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Overcoming methodological challenges due to COVID-19 pandemic in a non-pharmacological caregiver-child randomly controlled trial

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ABSTRACT

The current situation due to the COVID-19 pandemic has had huge consequences in all aspects of our lives, including the development of research activities. Studies involving face-to-face interaction with people, such as randomized controlled trials, were the first affected. The objective of this article is to present the insights on challenges brought by the COVID-19 pandemic onto an ongoing randomized controlled trial assessing a non-pharmacological intervention carried out with the participation of caregiver-child dyads. Findings contribute to the scarce literature on online synchronous data collection for quantitative studies, when in addition to the data it is necessary to assess observable behaviors. Video-conferencing proved to be a feasible alternative to face-to-face assessment interviews, which require video recording, and should be considered as a viable option for quantitative investigations of different disciplines, as it decreases risks due to face-to-face contact and mobility of participants and researchers, in continental countries like Brazil.

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COVID-19; online data collection; pandemic; randomized controlled trial; synchronous data collection

Introduction

The ‘coronavirus disease 2019’ (COVID-19) has physically, socially and economically affected people’s lives, with the pandemic being considered the greatest challenge of this century. The key measures regarding staying at home and adopting social distancing, threatened the integrity of the activities performed by academics. Universities have moved all their activities, both educational and investigative, to remote work. Empirical studies involving face-to-face interaction with people, either for implementation of interventions or data collection (as assessments, for example), were affected first because of the risks involved.

In this regard, challenges arising from the pandemic have forced researchers to be flexible and to innovate in the ways they carry out their activities by adapting studies to the current context (Fleming et al., 2020; Superfine, 2020; Weissman et al., 2020). Nevertheless, after a review during September 2020 of published articles about the methodological research challenges during the COVID-19 pandemic, few results were obtained, albeit numerous initiatives discussing this topic in blogs, webinar series, podcasts, journal interviews, posts of experiences of organizations on their websites, etc., were retrieved.

The editorial published by the Journal of Mathematics Teacher Education discussed that it might be too early to obtain results about researches that describe their data collection processes during the pandemic (Superfine, 2020). One published scientific article was about the experience of a qualitative study in New Zealand that adapted face-to-face group interviews with vulnerable people prior to COVID-19 to an online format during lockdown (Dodds & Hess, 2020). Meanwhile, other published articles shared their reflections about the opportunities and challenges of researching during the COVID-19 pandemic in their respective areas of interest such as information systems (Fink, 2020), obstetrics, specifically, during pregnancy (Mourad et al., 2020), heart failure (Anker et al., 2020) and music therapy (Bradt, 2020).

In relation to quantitative research, a longitudinal observational study with elderly people transferred their face-to-face visit for data collection to a virtual one during the pandemic without risks for both participants and field researchers (Udeh-Momoh et al., 2020). Likewise, Upadhaya et al. (2020) carried out a study to assess how the pandemic was affecting the ongoing oncology clinical trials and the planning of future trials. The pandemic had a major impact on patient enrolment, clinical research infrastructure and patient consultations.

Several papers discussed about conducting clinical trials in the midst of the COVID-19 pandemic and claimed some main recommendations regarding the implementation of the intervention and data collection of randomized controlled trials in order to continue the studies (McDermott & Newman, 2020; Mitchell et al., 2020; Shiely et al., 2021; Singh & Chaturvedi, 2020). In this regard, the virtual visit emerges as the ideal option to continue with the trials while ensuring the safety of the participants and the researchers (Singh & Chaturvedi, 2020; Van Dorn, 2020; Waterhouse et al., 2020). Besides the methods, and adaptations to data collection, statistical analysis and presentation of the results should consider the impact of the pandemic on the study (Fleming et al., 2020). Notwithstanding, no publications were found on the challenges of adapting non-pharmacological trials in the midst of the COVID-19.

