Supporting Family Members with severe grief reaction during the COVID-19 Pandemic
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Abstract

Background: Severe grief reactions (SGR), or complicated grief, are experienced by 2-3% of the population after the loss of a loved one, and can be associated with declining health, social distress, increased use of healthcare resources and higher mortality. SGR can be related to the circumstances of the patient at the end of life, particularly in deaths that were unexpected or traumatic, when the family member was unprepared or unsupported. The COVID-19 pandemic has affected many aspects of end-of-life care. For example, infection control measures may reduce interactions between long-term care residents and family members, and have often limited in-person family visiting to the final hours of life, or no visiting at all for patients with COVID-19. Anecdotally, this disruption of normal interactions has been difficult for patients and families alike, and we know that isolation and lack of closure with a loved one can contribute to the risk of SGR. The prevalence of SGR is expected to rise amid increased challenges in supporting a surge of people with SGR due to physical distancing and limited bereavement resources.

Methods: The proposed mixed methods explanatory study includes both retrospective and prospective data collection. The quantitative components will principally consist of natural experiments to identify patient/FM characteristics indicating a high risk of SGR during the COVID-19 pandemic. The qualitative components will deepen our understanding of the impact of COVID-19 on bereavement, while providing formative evaluation for the virtual support groups. Study subjects will include all patients who died in an acute care facility in Ottawa (The Ottawa Hospital, Queensway-Carleton Hospital, and Hôpital Montfort) from November 1 1, 2019 until August 31, 2020, and their primary contact (as indicated in their medical record).

Significance: Early identification of FMs at risk of SGR provides an opportunity for early intervention with the hope of preventing or reducing the severity of the SGR, but it also enables prioritization of those in greatest need, should demand exceed resources. Moreover, because we are still early in the pandemic, we are able to collect clinical data about the circumstances of the death, and consistently collect bereavement data for family members of people who died before and after the pandemic struck, and before and after the availability of virtual support groups. We therefore have a unique opportunity to conduct two natural experiments- studying the impact of the COVID pandemic on bereavement, and studying the effect of virtual support groups on symptoms.

BACKGROUND AND RATIONALE

When people die, it is normal for their bereaved family members (FMs) to experience grief. This grief usually diminishes, but in some cases FMs suffer from severe grief reaction (SGR) with intense yearning or separation distress, as well as emotional, cognitive and functional impairment lasting months or years.[1] SGRs have been variously labelled as Complicated Grief (CG)[2], Prolonged Grief Disorder (PGD)[3], or Persistent Complex Bereavement-Related Disorder (PCBRD[4], included in the Diagnostic Services Manual ver. 5), and may also feature other psychiatric morbidity such as depression or post-traumatic stress disorder (PTSD). SGRs are linked with declining health, use of healthcare resources, and even death.[5,6]

The COVID-19 pandemic has affected many aspects of end-of-life care, even for those who die of illnesses other than COVID-19. For those admitted to acute or long-term care, visitor restrictions have significantly impacted family presence in the final hours of life. Videoconferencing and telephone interactions are not feasible for many elderly or dying patients, and are not recommended when patients are actively dying.[7] Supportive interactions from healthcare providers are also limited by infection control measures. COVID-19 can also enhance feelings of guilt; FMs may have unwittingly transmitted COVID-19 during a visit, or the FMs may feel guilt for not having taken them out of a Long-Term Care facility prior to an outbreak.[8] All of these factors will likely increase the risk of SGR. Moreover, despite the increase in mortality rate caused by a pandemic, the disruption in normal services (e.g. cancer care) actually results in reduced use of hospice and palliative care[9], which are known to protect against SGR.[10]

Many bereaved FMs would appreciate bereavement support[4,11,12], and bereavement support has been identified as a clinical and research priority.[13,14] Yet few acute or long-term care settings (where most death occurs in Canada) have devoted resources toward bereavement screening or support,[15] so many FMs seek support from therapists or community-based bereavement groups outside of the public healthcare system.

There are effective treatments for established SGRs (i.e. >6 months post-death),[16] including individual psychotherapy tailored to Complicated Grief.[17] Group therapy may also be beneficial, as illustrated in a naturalistic controlled trial of bereavement counselling delivered through a community-based organization.[18] But these therapies may not be as effective during the pandemic; Glickman et al. found that feelings of guilt and avoidance were two of the most important mediating factors mediating the response to complicated grief treatment.[19] Since feelings of guilt appear to be common in COVID-19 deaths, and social distancing rules have the potential to reinforce avoidant behaviour, these could undermine the effectiveness of standard therapies.[20] More importantly, SGR treatments are usually based on in-person sessions; these are limited resources that may not be able to accommodate a major surge in SGR incidence triggered by the pandemic, and physical distancing rules would preclude their use in a pandemic.

