











Identifying the key characteristics of clinical fear of cancer recurrence: An international Delphi study

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Abstract

Objective: Without an agreed-upon set of characteristics that differentiate clinical from nonclinical levels of fear of cancer recurrence (FCR), it is difficult to ensure that FCR severity is appropriately measured, and that those in need of intervention are identified. The objective of this study was to establish expert consensus on the defining features of clinical FCR.

Method: A three-round Delphi was used to reach consensus on the defining features of clinical FCR. Sixty-five experts in FCR (researchers, psychologists, physicians, nurses, and allied health professionals) were recruited to suggest and rate potential features of clinical FCR. Participants who indicated they could communicate diagnoses within their clinical role were also asked to consider the application of established DSM-5 and proposed ICD-11 diagnostic criteria (Health Anxiety, Illness Anxiety Disorder, Somatic Symptom Disorder) to clinical FCR.

Results: Participants' ratings suggested that the following four features are key characteristics of clinical FCR: (a) high levels of preoccupation; (b) high levels of worry; (c) that are persistent; and (d) hypervigilance to bodily symptoms. Of participants whose professional role allowed them to diagnose mental disorders, 84% indicated it would be helpful to diagnose clinical FCR, but the use of established diagnostic criteria related to health anxiety or somatic-related disorders to clinical FCR was not supported. This suggests that participants consider clinical FCR as a presentation that is specific to cancer survivors.

Conclusion: Clinical FCR was conceptualized as a multidimensional construct. Further research is needed to empirically validate the proposed defining features.

KEYWORDS

cancer, Delphi, definition, expert consensus, fear of cancer recurrence, oncology

Fear of cancer recurrence (FCR) impacts most cancer survivors¹ and is defined as the "the fear, worry or concern relating to the possibility that cancer will come back or progress."² p.3266 Given the implications of a cancer diagnosis and treatment, experiencing FCR is reasonable

and expected.³ While FCR can be adaptive,²⁻⁴ when it is experienced at high levels of severity it leads to significant distress, decreased quality of life,¹ and increased health care use.^{5,6} The lack of established characteristics that differentiate normative from clinically severe FCR

is a gap in FCR research,^{2,7-10} since these characteristics would facilitate the accurate measurement of FCR severity, the severity of FCR requiring intervention, and appropriate intervention intensity.^{7,9,10}

Previous work has been conducted on identifying potential features of clinical FCR. For example, items more commonly endorsed by respondents considered to have clinical FCR on the Fear of Cancer Recurrence Inventory (FCRI)¹¹ included: experiencing fear, worry, and anxiety; functional impairment; and frequently thinking about the negative impact that a cancer recurrence would have on one's life.¹¹ Similarly, qualitatively analysed interviews with 40 breast, lung, colorectal, and prostate cancer survivors identified the following potential features of clinical FCR: death-related thoughts; feeling alone; belief that the cancer will return; intolerance of uncertainty; recurrent thoughts and images lasting at least 30 minutes, occur daily, are difficult to control, and cause distress; and impairment in functioning.¹² The next step in FCR research is to establish consensus on the defining features of clinical FCR.^{2,7,8}

Preliminary work on establishing consensus on the defining features of clinical FCR was conducted at an International Colloquium in 2015 at the University of Ottawa.^{2,8} Using one round of rating potential features of clinical FCR, 12 clinicians/clinician-researchers, 10 trainees with FCR research experience, one government funded cancer survivorship organization representative, and two patient representatives who attended the colloquium identified five potential features of clinical FCR. These were: (a) high levels of preoccupation, worry, rumination, or intrusive thoughts; (b) maladaptive coping (eg, excessive reassurance seeking, avoidance); (c) functional impairment; (d) excessive distress; and (e) difficulties making plans for the future.²

To extend this work, a larger-scale Delphi study was needed to reach expert consensus on the defining features of clinical FCR. Further, consensus was needed regarding the number of features and for how long they must be present to identify clinical FCR in a cancer survivor. When considering defining features of clinical FCR, an important distinction between *identifying* and *diagnosing* clinical FCR must be made. Identifying cancer survivors with clinical FCR based on the presence of certain features for research purposes, coordinating care, providing services, etc. can be done by researchers and health care professionals, as appropriate. In contrast, communicating a *diagnosis* is considered a controlled act and can only be done by specific professionals within their clinical role (eg, in Canada, Psychology Act, 1991).¹³ Given the stigma associated with a diagnosis of a mental health condition and the normative response of FCR among cancer survivors, it was important to obtain expert consensus on whether clinical FCR should potentially be considered a "diagnosis."⁸