There is substantial evidence about the online data collection for both qualitative and quantitative research. Regarding qualitative studies, several papers report the use of e-mail, instant messaging and videoconferencing to conduct online asynchronous and synchronous, semi-structured interviews and virtual focus groups (Bampton et al., 2013; Bolderston, 2012; Janghorban et al., 2014; Lobe & Morgan, 2021; Meho, 2006; Pearce et al., 2014; Salmons, 2014; Weller, 2017).

The use of asynchronous online e-mail, web-based and mobile surveys is extremely popular for quantitative research (Ball, 2019; Hlatshwako et al., 2021; Sue & Ritter, 2012; Ye, 2007). Instead, synchronous online data collection, understood as the real-time communication between participant and interviewer via video and audio connection using a computer or other mobile device (e.g., tablet or mobile phone) (Lobe & Morgan, 2021; Nehls et al., 2015), is a much more innovative method, even more when using data collection instruments that require the assessment of observable behaviors (such as those related to child development) and video recording.

In this context of scarce literature about synchronous online quantitative data collection, the objective of this article is to present the insights on the challenges brought by the COVID-19 pandemic onto an ongoing randomized controlled trial assessing a non-pharmacological intervention involving the participation of caregiver-child dyads. Despite the challenging process, important lessons were learned that could be applicable in other contexts. Therefore, it is highly relevant to share our experience on carrying out the feasibility test to adapt the face-to-face visit to the virtual one, and the subsequent online data collection to contribute towards filling gaps in the existing literature on synchronous online quantitative data collection.

BEM program experience

Research context previous to COVID-19 pandemic

BEM Program (an acronym for *Brincar Ensina a Mudar* in Portuguese, which in English is Play Teaches Change) is an innovative play-focused online responsive parenting program which aims to build positive parenting skills to improve caregiver–child interaction for enhancing the development of children aged 12 to 23 months in socially disfavored families. Female caregivers receive video classes and text and audio messages through WhatsApp, which demonstrate playful activities that can be integrated into their daily household chores using resources available in their homes.

A randomized controlled trial was carried out with the objective of assessing the effectiveness of the BEM Program on female caregivers' engagement in age-appropriate play activities with the child while doing the household chores, perceived stress and parenting sense of competence, quality of caregiver–child interaction and child development. In order to achieve the required sample size, the field study was conducted in two cohorts. Cohort 1 was recruited in July 2019 and received the intervention between October and November 2019; cohort 2 was recruited in January 2020 and received the program during April and May 2020, during COVID-19 pandemic.

Data were collected at two different time points: baseline and endline by trained examiners using tablets with several instruments inserted in the REDCap (Research Electronic Data Capture) software, which allowed data collection offline and direct transmission of responses to a database. Tablets were also used for recording three 5-min videos used to assess two of our outcomes.

A combination of program-specific questionnaires and standardized scales were used to evaluate each of the studied outcomes. Caregiver's engagement in age-appropriate play activities with the child while doing the household chores was assessed using a questionnaire created and pre-tested by the researchers. In addition, this outcome was evaluated by analyzing two 5-min videos, using another instrument created by the research team for this purpose, also included in REDCap.

Perceived stress was measured using the Perceived Stress Scale, the sense of parental competence was evaluated through the Brazilian version of the Parenting Sense of Competence Scale (PSOC) and parental reflective functioning was assessed through the Parental Reflective Functioning Questionnaire (PRFQ). These three instruments were answered according to a Likert scale, for which participants got a printed version of the scale, so they could read the items and the Likert scale.

Child development was assessed using the Brazilian version of the Ages and Stages Questionnaires (ASQ-BR), a screening tool that measures development of children aged 0 to 5 and a half years, in five key domains: communication, gross motor, fine motor, problem solving, and personal-social (Filgueiras et al., 2013). Finally, the quality of caregiver–child interaction was measured by the Coding Interactive Behavior (CIB), a tool for coding parent–infant interactions with children ranging from 2 to 36 months of age, using a set of observable behaviors (Feldman, 1998). A 5-min video of an interaction between the caregiver and the child while playing is coded on a 5-point scale (Feldman, 1998).