Internet-based interventions have shown promise in preventing mental disorders[22] and treating symptoms of post-traumatic stress.[23] A randomized controlled trial of an email-based intervention was shown to improve complicated grief symptoms[24], with a high acceptance and low drop-out rate. Internet-based self-help interventions have also improved grief symptoms in bereaved older adults.[25] However, there is little data on the use of virtual group sessions as part of a bereavement support program- this is a critical gap in the literature, given that group therapy is one of the more accessible and scalable options available. Many community-based organizations are planning to provide their

usual support group sessions virtually, including Bereaved Families of Ontario, which has been supporting bereaved FMs for more than 40 years.

RESEARCH OBJECTIVES

1. Determine the impact of the COVID-19 pandemic on the bereavement experience of FMs.
2. Identify patient/FM characteristics indicating a high risk of SGR during the COVID-19 pandemic.
3. Assess the feasibility, acceptability and preliminary efficacy of virtual support groups (VSG).

METHODS

Design

We propose a mixed methods explanatory design, including both retrospective and prospective data collection. The quantitative components will principally consist of natural experiments to address objectives #1, #2, and #3. The qualitative components will deepen our understanding of the impact of COVID-19 on bereavement (Objective #1), while a providing formative evaluation for the VSG (Objective #3).

Study Setting

Study subjects will include all patients who died in an acute care facility in Ottawa (The Ottawa Hospital, Queensway-Carleton Hospital, and Hôpital Montfort) from November 1st, 2019 to August 31st, 2020, and their contacts (as indicated in their medical record). The Virtual support groups will be organized by Bereaved Families of Ontario – Ottawa through a virtual platform.

Study Participants

We will collect retrospective data from approximately 550 deceased patients. We plan to recruit approximately 200 FMs for the prospective portion of the study with an expected 100 FMs participating in the VSG and 20 FMs in the qualitative interviews. Note that family members will participate in the virtual support group as part of routine care available to them – the support group is not a study-specific intervention, nor will any research team members be involved in the administration of the virtual support group. The scope of the research study related to the virtual support group is to a) inform the 200 bereaved family participants about the support group, so that they may seek out this care available to them and b) conduct qualitative interviews with 20 participants who attended the virtual support group. As such, while we will obtain consent for conducting the qualitative interviews, consent will not be obtained for participation in the virtual support groups.

Phase 1: Retrospective chart review

We will abstract clinical information from the medical records of all patients who died in an acute care hospital in Ottawa from November 1st, 2019 to August 31st, 2020.

<u>Data Collection</u>
A trained and experienced research assistant will abstract clinical data related to the patient's admission, including admitting service, sex, gender, admitting source, diagnosis, comorbidities, resuscitative measures, presence of family at or soon before the time of death, comfort medications

ordered/used, and the involvement of the palliative care consultation team. De-identified data will be entered into the secure OHRI Electronic Data Capture System (EDCS) platform to allow consolidated data collection across all participating sites. Data transferred from each site into the EDCS will be limited to non-identifying information, with the exception of age, sex, gender, date of hospital admission (to calculate length of time in hospital), date of death (to calculate hospital length of stay and to establish the amount of time from patient death to when the Phase 2 questionnaires – see below –are completed by family members), and medical history. These variables are required for sub-group data analysis and for inclusion in regression models.

Each site will additionally have a local participant Master File which includes the study ID, patient name, medical record number (MRN), date of birth, and a column indicating whether or not the participant's chart abstraction has been completed and data entered into the online data collection platform (EDCS). Patient name and MRN are needed for data verification and to facilitate accurate chart review. Date of birth is required to calculate age.

Performance Measurement, Health Records, or Decision Support departments at each site willy be consulted as needed to assist in data collection and for decedent cohort (i.e.study sample) identification.

Phase 2: Prospective Bereavement Data Collection

We will offer enrolment to the FM contacts indicated in the medical record of each patient who were identified in the retrospective chart review, beginning at minimum 6 months after the death of the patient. A list of FM contact names, phone number, and relationship to the deceased patient will be generated to all research assistants to contact FMs and offer study enrollment. For FMs who agree to enroll (our previous study found a 40-50% enrolment rate)[10], we will collect basic demographic, mental health, and spirituality data similar to our previous work, as well as focused assessments of grief and relationships:

- The Brief Family Relationship Scale (BFRS)[27] to determine closeness of FM to the deceased
- The Inventory for Complicated Grief-revised (ICG-r)[28] to determine the severity of their grief symptoms. Those who enrol will complete the ICG-r at baseline (upon enrollment) and again 6-months later. A recent meta-analysis of psychological interventions for grief suggestd that the ICG-r is superior to other grief measurement tools for measuring the effect of bereavement interventions.[29]