When FCR is experienced at clinical levels, presenting symptoms may be similar to established diagnostic criteria for mental disorders, including anxiety disorders and hypochondriasis.^{14,15} Although the authors found some overlap between these disorders and FCR,^{14,15} newer, health-related diagnoses have been proposed that may be a better fit. The proposed diagnostic criteria for Health Anxiety (HA) in the upcoming eleventh edition of the International Classification of Diseases (ICD-11) appear to overlap with the defining characteristics of clinical FCR proposed at the FCR colloquium (Supplementary

File 1).^{2,16} Based on this, consideration of established *health-specific* diagnostic criteria that are potentially related to clinical FCR, including ICD-11 criteria for Health Anxiety¹⁶ and the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)¹⁷ criteria for Illness Anxiety Disorder (IAD) and Somatic Symptom Disorder (SSD),¹⁷ was pertinent and has not been previously proposed.

The present study was a formal Delphi on the defining features of clinical FCR that aimed to: (1) reach expert consensus on the characteristics that differentiate clinical from non-clinical FCR; (2) examine experts' views on using these features to (a) identify and (b) diagnose cancer survivors with clinical FCR; and (3) explore experts' views on applying already established diagnostic criteria (ie, HA, IAD, and SSD) to clinical FCR.

1 | METHOD

1.1 | Participants

As the purpose of this study was to establish consensus on the defining features of clinical FCR, participants needed to have some expertise related to FCR. The inclusion criteria for expert participants were: (a) researchers (who have authored/co-authored a peer reviewed article on FCR within the last 5 years); (b) nurses, social workers, physicians, psychologists, or other allied health professionals (with at least 5 years of experience working with cancer survivors); (c) able to read and write in English; (d) access to a computer with an internet connection and; (e) willing to provide an email address to receive Rounds 2 and 3 of the Delphi study questionnaires (Figure 1).

Participants were recruited via email through professional organizations related to psycho-oncology and cancer survivorship, through contacting authors of recently published articles on FCR, and through snowball sampling (ie, encouraging those who received the recruitment emails to forward it to colleagues who may be interested in participating). There are no clear guidelines published regarding the number of participants needed in Delphi studies,¹⁸ but the goal was to recruit a minimum of 50 participants in Round 1 in order to account for potential dropout across the three Delphi rounds.¹⁸

1.2 | Procedure

1.2.1 | Round 1

Qualtrics survey software was used to distribute and collect the data from the Delphi rounds. A link to the first of three Delphi rounds was included in the recruitment email. The Round 1 questionnaire contained a brief socio-demographic and eligibility-screening questionnaire. Those who did not meet the inclusion criteria did not complete the subsequent questionnaires. Participants were then presented with the suggested characteristics of clinical FCR from the International Colloquium on FCR and were asked to rate the extent to which they thought each item was a characteristic of clinical FCR using a 10-point rating scale where 0 indicated the item "is not a

