Community of Inquiry Framework: Research Trends Between 2000-2020

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Abstract
The current study aimed to understand the trend in the community of inquiry that many researchers have been working on for over 20 years. Within the scope of this aim, 102 studies were reviewed with regards to some variables: most preferred keywords and words in abstract, year of publication, authors, journals, geographical distribution, academic disciplines, research methods, course delivery methods, participant type, and references. The findings demonstrate that the articles reviewed were from 216 authors in 20 countries. Most of the studies were from the Social Sciences field, and the continent with the most studies was North America. Quantitative research methods were mostly preferred in the studies, and the study group of a great majority the studies were higher education students. Finally, various recommendations were made for future research after determining gaps that exist in the current literature.

Keywords: Community of Inquiry, systematic review, bibliometric mapping analysis

The community of inquiry (CoI) framework was developed by a group of researchers between 1997-2001 (CoI, 2020) and has since attracted significant international attention (CoI, 2020; Garrison & Arbaugh, 2007). The CoI model, which has been verified many times by structurally different studies (e.g., Caskurlu, 2018), suggests that learning can occur via the interaction of three basic elements in the community: social presence (SP), cognitive presence (CP), and teaching presence (TP) (Garrison et al., 2000). Moreover, Garrison et al. concluded that these basic components of CoI can increase or decrease the quality of learning outcomes and educational experience.

Different definitions have been put forward by some researchers (e.g., Gunawardena & Zittle, 1997) for SP that may also be used to investigate the quality of social interaction within online learning environments (Kim et al., 2011), and which has become one of the primary concepts in online learning (Lowenthal & Dunlap, 2010). In the context of CoI, SP can be defined as “the ability of participants to identify with the community (e.g., course of study), communicate purposefully in a trusting environment, and develop inter-personal relationships by way of projecting their individual personalities” (Garrison, 2009, p. 352).

CP was operationalized through the practical inquiry model (Garrison, Anderson, & Archer, 2001) and defined by Garrison (2006) as the process of creating meaning with the collaborative inquiry. From the perspective of the practical inquiry model, CP can be defined as a research process that involves determining/defining an issue, dilemma, or problem (triggering event), then conducting a detailed investigation on information related to this issue (exploration), combining ideas to develop a meaningful structure or for obtaining a solution (integration), and then testing indirectly or directly the usefulness or validity of the solution (resolution) (Garrison, 2006; Garrison et al., 2001).

Finally, TP has been defined as “the design, facilitation, and direction of cognitive and social processes for the purpose of realizing personally meaningful and educationally worthwhile learning outcomes” (Anderson et al., 2001, p. 5). This begins prior to the start of a course (e.g., in the preparation and planning by an instructor of a subject related to a course) and continues throughout the course (e.g., an instructor facilitating discussions) (Anderson et al., 2001; Ke, 2010).

In the study by Castellanos-Reyes (2020), 20 years of the CoI framework was divided into two decades, with the conclusion that CoI was one of the most widely preferred frameworks in online education. In this context, the current study aims to reveal trends associated with CoI research. When the literature is examined, certain review studies stand out related to CoI (e.g., Kim & Gurvitch, 2020; Kozan & Caskurlu, 2018; Stenbom, 2018).

In the study conducted by Kozan and Caskurlu (2018), studies were reviewed in order to reveal the factors or new presence types suggested as further contributions to the framework of CoI. For this purpose, the researchers searched for studies across different platforms (e.g., Web of Science [WOS], PsycINFO, ERIC, and Google Scholar) published in the English language between 1996 and March 2017. As a result, of the 23 studies that matched the inclusion criteria and were reviewed in their research, 12 recommended a fourth presence to the framework of CoI. In addition, 11 of the studies expanded on the existing presences by suggesting a new dimension. In another study, Stenbom (2018) reviewed 103 articles from the Scopus, WOS, and ERIC databases published between 2008 and 2017, and applied the CoI data collection tool developed by Arbaugh et al. (2008). Finally, Kim and Gurvitch (2020) provided a systematic review of issues and trends in online learning and teaching in higher education. As such, articles published between 2009 and 2019 related to
the CoI were identified from four different sources. In total, 23 articles matched all inclusion criteria, which were then classified according to education level, course setting, research method, types of CoI component, discipline orientation, learning outcome, and instructional strategy. The current study, unlike previous research, aimed to reveal recent trends regarding CoI research over a 20 year period. To accomplish this, searches were performed against the WOS Core Collection database for articles or reviews having one of the following expressions included in the title: “CoI,” “coi,” “COI,” “Community of Inquiry,” “community of inquiry,” “Communities of Inquiry,” or “communities of inquiry,” published in the English language between 2000-2020, and a journal indexed in SSCI. The study has five research questions indicated below:

1. What were the most preferred keywords, and words in the abstract?
2. When, by whom, and where were the studies published?
3. What kinds of distribution were presented in terms of continents, countries, academic discipline, and research methods used?
4. What types of participants and course delivery methods were selected?
5. Which were the top 10 most referenced articles in the reviewed studies?

Method

In this study, besides the systematic review, bibliometric mapping analysis (BMA) was used for the most commonly preferred keywords and words in the abstract sections. A systematic review is a special type of literature review that tries to bring together all the empirical evidence that meets pre-established conformity criteria to answer certain research questions (Liberati et al., 2009) and is characterized by being methodical, transparent, comprehensive, and replicable (Siddaway, Wood, & Hedges, 2019). On the other hand, BMA is largely related to computer algorithms and visualization techniques based on available data generates quantitative information by summarizing publications, and gives objective and reliable results compared to the other techniques (Aria & Cuccurullo, 2017; Heersmink et al., 2011; Hung & Zhang, 2012).

Data Collection

In research proposing to reveal trends within a particular research area, certain criteria such as articles published in certain journals (e.g., Bozkurt et al., 2015), impact factors of the journals (e.g., Gaudino et al., 2020), or articles published in various scientific databases (e.g., Kim & Gurvitch, 2020), may be taken into consideration in the determination of researches published within a specified time interval. In the current study, articles were examined that were published in journals indexed in SSCI, which is considered one of the most prestigious indexes in the WOS and has been used as a source for several review studies (e.g., Akçayır & Akçayır, 2018). Furthermore, with a pioneering study on the CoI (Garrison et al., 2000) the time interval for searches applied in the current study was determined as starting from 2000 through to 2020. Only English language publications were included since most major journals accept English language articles and it is one of the most widely used languages worldwide in the circulation of scientific information (Ammon, 2011; González-Alcaide et al., 2012; Hamel, 2007).
The specific search terms were used in the WOS database on January 10th, 2021 (TI = “CoI” or TI = “Community of Inquiry” or TI = “Communities of Inquiry,” Document Type = Article or Review, Language = English, Indexes = SSCI, and Timespan = 2000-2020). This search showed that a total of 131 studies were identified that had “CoI,” “coi,” “Community of Inquiry,” “community of inquiry,” “Communities of Inquiry,” or “communities of inquiry” in the title, were published in an SSCI-indexed journal, were prepared in English, and were published between 2000 and 2020. The identified articles were downloaded as full texts to a computer in electronic format. When examined in detail in terms of their suitability for the research (see Table 1), it was determined that 102 articles were indeed related to the purpose of the current study (see Figure 1).

### Table 1
**Exclusion and Inclusion Criteria**

<table>
<thead>
<tr>
<th>Exclusion Criteria</th>
<th>Inclusion Criteria</th>
</tr>
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<tbody>
<tr>
<td>Editorial studies or article reviews.</td>
<td>Articles include specific search terms.</td>
</tr>
<tr>
<td>Studies with missing or inconsistent WOS data.</td>
<td>The main content focuses on CoI.</td>
</tr>
<tr>
<td>Articles in various contexts in spite of meeting search term.</td>
<td>Articles are prepared in English and indexed in SSCI.</td>
</tr>
</tbody>
</table>

### Figure 1
**Article Selection Process**

[Diagram showing the selection process with stages labeled as: Records identified through database searching (n = 131), Additional records identified through other sources (n = 0), Records after duplicates removed (n = 129), Records excluded (n = 0) after screening (n = 129), Full-text articles assessed for eligibility (n = 129), Full-text articles excluded, with reasons (See Table 1) (n = 27), and Studies retained for review (n = 102).]
Data Analysis

VOSviewer software tool was used for BMA of the reviewed articles. In addition, the publication classification form (PCF) as seen in Table 2 was designed by the researcher, taking into consideration the forms used in previous similar studies (e.g., Akçayır & Akçayır, 2017; Tsai & Chiang, 2013) and descriptive statistics were used to present the results. Short notes were also created regarding certain information about each article (e.g., whether the CoI survey instrument was used in the study; what instrument was used, etc.).