Phase 3: Virtual Support Groups

FMs who participate in the prospective bereavement data collection (i.e. Phase 2) will be invited to attend a virtual support group (VSG) led by Bereaved Families of Ontario- Ottawa (BFO). In pre-COVID times, BFO presented monthly "*Support and Share*" nights with guest speakers, followed by breakout peer support groups for all different types of losses: loss of child, spouse, parent, loss by suicide, etc. These groups are facilitated by trained volunteers with a shared loss and include between 75 and 150 participants. These Support and Share Nights serve as intake sessions- interested participants from the breakout groups can attend "*Closed Groups*" where a smaller group of participants (up to 12) explore their grief more deeply. These run over 8-10 consecutive weeks with the same group of participants. They are led by trained facilitators who have experienced similar losses. Each week has a different theme, based on evidence-based components of bereavement support (e.g. writing a letter to the deceased). The sessions were put on hold in March by the pandemic, but

BFO plans to begin holding these *Closed Groups* by videoconference (these will be the VSGs) again in September 2020.

All participants in the prospective bereavement data collection component of this study will be invited to participate in the VSGs (see approved Virtual Support Group Information Sheet), regardless of the severity of their symptoms. Those with severe symptoms (indicated by an ICG-r score >25)[29] will be notified that their symptoms are considered to be severe, with a suggestion to attend the VSGs. A recent meta-analysis of psychological interventions for grief found higher effect sizes in studies of participants who were >6 months post-loss, and those with higher baseline symptom levels.[29] However, no participant in our study will be randomized to any treatment assignment, and the decision to attend the VSG will be left to the FM. Family members will participate in the virtual support group as part of routine care available to them by BFO. The support group is not a study-specific intervention, nor will any research team members be involved in the administration of the virtual support group, and no data will be collected from the virtual support group online sessions. The scope of the research study related to the virtual support group is to a) inform the 200 bereaved family participants about the support group, so that they may seek out this care available to them and b) conduct qualitative interviews with 20 participants who attended the virtual support group (see Phase 4 below). As such, while we will obtain consent for conducting the Phase 2 questionnaires and the Phase 4 qualitative interviews, consent will not be obtained for participation in the virtual support groups. Any participant who expresses suicidal ideation or intention, or other concerning features of severe grief reaction, will be referred for urgent assessment and professional support through their family physician or the emergency department, as per usual practice with BFO.

Phase 1-3: Quantitative Data Analysis

To address research objectives #1 and #2, we will divide the patients (and FMs) into three groups:

a. Pre-COVID: Deaths that occurred in an acute care hospital before the impact of the pandemic was first felt in Ottawa (November 1st, 2019-February 29th, 2020): approximately 160 patients.
b. COVID: Deaths that occurred in an acute care hospital due to COVID-19 (March 1st – August 31st, 2020). Approximately 250 COVID-19 deaths have been reported between January and June 2019 in Ottawa by Ottawa Public Health, of which preliminary data suggestapproximately 80 patients died in acute care.
c. Non-COVID: Deaths that occurred in an acute care hospital between March 1st – August 31st, 2020 but were not COVID-19 related: approximately 160 patients.

To assess the overall impact of the pandemic, we will perform statistical comparisons of clinical and end-of-life care metrics for the Pre-COVID vs. COVID and Non-COVID groups combined. Patients will be matched based on their health and demographic profiles in a 2:1:2 ratio (2 decdenets in pre-COVID period: 1 decedent during the pandemic who died of COVID-19: 2 decedents who died during the pandemic of non-COVID-19 causes). We will compare the COVID vs. Non-COVID groups to determine how much of the impact was specifically associated with COVID infection as opposed to the pandemic in general. Pairwise comparisons will be performed using an unpaired t-test or Mann-Whitney test as appropriate for the distribution of the data. We will then also use logistic regression analysis to identify factors associated with an ICG score >25 (i.e. severe scores).

To address research objective #3, we will compare the changes in ICG scores between baseline and 6-months post-baseline for FMs who did versus did not participate in the VSGs (i.e. the difference in differences). This comparison is important since grief symptoms typically improve over time even without intervention. In addition, group allocation is not random and so our analysis may be

confounded by the possibility that people who choose to participate in support groups have more severe symptoms.[22] We will therefore perform an adjusted analysis similar to Newsom et al. in their naturalistic controlled trial of community-based bereavement support.[18] We will estimate an average score for the outcome variable at each time point for the support-group and no-support-group (control) conditions. Where baseline differences in clinical, demographic or loss-related variables exist, these variables will be added as covariates. Assumptions of linearity, multicollinearity, homoscedasticity, and normality of residuals will be tested prior to analysis.