Methodological reconsiderations due to COVID-19

In March, when the WHO declared COVID-19 as a pandemic, our research was in the implementation stage of the intervention. Due to the fact that BEM Program is an intervention delivered remotely through WhatsApp, it was possible to maintain its implementation without being affected by the context of social distancing. Otherwise, the endline data collection for cohort 2 that was scheduled to start in June 2020 required some reconsiderations. Prior to COVID-19, the data collection consisted of home visits to conduct face-to-face interviews and to record the videos. However, as it was no longer feasible to keep the home visits, the data collection methods were adapted to allow the continuity of the research.

There was agreement among the research team that a synchronous online format, such as a video-conferencing interview, was the most suitable method for data collection due to the specific characteristics of the data collection instruments which require the assessment of observable behaviors and video recording. Additionally, online video-conferencing became one of the main means of communication between people during the COVID-19 pandemic. Therefore, it might be feasible and accepted by the participants because having a smartphone with Internet access was an inclusion criterion for participating in the research.

Moreover, the Research Ethics Committee authorized the adaptation of the data collection to an online format. From an ethical point of view, there were no differences between face-to-face and online interviews, as both required the usual ethical considerations, such as obtaining informed consent and protecting the anonymity, privacy and confidentiality of the participants.

As mentioned above, virtual visit was one of the recommended strategies to maintain the continuity of trials, however, regarding the specific characteristics of our data collection instruments the research team identified six main challenges to face when collecting synchronous data online: 1. Internet access, 2. Use of video-conferencing platforms, 3. Duration of the assessment, 4. Use of Likert Scales, 5. Child development assessment, and 6. Quality of videos recorded.

Hence, considering these challenges of changing from face-to-face to synchronous online data collection, a feasibility test was conducted. The main objectives of this test were 1. to evaluate the different actions proposed to overcome each challenge and 2. to identify other changes or adaptations needed to carry out an online data collection by a video-conference interview.

This feasibility test consisted of conducting five videoconference interviews, one for each examiner. Five caregivers, from the first cohort who had already received the intervention and the endline data collection, were selected and invited to participate in the test. After contacting them, a researcher explained the new online format and that they had the opportunity to choose between using WhatsApp or Zoom. The participants who reported Internet access problems, received the Internet credits recharge on their cell phones.

Besides the examiner, the researcher responsible for the data collection process also participated as a listener in each of the video-conferences. She was evaluating the feasibility of implementing the proposed adaptations and identifying any other difficulties or challenges that might appear during the interview or video recording.

The proposed adaptations for each identified challenge that were implemented in the feasibility test are explained in the following paragraphs. Regarding Internet access, caregivers might have access to the Internet but not have enough internet bandwidth to perform video-conferencing interviews. Additionally, in the case of caregivers who used a prepaid cell phone plan, the time to make the online video-conferencing could be limited. To overcome these challenges related to Internet access, the research team proposed to provide the Internet for data collecting, by recharging credits for Internet access to the participant's cell phone that would be used for the video-conference, a few minutes before the scheduled time. This ensured that the credits were used for the data collection purpose.

In relation to the use of video-conferencing platforms, the lack of familiarity of the caregiver in participating in video-conferencing interviews might represent a challenge. Therefore, it was important to determine which was the best video-conferencing platform for our sample, according to caregivers' familiarity with the platform and the platform's advantages and disadvantages when collecting data online. The researcher team decided to test two platforms: WhatsApp, which was a requirement to participate in the research; and Zoom, one of the most used video-conferencing platforms in Brazil during the COVID-19 pandemic (Passos, 2020).

The duration of the assessment was one of the main concerns of the research team, because each home visit for data collection including the interview and video recording lasted on average 2 hours. This period of time was already a challenge during face-to-face data collection, since the participation and collaboration of the child were required; as well as the attention and collaboration of the caregiver, which could be more complicated when being online. Consequently, it was necessary to

test if we could replicate the experience of face-to-face interviews during a video-conference in order to determine its duration.