Table 2
Publication Classification Form

<table>
<thead>
<tr>
<th>Column heading</th>
<th>Description and/or example</th>
</tr>
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<tbody>
<tr>
<td>Academic discipline</td>
<td>Discipline in which the research was conducted. The Frascati manual (prepared by OECD experts) was used for academic discipline classification.</td>
</tr>
<tr>
<td>Authors’ country</td>
<td>According to the address information declared by the author(s).</td>
</tr>
<tr>
<td>Cited references</td>
<td>References cited in the reviewed articles.</td>
</tr>
<tr>
<td>Countries of study</td>
<td>Country/ies where the research was conducted.</td>
</tr>
<tr>
<td>Delivery method</td>
<td>Delivery method of the course within the scope of the research.</td>
</tr>
<tr>
<td>Number of authors</td>
<td>Number of authors in the study.</td>
</tr>
<tr>
<td>Reference</td>
<td>Author (Year). The name of the study. Name of the Journal, Vol(Issue), Page ranges.</td>
</tr>
<tr>
<td>Research method</td>
<td>Research method applied in the study.</td>
</tr>
<tr>
<td>Type of participant</td>
<td>Type of participants in the sample or target group of the study.</td>
</tr>
</tbody>
</table>

- Natural Sciences
- Engineering & Technology
- Medical & Health Sciences
- Agricultural Sciences
- Social Sciences
- Humanities
- Mixed (studies that bring together multiple academic disciplines)
- Unspecified (studies with no specified academic discipline or cannot be determined)

Turkey
Note: separate columns were to record this information for each author.

USA

- Blended
- Fully online
- Mixed (blended + online)
- Unspecified (studies with no delivery method or cannot be specified or determined)

2

- Qualitative
- Quantitative
- Mixed (qualitative + quantitative)
- Other

- K-12
- Higher Education (Associate, Bachelor’s, Master’s, Doctorate)
- Adult
- Teacher (K-12 teachers)
- Faculty member
- Mixed (studies with more than one participant type)
- Unspecified (studies with no participants, or no participant type specified, or cannot be determined)
Results

Most Commonly Used Keywords

Since 13 of the 102 examined articles did not have keywords, these analyses were conducted based only on those articles in which keyword entries were present. The results indicated four clusters (see Figure 2), with “community of inquiry” (f = 57) as the most used keyword, followed by “online learning” (f = 27), “teaching presence” (f = 21), “cognitive presence” (f = 18), and “social presence” (f = 18).

Figure 2
Most Preferred Keywords

![Diagram showing the relationship between keywords]

Most Preferred Words in Abstract

33 of the 102 examined articles included copyright statements in the abstract section and after they were cleared, the analyses were conducted. As indicated in Figure 3, the results showed that there were two clusters, with the word “community” (f = 98) as the most used term in the abstract of the examined researches, followed by “study” (f = 81), “inquiry” (f = 74), and “student” (f = 69).
The 102 studies were produced by a total of 216 authors from 20 countries. The most productive authors in the reviewed articles were Peter Shea (10 articles), Randy Garrison (eight articles), and Temi Bidjerano (eight articles), respectively. As presented in Table 3, the highest number of studies were published in 2010 and 2018 (n = 12, [11.76%]), with the majority of the studies written by two authors (n = 39, [38.24%]), while the highest number of authors in a single study (n = 11) was for the article by Carlon et al. (2012). Although the search extended back to the year 2000, no articles that met the criteria were published between 2000 and 2007, while there has been uninterrupted publication since 2008 (13 years), with an annual publication average of 7.85.

Table 3
Publication Year and Authors

<table>
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</table>
Journals

31 journals published 102 articles. Among them, 20 journals published only one article. The reviewed articles received a total of 3,282 citations according to WOS data dated January 10, 2021. Journals publishing more than one article are listed in Table 4, which indicates that the majority of the studies were published in The Internet and Higher Education (30 articles, 1,807 citations), followed by International Review of Research in Open and Distributed Learning (14 articles, 280 citations), Computers & Education (12 articles, 712 citations), and Interactive Learning Environments (five articles, 70 citations). Moreover, 56 articles (54.90% of 102) published in the three journals with the most publications received a total of 2,799 citations (85.28% of 3,282).