Phase 4: Family Member Interviews

To addess research objectives #1 and #3, FMs who participated in a VSG will be invited to participate in semi-structured interviews to determine how the FM perceived their loved one's end-of-life experience, their own bereavement experience, the usefulness of the VSG, and successes and challenges of the intervention. Approximately 20 interviews will be conducted, or until thematic saturation is reached. We will use maximum variation sampling based on grief severity (ICG scores), participant demographics, and whether or not the participants loved one died of COVID-19 versus other causes.

Semi-structured interviews will also be conducted with bereaved family members who did not attend any VSGs. This will be done to better understand their loved one's end-of-life experience, their own bereavement experience, their experiences of facilitators or barriers to attending VSGs, their reasons for not attending the VSG, and how they coped overall with their loss (e.g., the use of other coping strategies).

Qualitative Data Analysis

Qualitative interviews will be transcribed verbatim. Using an iterative thematic analysis,[30] a qualitative researcher will apply open coding (facilitated by ATLAS.TI software) to inductively find emerging themes and group them together based on labels relevant to the interviews or bereavement literature. The team will then discuss the emerging themes and interpret the qualitative findings for analysis with the retrospective and quantitative findings. Themes related to the VSGs will be fed back to the BFO facilitators as a formative evaluation to guide revisions to the conduct of the VSGs.

RECRUITEMENT & CONSENT

Recruitment will be necessary for the prospective portion of the study that involves family members participation. Family members will be asked to provide verbal consent to provide basic demographic information and complete questionnaires over the phone or secure online platform. Each participant who provides verbal consent will be invited to participate in a virtual support group that is provided by BFO-Ottawa outside of this research study. Family members who participated in the VSG will be invited to participate in a qualitative interview about their experience of the VSG – a separate, additional informed consent form will be provided to these participants. In addition, family members who did not participate in any VSGs will be invited to participate in a qualitative interview enquiring about their reasons for not attending – participants will be reconsented if they choose to take part in these interviews.

We will offer enrolment to the contacts of each patient who were identified in the retrospective chart review. Only family members of patients deceased between November 1st, 2019 to August 31st, 2020 from the three participating sites will be eligible to participate in the study. Contact information (name,

relationship, and phone number) of potential participants will be taken from the FM contacts listed on the deceased patient's medical record. A research staff member will call the bereaved family members to explain the project. Family members will be asked to verbally consent to the first phase of the study which includes the demographic and grief questionnaires.

Following the completion of the questionnaires, participants who are interested in being involved in the subsequent phases of the study will provide phone/video consent to participate in a qualitative interview, and will also provide their address so the research team member can mail the copy of the consent form to the participant.

KNOWLEDGE TRANSLATION AND DISSEMINATION PLAN

Feasibility and scalability are key factors for future knowledge translation (KT) and dissemination. Partnering with BFO-Ottawa for their VSGs will allow for rapid implementation of the intervention, with potential scalability of the approach to other BFO chapters across Ontario and partner organizations across Canada. We will also be working with Canadian Virtual Hospice (CVH), which is world-renowned for their web-based end-of-life and bereavement support tools, such as mygrief.ca. Building on the findings from this study, our team plans to collaborate with the Ontario Centre for Learning, Research and Innovation in Long-Term Care at Bruyère (CLRI), which has a strong presence in Long-Term Care and works to implement effective interventions to improve quality of care and quality of life. As >80% of COVID deaths have taken place in LTC residents, CLRI will help to ensure engagement of the bereaved from these as we believe it is important to work alongside of them to ensure that proper bereavement support resources can be accessed by residents who have lost friends in LTC homes and their families. CLRI will be important in the dissemination of the virtual support program in future to long-term care homes that have been particularly hit by COVID-19. Our team will also work with Champlain Hospice Palliative Care Program that works across LTC, hospice, hospital and community to coordinate a full and cohesive response to palliative care and bereavement.

TIMELINE

	2020				2021									
Month	**S**	**O**	**N**	**D**	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**
Ethics Approval (September-November 2020)														
Phase I: Retrospective chart review (Quantitative- October 2020 – February 2021)														
Phase II: Prospective Bereavement Data Collection (Quantitative- October-December 2020, April-June 2021)														
Phase III: Virtual Support Groups (October 2020 – March 2021)														
Quantitative Data Analysis (June – August 2021)														
Phase IV:FM Interviews (November 2020 – June 2021)														
Qualitative Data Analysis (January - August 2021)														
Knowledge Translation and Dissemination (August -October 2021)														

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