To respond to the Perceived Stress Scale, the PSOC and the PRFQ participants received a printed image with the Likert scale options. Due to the fact that feasibility tests confirmed the usefulness of this visual resource to facilitate the interviewee's answers, the research team considered it relevant to keep the visual resource during the online video-conferencing. To overcome this challenge, the caregivers who used WhatsApp would receive the digital image of the scale by a message that they could access during the interview. On the other hand, the participants who used Zoom would be able to watch the digital image on the screen of their device, since the examiner would use the Zoom's screen sharing function.

When caregivers claimed ignoring how to respond to some ASQ-BR items, it was necessary for examiners to ask the child to perform the task that was being assessed, some of which could demand the use of specific materials. Thus, such process could be more challenging through online video-conferencing, as caregivers could have difficulty asking the child to perform the task or might not have the materials. In this case, the research team decided to test the use of the ASQ-BR online.

Finally, video recording of three scenes of dyadic interaction was one of the main challenges to achieve a complete data collection. The complexity of fulfilling this was related to three aspects: 1. The three videos were recorded at different time points during different activities, 2. The caregiver was not always accompanied by someone else who could record, 3. The impossibility of recording audio and video when the video-conference was made using WhatsApp.

Giving clear and specific instructions to guide caregivers, or another person who recorded the videos, on the appropriate position of the cell phone for recording the videos and the specific elements that should be recorded would be the key to obtaining the videos of sufficient quality. When WhatsApp was used to conduct the video-conference, the research team suggested that the examiners used their tablets to record the screen of the cell phone where the video-conference was being held.

After conducting the feasibility test, caregivers recognized that receiving the Internet for the video-conference facilitated their participation in the research. According to the caregivers' preferences, three video-conferences were by WhatsApp and two were using Zoom. While testing both platforms, it was possible to identify its advantages and disadvantages when collecting data for our research project.

The advantages of using WhatsApp were that all the caregivers already used it and they knew how to use it. Also, WhatsApp was an application that they already had on their cell phones and did not need to download it. On the other hand, the main disadvantage of using WhatsApp was the difficulty for recording the videos, as the platform did not allow online audio-video recording. The advantages of using Zoom were its audio-video recording and screen sharing functions. The disadvantages of using Zoom were the little familiarity of the caregivers with the platform, and that it is necessary to use a computer or to download the application if using the cell phone or tablet. Therefore, considering that both applications had advantages and disadvantages for the data collection, the research team decided to allow the caregivers to choose which platform they preferred to use.

On average, the online video-conferencing lasted 1h20min, a convenient time for the caregiver and the child to pay attention and be collaborative. Regarding the different instruments used for data collection, the Perceived Stress Scale, the PSOC and PRFQ were applied without any difficulty. Either sending the virtual image of the scale or sharing the screen, the caregivers were able to answer the instruments using the visual resource.

As expected, the ASQ-BR to assess child development was the most difficult instrument to use in an online format. Examiners confirmed that the caregivers did not have the materials and had difficulty asking the children to perform the assessed items. To overcome this challenge, we created a simple list of materials, including these that the caregivers might have at home, such as shoelace,

pot with lid, paper, pencil, plastic bottle, spoon This list was sent before the video-conference asking the caregivers to have all the materials at the moment of the interview. Moreover, the examiners team and the researcher responsible for the data collection had a meeting to review the ASQ-BR and how the items should be explained to the caregivers, so they could be able to ask the children to perform the assessed task.

In relation to the video recording, the strategies that were tested to fulfill this task were successful. Regardless of which platform was used for the online video-conference and if there was a third person who could record the videos, it was feasible to record the three videos.