Table 4

<table>
<thead>
<tr>
<th>Journals</th>
<th>Article Count</th>
<th>% of Total</th>
<th>Citation Count</th>
<th>% of Total</th>
</tr>
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<tr>
<td>The Internet and Higher Education</td>
<td>30</td>
<td>29.41</td>
<td>1,807</td>
<td>55.06</td>
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<td>International Review of Research in Open and Distributed Learning</td>
<td>14</td>
<td>13.73</td>
<td>280</td>
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<tr>
<td>Computers &amp; Education</td>
<td>12</td>
<td>11.76</td>
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<td>21.69</td>
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<td>Interactive Learning Environments</td>
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<td>4.90</td>
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<td>British Journal of Educational Technology</td>
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<td>3.92</td>
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<td>Journal of Educational Computing Research</td>
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<td>Distance Education</td>
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<td>Journal of Computer Assisted Learning</td>
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<td>1.96</td>
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<td>Quest</td>
<td>2</td>
<td>1.96</td>
<td>2</td>
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</table>

* Journals with same number of articles are listed in ascending alphabetical order of the journal name

Continents and Countries

The articles were carried out in 19 countries across six continents. Half of the researches were carried out in North America (n = 51, [50.00%]). At the national level, the US had the highest number of studies (n = 37, [36.27%]). Results with regards to continents and countries were presented in Table 5.

Table 5

<table>
<thead>
<tr>
<th>Continents</th>
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<tr>
<td>Africa (3)</td>
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<td></td>
<td>Turkey (7)</td>
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<td></td>
<td>South Korea (2)</td>
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</table>

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Academic Discipline

The Frascati manual, which has been used by different researchers (e.g., Babić et al., 2016) and was prepared by experts for the Organisation for Economic Co-operation and Development (OECD, 2007), was used in the current study to determine the academic disciplines. The academic disciplines of the 102 examined articles were analyzed according to the aforementioned classification, and unspecified or undetermined academic disciplines were included in the “unspecified” category (see Figure 4). The largest number of research articles was produced in the Social Sciences field \((n = 39, [38.24\%])\), followed by 29 articles termed as mixed studies that involved more than one identifiable academic discipline.

![Figure 4: Academic Discipline](image)

Research Method

In the current study, similar to Tsai and Chiang (2013), research methods were classified into four basic categories: quantitative, qualitative, mixed, and other. The results showed that quantitative studies \((n = 45, [44.12\%])\) were frequently preferred. Then, mixed \((n = 26, [25.49\%])\), qualitative \((n = 19, [18.63\%])\), and other \((n = 12, [11.76\%])\) were mostly used methods, respectively. The studies classified under the “other” category included literature review studies (e.g., Kim & Gurvitch, 2020), strategies that could be considered in course design to create a CoI for online courses (e.g., Fiock, 2020; Tan et al., 2020), new presence types or dimensions studies suggested to contribute to the CoI (Kozan & Caskurlu, 2018), and personal perspectives on the CoI or its core elements (e.g., Annand, 2011; Garrison et al., 2010).
Course Delivery Method

In the current study, course delivery methods were classified into four basic categories: online, blended, mixed, and unspecified. Since it was not possible to determine a course delivery method classification for some of the 102 examined articles (e.g., Kozan & Caskurlu, 2018), “unspecified” was included in the options while the “mixed” option was included for studies (e.g., Harrell & Wendt, 2019) that simultaneously employed both online and blended course delivery methods. The results showed that the most commonly used course delivery method was online (n = 60, [58.82%]), followed by blended (n = 26, [25.49%]), and then mixed (n = 8, [7.84%]).

Type of Participant

A great number of study participants were higher education students (n = 74, [72.55%]). Since it was not possible to classify participant type for some of the articles (e.g., Kovanović et al., 2019), “unspecified” was included as an option. For researches including multiple participant type (e.g., Cohen & Holstein, 2018), the “mixed” alternative was also included. These results were presented in Figure 5.