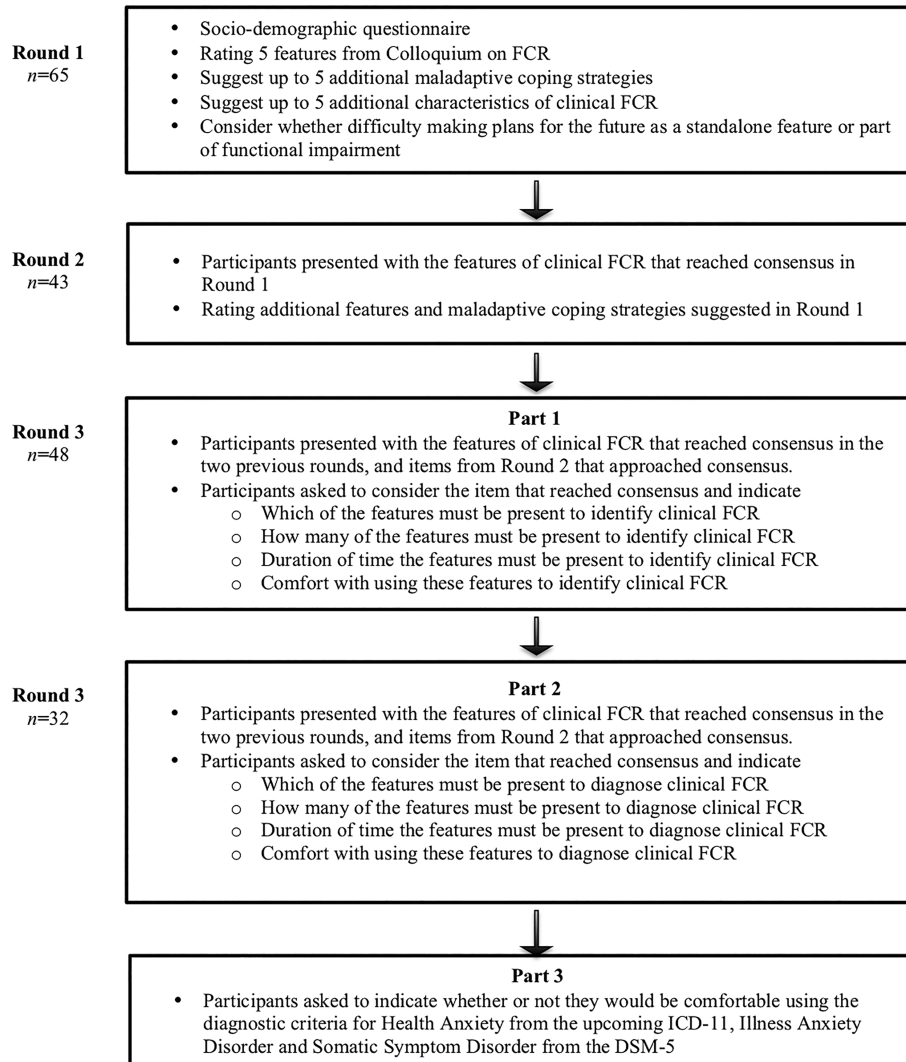


FIGURE 1 Structure of the Delphi rounds

characteristic of clinical FCR” and 10 indicated the item “is a characteristic of clinical FCR.” In this round, participants also had the opportunity to list up to five additional characteristics of clinical FCR and up to five additional maladaptive coping strategies associated with clinical FCR. From a methodological standpoint, presenting previously suggested items of clinical FCR focused the additional suggestions, which streamlined the analysis by making the volume of suggestions more manageable.¹⁸

Participants were also asked to consider whether the item “difficulty making plans for the future” from the results of the Delphi conducted at the International Colloquium on FCR should be considered a standalone feature of clinical FCR or an aspect of functional impairment. This question was included because impairment in functioning could encompass difficulties making plans for the future.²

1.2.2 | Consensus

There are multiple ways in which consensus can be defined for Delphi studies, and thus it is recommended that a consensus rating be established before the start of the Delphi rounds.¹⁸ For the present

study, a characteristic of clinical FCR was considered to have reached consensus when at least 70% of participants rated the item 8/10 or higher. Using a high cut-off of eight on a 10-point rating scale was chosen to avoid obtaining features that could apply to cancer survivors who are not experiencing clinically significant levels of FCR. A consensus level of 70% of participants rating the item 8/10 or higher for specific features of clinical FCR to be retained was chosen to be both conservative, and to ensure that consensus would be reached (ie, a consensus level of 100% is not feasible).¹⁹

The results from Round 1 were summarized by calculating the percent of participants who rated each item 8/10 or higher. For the Yes/No and fixed response option questions, the percentage of participants choosing each response option was calculated. Content analysis was used to summarize participants' responses to open-ended questions. Similar statements across participants were grouped together, and a summary statement for each group was assigned to represent the overall meaning of the responses.^{18,20} The content analysis was conducted by hand by the first author and checked by the last author. Data collection for Round 1 occurred from 1 February 2018 to 30 March 2018.

1.2.3 | Round 2

The items from Round 1 that reached consensus were presented to participants along with the content analysed suggestions of additional potential features of clinical FCR from Round 1. In Round 2, participants were asked to rate these additional potential features of clinical FCR as in Round 1, using the same 10-point rating scales.