Finally, we collected data regarding the caregivers' opinions and preferences about the online data collection with the following two questions: 'What do you think about the virtual visit?' and 'Do you have any suggestion to improve the virtual visit?'. The participants recognized that the online data collection facilitated their participation in the study because they felt more comfortable, several of them did not want to receive the examiner at home; they could schedule the video-conference in the morning before going to work or in the evening when they arrived and it was easier to reschedule the interview, in case of any inconvenience. Also, they referred that it was easy to follow the examiners' instructions and not as hard as they thought it would be. Notwithstanding, caregivers reported the quality of the Internet as a difficulty to perform the video-conference.

The results of the feasibility test showed that it was possible to keep the structure and all the instruments used during the face-to-face data collection in the online format that the proposed adaptations were appropriated for conducting the video-conferencing interview, assessing the child development and video recording, and that the online data collection was well accepted by the caregivers. Therefore, the research team decided to implement the synchronous data collection through video-conferencing with the caregiver-child dyads participating in the study.

The positive results of the feasibility test were reflected in the higher percentage of acceptance of the video-conference interview when performing the synchronous online data collection with the 35 caregiver-child dyads participating in the study. We achieved 78% of the endline data collection when it was virtual compared to 64% achieved through face-to-face data collection. On the other hand, as expected and referred by the caregivers, the access to the Internet and technology represented a limitation of the video-conferencing interview. 11% caregiver-child dyads were unable to participate in this endline data collection because they did not have a cellphone or another device, or they did not have Internet bandwidth to perform the video-conference.

Discussion

The objective of this article was to present preliminary reflections on the challenges brought by the COVID-19 pandemic in an ongoing randomized controlled trial involving the participation of caregiver-child dyads. The BEM Program is a completely remote intervention, thus the impact of the pandemic on our research was exclusively in the data collection process which had to be modified and adapted to an online format.

In this case, conducting a randomized controlled trial to assess the effectiveness of the BEM Program had the goal to yield the highest level of evidence in evaluating an intervention that promotes responsive parenting and its encouraging consequences on child development. Therefore, the continuity of the research was overriding for the benefit of the families participating in the study and the future families who may have access to the intervention.

Despite the context of crisis, researches cannot stop. Historically, universities have existed not only as institutions for the creation and dispersion of knowledge, but also as spaces for struggle and transformation in the midst of the countries' social, political and economic crises. COVID-19 pandemic and its long-lasting consequences are not an exception: inequalities, as well as unemployment, will increase; the provision of public education and health services will worsen. Academics have had to reinvent the way they teach and research in order to keep improving the well-being of the population.

In this sense, the COVID-19 has represented an enormous challenge as long as it has been a valuable opportunity for researchers to approach with innovative strategies to their objects of study. Such strategies have been developed for both implementing interventions and collecting data that do not require face-to-face interaction between the researcher and the participant. As the situation evolves, researchers around the world will continue to adapt and improve their research activities as accurately and safely as possible. Therefore, the new strategies may be useful not only in the current context of social distancing, but they may be innovative perennial solutions that allow researching in other situations, such as participants dispersed over large geographical areas even when social distancing measures are not in place.

The success in the continuity and culmination of BEM Program research, during the COVID-19 pandemic, was based on the fact of having a completely remote intervention, and the researchers' ability to adapt the home visit to a synchronous online format. It should be considered that the expectation of fully replicating the face-to-face visit in the virtual environment might not be possible in all contexts, hence the importance of performing feasibility tests before implementing the online interview. Conducting such test was one of the most important lessons learned from the BEM Program experience of adapting the face-to-face visit to an online format. To prove the adaptations before making final decisions and implementing them with the study participants allowed us to maintain the integrity of the trial.

Virtual visit was one of the recommended strategies to maintain the continuity of the studies (Singh & Chaturvedi, 2020; Van Dorn, 2020). Due to the characteristics of the data collection instruments of this research, both audio and video were necessary at the time of the interview. Thus, compared to other techniques of remote data collection such as online surveys, e-mail or phone calls, synchronous video-conferences were the ideal option to collect data. In addition, video-conferencing is the better way to tend to replicate person, face-to-face interviews which are the 'gold-standard' for data collection. Using real-time video creates a more comfortable environment that facilitates the interaction and connection with the interviewees, making the experience more personal than through other means (James & Busher, 2012).