Figure 5
Type of Participant

![Bar Chart](chart.png)

References

Among the 102 reviewed studies, the 10 most cited studies were determined in the reviewed articles (see Table 6). According to Table 6, while the most cited (n = 85) article was Garrison et al. (2000), the most productive authors were D. Randy Garrison (nine articles), Terry Anderson (four articles), and Walter Archer (four articles). The article with the most references was Cooper, Forino, Kanjanabootra, & von Meding (2020) (number of references, n = 124), and the average number of references in the reviewed articles was 51.
Table 6
Top 10 References Among the 102 Reviewed Papers

<table>
<thead>
<tr>
<th>References</th>
<th>Papers</th>
</tr>
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</table>
Discussion

The current study purposed to examine research trends related to the CoI over the past two decades, and involved analyses with both BMA and systematic review. The reviewed articles were analyzed using BMA with regards to most preferred keywords and words in abstract. Reviewed articles were also analyzed through systematic review in terms of their year of publication, authors, journal, geographical distribution, academic discipline/s, research method, course delivery method, participant type, and references.

The results showed that the most preferred keywords were: community of inquiry, online learning, teaching presence, cognitive presence, and social presence. Not surprisingly, the results imply that the reviewed studies relate mainly to online learning, the CoI, and its main elements. Considering that the CoI framework provides a collaborative-constructivist point of view to understanding the online learning experience (Arbaugh et al., 2008), it may be said that these keywords support the literature. The frequently preferred words in the articles’ abstract were “community,” “study,” “inquiry,” and “student,” which also support these findings.

With regard to the publication year of each article (search range: 2000-2020), 61 studies (59.80%) were published since 2015, suggesting that the number of studies about CoI has increased recently. This situation may have resulted from recent technological developments and the increase in demand for online learning. Since all but 19 (18.63%) of the reviewed articles have multiple authors, this result indicates a tendency towards more collaborative study among authors. Furthermore, from the 102 articles reviewed in this study, Peter Shea, Randy Garrison, and Temi Bidjerano authored the most articles. These findings were also notably supported by other recent studies (e.g., Bozkurt et al., 2015; Stenbom, 2018). The findings showed that the most preferred journals were The Internet and Higher Education, International Review of Research in Open and Distributed Learning, and Computers & Education, with a total of 56 articles (54.90% of 102) published in these three journals, which were cited 2,799 times (85.28% of 3,282). These findings are supported by recent research (e.g., Stenbom, 2018) and are also in line with the journal’s impact factors and the ranking and quartile level in the category provided by WOS.

Although the studies were mostly conducted in North America, which is where the CoI framework emerged (e.g., Anderson et al., 2001; Garrison et al., 2000, 2001), Table 5 illustrates global research interest in the CoI. As seen in Table 5, the two countries (US and Canada) where the most research was conducted are both English-speaking countries. The findings are in line with earlier systematic review reports (e.g., Stenbom, 2018) which stated that even though studies are conducted globally, more studies are conducted in some individual countries than conducted in some continents (Crompton & Burke, 2018). However, all of the studies were published in English, and researches prepared in other languages may have been carried out. Although Arbaugh et al. (2010) stated that the CoI might be more applicable for applied rather than pure disciplines, the findings of the current study have shown that most of the research was conducted in the field of Social Sciences (n = 39, [38.24%]), and that these results are in line with previous researches (e.g., Kim & Gurvitch, 2020). Also, the current study’s results showed that, among the six subcategories in the FOS classification of the Frascati manual, no articles were found that had been published in the field of Agricultural Sciences. However, it should not be overlooked that articles classified under the mixed category (n = 29, [28.43%]) may have included an academic discipline related to Agricultural Sciences.
The quantitative research method was reported as the most frequently used that is in line with a previous systematic review research carried out by Kim and Gurvitch (2020). However, this result may not be that surprising because the CoI survey instruments, which allowed for quantitative data about the CoI to be collected, were used in 56 (54.90%) of the 102 articles examined in the current study. When the CoI survey instruments used in these 56 articles were examined, it could be seen that the majority of the survey instruments used were those developed by Arbaugh et al. (2008). In some studies, the instruments were used without any modifications (e.g., Watts, 2017), or with only minor changes (e.g., Hilliard & Stewart, 2019), while others had adapted them to different languages (e.g., Heilporn & Lakhal, 2020), and some researchers had developed new tools based on the CoI survey instrument (e.g., Choy & Quek, 2016). The study conducted by Stenbom (2018), a systematic review of the CoI survey developed by Arbaugh et al. (2008) was conducted, in which 103 articles were examined that had been published between 2008 and 2017, which proved that the CoI survey provides results that are both valid and reliable. Quantitative research methods might have been preferred more by researchers since it allows for working with relatively larger and broader samples, and is considered to increase the generalisability of the findings. Olpak and Kılıç Çakmak (2018) also supported this finding, and stated that the three main elements (cognitive, social, and teaching presence) in the model were being increasingly analysed together with the development of surveys which provide opportunities to determine perceptions of the CoI.