The results of Round 2 were analyzed by calculating the percentage of participants rating each item 8/10 or higher. The data were collected for Round 2 from 30 April to 21 May 2018.

1.2.4 | Round 3

The final Delphi round consisted of three sections focused on: (a) identifying individuals with clinical FCR; (b) diagnosing individuals with clinical FCR; and (c) applying previously established diagnostic criteria to clinical FCR.

Specifically, participants were asked to indicate whether they believed that it would be useful to identify individuals with clinical FCR. Those who responded "Yes" were presented with the items that reached consensus from the first two Delphi rounds. Participants were then asked to indicate which of the characteristics, how many characteristics, and the duration that these characteristics need to be present to warrant the *identification* of clinical FCR in a cancer survivor.

Participants were then asked to indicate whether they could communicate a diagnosis in their profession.* Only those who answered yes completed the remainder of Round 3. These participants were then asked to indicate whether they thought it would be helpful to diagnose clinical FCR. Those who responded "Yes" were presented with the items that reached consensus in the previous two rounds. Participants were then asked to indicate which of these features, how many, and the duration required to warrant a *diagnosis* of clinical FCR. Descriptive statistics were calculated (mean, median, and range) for the number of characteristics, and the duration of time each characteristic must be present in order to identify and/or diagnose an individual with clinical FCR.

The final section of Round 3 asked participants to consider the applicability of the upcoming ICD-11 criteria for Health Anxiety, and the DSM-5 criteria for IAD and SSD to clinical FCR. The diagnostic criteria for these three disorders were presented to participants, who were then asked to indicate whether or not they would feel comfortable using these diagnostic criteria to diagnose an individual with clinical FCR. The percentage of participants responding "Yes" was calculated for these questions (Supplementary Figure 1, Supplementary files 1 and 2).

1.3 | Ethical Approval

Ethical approval was provided by the University of Ottawa Research Ethics Board (H-08-17-45). The consent form was presented first upon clicking the Round 1 questionnaire link. Participants provided consent by clicking "I consent."

2 | RESULTS

2.1 | Participants

Sixty-five experts participated in the first Delphi round. The majority of participants were women ($n = 51$), from Canada or the United States, and identified themselves as psychologists or research psychologists (Table 1). Participants had been working with cancer survivors for 15 years on average (range 3-37). Sixty-five participants completed Round 1, 43 participants completed Round 2, and 48 participants completed Round 3.

2.1.1 | Round 1

In Round 1, the items "high levels of preoccupation" (75%) and "high levels of worry" (80%) reached consensus as defining features of clinical FCR. Fifty-six additional features of clinical FCR and maladaptive coping strategies were suggested by participants and were grouped into overarching categories (Supplementary file 2). Suggestions included more specific descriptions of the anxiety, fear, and worry related to the possibility that the cancer could return (eg, "fear is in excess of objective evidence that they are likely to experience a recurrence"); hypervigilance to bodily sensations ("high attention for bodily symptoms and cancer-related issues"), emotional reactions to FCR (eg, irritability, crying, and distress), and a number of maladaptive coping strategies (eg, excessive reassurance seeking, excessive information seeking, substance use, lifestyle changes, behavioural avoidance, and cognitive avoidance) were also suggested. Impaired cognitive processes (ie, "misinterpretation of symptoms," "high perceived risk of recurrence") and various aspects of functional impairment (eg, difficulties sleeping, changes in roles and relationships etc.) were also suggested by participants as potential defining features of clinical FCR, and were presented for rating in Round 2.

TABLE 1 Participant professions and geographical locations

Profession	# Participants	Geographical Location	# Participants
Physician	5	Africa	2
Psychologist	23	Asia	3
Researcher	6	Australia and New Zealand	10
Researcher, Nurse	3	Canada	12
Researcher, Physician	3	Europe	16
Researcher, Psychologist	18	South America	2
Nurse	2	United Kingdom	7
Social worker	4	United States	13
Other allied health professional	1		

2.1.2 | Round 2

The item "hypervigilance or hypersensitivity to bodily sensations or physical symptoms for signs of cancer recurrence" reached consensus (70%) as a defining feature of clinical FCR in Round 2. Items related to persistent (67%) and uncontrollable (65%) worry, along with the use of maladaptive coping (65%), impairment in functioning (67.5%), and difficulties making plans for the future (66%) approached consensus (Supplementary File 2). Given that they were so close to reaching consensus, these items were presented again in an attempt to clarify experts' views during Round 3.