These features of the synchronous video-conferencing allowed us to overcome the two biggest challenges of our data collection that are not well documented in the literature: to assess the child development and to record the videos. Furthermore, by conducting the feasibility test and collecting data from the 35 caregiver-child dyads we confirmed that non-pharmacological randomized controlled trials that assess interventions and outcomes with a more social approach, such as ours, and other types of social research that might require, in addition to interviews, observable behaviors assessment or video recording could be carried out through a synchronous online data collection. In this sense, this paper contributes towards filling gaps in the existing literature on synchronous online quantitative data collection.

The positive response of the caregivers to the online assessment which was reflected in a greater percentage of acceptance of the video-conference interview compared to the home visit is explained by the fact that caregivers felt safer and more comfortable without being visited by an examiner at home. Socioeconomically disadvantaged families might feel uncomfortable or threatened with the presence of a strange person in their homes. Dodds and Hess (2020) reported as the most important benefit in adapting a group interview to a virtual format for their study was that participants felt more relaxed and less intimidated. In addition, in our experience, another reason for the greater participation of the caregivers was the enlarged availability of examiners' schedules as they did not need to travel to the participants' home, so it was possible to schedule data collection interviews at times when caregiver's availability was higher. Other authors identified time effectiveness as a key advantage of performing online data collection (Archibald et al., 2019).

Additionally, another aspect that may explain the higher engagement of caregivers with the online interview was that they had the opportunity to select between two video-conferencing platforms. By doing this, the participants used a platform that did not require them to install an external program on their personal devices, as well as, this would accommodate different levels of

technology knowledge and skills and would not be limited by operating system compatibility problems. Therefore, with this solution, we were able to address one of the main difficulties identified by other researchers when collecting data online (James & Busher, 2012).

However, it is important to point out that in order to conduct virtual data collection both participants and researchers should have some level of digital literacy (Lobe & Morgan, 2021). In our case, the participants were used to using smartphones and digital communication forms. Therefore, it should be noted that our results must be understood based on this specific characteristic of our sample, which might represent a limitation of our findings.

Furthermore, as it was an endline data collection, the caregivers already knew the examiners and how the process was like, they knew the instruments and when and how the videos were recorded. As in the research carried out by Udeh-Momoh et al. (2020), the results only showed the success of the online format for a specific moment of the research. Therefore, it would be relevant to investigate the acceptance of the caregivers and the success of the online format if the entire research was online since the recruitment. Moreover, new studies should analyze the long-term implications of conducting online format research in a different context than the current one.

It is worth noting the paradox of online data collection which was reflected in our results. As we increased the number of interviews by eliminating barriers associated with the face-to-face visit, we lost the opportunity to collect data from some dyads due to the barriers imposed by technology. Despite the fact that the characteristics of the participants in our sample are homogeneous, the synchronous video-conferencing interview could favor selection bias by excluding participants with fewer resources. Due to the current health situation, we lost the data from these dyads; however, under normal conditions the selection bias could be overcome by offering different interview methods to the participants (Pearce et al., 2014).

Conclusion

Researchers must be flexible and innovative to ensure the integrity of their studies, despite the situations that might affect them. The synchronous online data collection has been presented as a second choice or alternative when the face-to-face interview is not feasible. Nevertheless, adapting research during the COVID-19 pandemic has provided unprecedented insights into online data collection. Findings contribute to the scarce literature on synchronous online data collection for quantitative studies. Video-conferencing proved to be a feasible alternative to face-to-face assessment interviews which require video recording, and should be considered as a viable option for quantitative investigations of different disciplines, as it decreases the risks due to face-to-face contact and mobility participants and researchers, mainly in continental countries like Brazil.

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