The results also showed that, among the delivery methods, the most preferred course delivery method was fully online (n = 60, [58.82%]). In this context, it can be said that these findings are consistent with the literature, as CoI is a framework for both blended and online courses (Akyol, Garrison, & Ozden, 2009; Wicks, Craft, Mason, Gritter, & Bolding, 2015; Zhang, 2020), and one of the most frequently used models for online learning in higher education (Boston et al., 2009; Harrell & Wendt, 2019). It was revealed that a large number of the participants were higher education students. This could be due to the CoI framework having been developed in a study conducted within higher education institutions, or from a researcher’s preference for purposeful or convenient sampling methods. The results of the research studies conducted in order to identify trends in distance education research (Bozkurt et al., 2015), or systematic reviews (Kim & Gurvitch, 2020; Stenbom, 2018) are also consistent with these findings. Additionally, Harrell and Wendt (2019), noted that previous research findings had mainly focused on the higher education context.

Finally, when the references in the reviewed articles are examined, it is seen that the most citations were made to the study (Garrison et al., 2000) in which the CoI framework is set forth. Furthermore, not surprisingly, it also appeared that D. Randy Garrison participated in nine of the top 10 most referenced studies. In addition, it was determined that the top 10 most frequently referenced studies in the reviewed articles were related to 1) the CoI framework and its basic elements are revealed (e.g., Anderson et al., 2001; Garrison et al., 2000, 2001), 2) the development and validation of a data collection tool that attempts to operationalize the CoI framework (Arbaugh et al., 2008), and 3) evaluating of the literature and presenting projections for future studies (Garrison et al., 2010; Garrison & Arbaugh, 2007).

**Limitations, Identified Gaps, and Future Studies**

Since this systematic review was conducted by a single researcher, coefficients for the reliability of the analyses could not be calculated and agreement among independent observers could not be examined. Therefore, the method section explains in detail the approach taken within the scope of the current research. Also, the current study may be
considered limited by the potential for author misinterpretation of the information contained in the reviewed articles. Moreover, while the current study examined articles prepared in English and involved in journals which are indexed in SSCI, further researches may examine different types of documents (e.g., conference papers), indexed in various sources (e.g., ProQuest), or prepared in different languages.

The results obtained from the current review have certain gaps which should be considered. For instance, 62.75% of the examined studies used qualitative or quantitative research methods. Further studies could therefore focus on the mixed-method research design in order to reveal different views and understandings that may have been overlooked in studies which used only a single research method, since mixed-method studies are considered suitable for answering large and complex research questions (Johnson & Onwuegbuzie, 2004).

Although the current study’s results revealed that research on the CoI has been predominantly concentrated in North America, other countries (e.g., Turkey) are conducting more research, and that researchers often work collaboratively in such studies. It may be beneficial, therefore, for researchers to plan new studies that address different cultures by considering variables (e.g., course design, instructor behaviour, student characteristics, and learning approach) that may impact students’ learning in order to provide more in-depth information about the CoI. Moreover, the current study’s results revealed that studies are frequently conducted in the field of Social Sciences and with higher education students. In this context, it is recommended that future studies be conducted with students from different educational levels and academic disciplines.

**Conclusion**

In total, 102 articles prepared in journals indexed in SSCI about the CoI were analysed in the current study in terms of various variables. The study was performed with both BMA and systematic review of recent studies. The BMA provided an overview of the trends with regards to the frequently preferred words in the abstract and keywords. The systematic review was conducted to examine the studies with regards to their year of publication, the authors, the journals that the studies were published in, geographical distributions, the academic disciplines studied, the research methods employed, course delivery methods, the types of participants, and references in each study. The study presented an up-to-date evaluation and gaps in this field for future researches.

**Declarations**

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The author asserted that ethics board approval was not required for this study in their country.

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