2.1.3 | Round 3

Based on Rounds 1 and 2, the following items were presented to participants in Round 3: (a) high levels of preoccupation and (b) high levels of worry (reached consensus in Round 1); (c) hypervigilance or hypersensitivity to bodily sensations or physical symptoms for signs of recurrence (reached consensus in Round 2); and (d) uncontrollable worry/fear/anxiety, (e) persistent anxiety/fear/worry, (f) presence of at least one maladaptive coping strategy, (g) impairment in functioning, and (h) difficulties making plans for the future (which were very close to consensus in Round 2). During this final round, persistent anxiety/fear/worry reached consensus (82%). Impairment in functioning was just below the consensus level with 64% of participants indicating that it must be present to identify clinical FCR. Uncontrollable worry (60%), difficulties making plans for the future (27%), and the use of maladaptive coping strategies (56%) remained below the 70% consensus threshold.

2.1.4 | Identifying clinical FCR

The following four items reached the predetermined consensus level: high levels of preoccupation (75%; Round 1); high levels of worry (80%; Round 1); hypervigilance or hypersensitivity to bodily sensations or physical symptoms for signs of recurrence (70%; Round 2); and persistent worry/fear/anxiety (82%; Round 3).

All participants believed that it is helpful to identify individuals with clinical FCR. The following two features of clinical FCR reached the predetermined consensus level (70% rating 8/10 or higher) as characteristics that *must be present to identify* clinical FCR: (a) Persistent worry/fear/anxiety (82%) and; (b) Hypervigilance or hypersensitivity to bodily symptoms for signs of cancer recurrence (73%).

The median number of characteristics that must be present for identifying an individual with clinical FCR was 3 (range 2-7; mean 3.42). Twenty-eight participants indicated that the duration should be measured in months, with a median of 3 consecutive months (range 1-12; mean 4.1). Overall, 93% of participants indicated that they would be comfortable using these criteria to *identify* cancer survivors with clinical FCR.

2.1.5 | Diagnosing clinical FCR

Thirty-two of the 48 (67%) participants indicated that their profession allows them to communicate diagnoses. Of these participants, 84% indicated that they believed that diagnosing clinical FCR would be helpful. Persistent worry/fear/anxiety reached consensus as a characteristic that *must be present to diagnose* clinical FCR (75%).

On average, these participants thought that a median of four characteristics must be present (range 2-6; mean 3.85) for a potential diagnosis of clinical FCR. Most of these participants thought the characteristics must be present for a median of 3 months (range 1-12; mean 3.77 months) after removing an outlier of 24 months. Eighty-one percent of the participants who can diagnose indicated that they would be comfortable using these criteria to hypothetically diagnose clinical FCR.

The majority of respondents who could diagnose preferred not to use existing diagnostic criteria to potentially diagnose clinical levels of FCR. Forty-four percent were comfortable applying ICD-11 criteria for Health Anxiety to clinical FCR, 31% were comfortable applying DSM-5 criteria for IAD, and 25% were comfortable applying DSM-5 criteria for SSD to clinical FCR.

3 | DISCUSSION

This study aimed to establish expert consensus on the defining characteristics of clinical FCR. Across three Delphi rounds, high levels of preoccupation and worry, which are persistent, and hypervigilance/hypersensitivity to bodily symptoms reached consensus as the four defining features of clinical FCR. At least three features must be present for at least 3 months to identify clinical FCR. Impairment in functioning, uncontrollable worry, difficulties making plans for the future, and maladaptive coping strategies were close to consensus and should be considered as potential candidates in future empirical work on defining features of clinical FCR. Most participants who could communicate diagnoses (in their clinical role) indicated the usefulness of diagnosing clinical FCR but did not endorse the application of established diagnostic criteria to clinical FCR.

The features of clinical FCR appear to be related to the severity of the worry/preoccupation (ie, high levels), the length of time worries and preoccupations are present (ie, are not transient), and hypersensitivity to bodily symptoms as a trigger. Current FCR measures contain items that could be used to assess these features of clinical FCR (FCRI²¹; Fear of Progression Questionnaire²²).

