19 pandemic, it becomes essential to determine and examine known (e.g., catastrophizing), and current contextual (e.g., type of lockdown measures) predictors of mental health outcomes in GI disorders so that better public health interventions targeting these populations can be developed. Clinical benefits of this project are likely to include guidelines to a more comprehensive assessment of mental health impact in GI populations during a global pandemic, but also, what type of targeted interventions to use depending on the most relevant predictor of psychological distress.

Role of the funding source

Not Applicable.

Declaration of Competing Interest

Outside the present work, A. Mikocka-Walus served as an invited speaker at IBD-related conferences co-organized by Crohn's & Colitis Australia (a charity), Janssen and Ferring and received a speaker's fee.

Outside the present work, S. Knowles served as an invited speaker at IBD-related conferences co-organized by Crohn's & Colitis Australia (a charity), Janssen and Ferring and received a speaker's fee and is a member of Medical Advisory Committee for Glutagen Pty Ltd.

Outside of the present work, M. van Tilburg was a consultant for Mahana Therapeutics Inc.

Outside of the present work, L.A. Graff has been a consultant for Roche Canada.

Outside of the present work, M Barreiro-de Acosta has served as a speaker, consultant and advisory member for or has received research funding from MSD, AbbVie, Janssen, Kern Pharma, Celltrion, Takeda, Gillead, Celgene, Pfizer, Ferring, Faes Farma, Shire Pharmaceuticals, Dr. Falk Pharma, Chiesi, Gebro Pharma, Adacyte and Vifor Pharma.

Outside of the present work, I.A. Trindade received consultancy fees from Pfizer Inc.

Outside of the present work Dr. C Bernstein has served on advisory Boards for AbbVie Canada, Amgen Canada, Bristol Myers Squibb Canada, Roche Canada, Janssen Canada, Sandoz Canada, Takeda Canada, and Pfizer Canada; Consultant for Mylan Pharmaceuticals and Takeda; Educational grants from Abbvie Canada, Pfizer Canada, Takeda Canada, and Janssen Canada. Speaker's panel for Abbvie Canada, Janssen Canada, Medtronic Canada, and Takeda Canada. Received research funding from Abbvie Canada and Pfizer Canada.

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