Functional impairment increased from 29% consensus in Round 1 to near 70% in Rounds 2 and 3. Considering the overall data, functional impairment may be a broad concept involving too many different components (eg, impact on sleep, role issues, and concentration) to reach consensus. Based on the data, it seems that functional impairment may be useful in identifying (66% agreement) but perhaps not diagnosing (53% agreement) clinical FCR.

Although the feature “uncontrollable worry/fear/anxiety” did not reach consensus, this feature may be conceptually related to high levels of persistent preoccupation and worry that did reach consensus. Similar wording among potential features of clinical FCR across Delphi rounds represented an additional challenge in interpretation. For example, it is unclear whether “preoccupation” can be present without “worry,” and if preoccupation and worry that is persistent differs meaningfully from “uncontrollable” worry/fear/anxiety. Given the nature of the Delphi method, it was difficult to clearly differentiate these terms as ratings are provided without discussion among participants.

The pattern of results regarding the characteristic “difficulty making plans for the future” was challenging to interpret. It was a suggested feature of clinical FCR at the colloquium on FCR in 2015,³ did not reach consensus in Round 1, approached consensus in Round 2, but was rated low in the final round as a feature that *must* be present to identify clinical FCR. Given the lack of clarity around this feature, additional research is needed on the role of planning for the future in the context of FCR in general, and its link to functional impairment.

The majority of suitably qualified participants in this study did not endorse the application of established diagnostic criteria for IAD and SSD from the DSM 5,¹⁷ and HA from the ICD-11¹⁶ to cancer survivors with clinical FCR. Previous work suggests that clinical FCR may share some similarities with, but is a separate construct to anxiety disorders and hypochondriasis.^{14,15,23} It appears that most participants view clinical FCR as a separate construct given that it is specific to cancer, and that it is present due to the experience of actually having cancer and coping with the real possibility of recurrence. Of the three diagnostic labels, HA was endorsed the most, and SSD the least. It appears that HA is a better fit for clinical FCR, but that the focus on the preoccupation with bodily symptoms in SSD does not capture the experience of clinical FCR.

3.1 | Limitations

Achieving consensus does not indicate that these *are* the defining features of clinical FCR.¹⁸ Additional studies are needed to provide empirical support for these characteristics. Starting the rounds by presenting the five potential features of clinical FCR suggested at the International Colloquium on FCR² may have influenced the results, resulting in bias in how respondents rated the items.¹⁸ However, participants had the opportunity to suggest additional features, and the entirety of the second round was based on the suggested features of clinical FCR from participants in Round 1. Ultimately, the authors interpreted the results of each Delphi round which introduces bias into the results.

3.2 | Clinical Implications

Currently, a clinician cannot give a formal diagnosis of “clinical FCR” as the criteria to do so have not been defined or approved.

However, the characteristics of clinical FCR suggested in this Delphi study can help clinicians and researchers identify and offer interventions to survivors experiencing clinical FCR. The preoccupation, worry, and hypervigilance in clinical FCR suggest intervention targets (ie, mindfulness, cognitive behavioural approaches).^{24–26}

Consideration of how the characteristics of clinical FCR will be used in clinical practice, and the specific diagnostic label for the presentation of clinical FCR is important. Patient/survivor-perspectives on the relevance, usefulness, and impact of a diagnosis of clinical FCR are also important research areas.

We suggest that screening tools for clinical FCR use items related the four features of clinical FCR that reached consensus. Current FCR measures contain potential items, but further refinements are needed. Since current FCR screening measures such as the severity subscale of the FCRI^{14,21} do not assess all of the proposed features of clinical FCR, this may explain the variability in reported clinical cut-offs.²⁷ Future research on the ability of these characteristics to accurately and meaningfully differentiate clinical and nonclinical levels of FCR is recommended (ie, through structural equation modelling).

4 | CONCLUSION

Using a Delphi method, persistently high levels preoccupation/worry and hypervigilance to bodily symptoms reached consensus as defining characteristics of clinical FCR. Future research is required to empirically validate these features of clinical FCR.

CONFLICT OF INTEREST

No

DATA AVAILABILITY STATEMENT

Data available from corresponding author upon reasonable request.

ENDNOTE

*The controlled act of communicating a diagnosis is only applicable to specific professions.¹³ When considering a hypothetical diagnosis of clinical FCR, only those who could diagnose within their professional role were included in this section.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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