STUDY PROTOCOL

COVID-19 IDD: A global survey exploring the impact of COVID-19 on individuals with intellectual and developmental disabilities and their caregivers [version 1; peer review: 1 approved, 1 approved with reservations]

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Abstract
Background: This protocol outlines research to explore the impact of coronavirus disease 2019 (COVID-19) on individuals who have intellectual and developmental disabilities and their caregivers.
Evidence suggests that people with intellectual and developmental disabilities experience disparities in healthcare access and utilisation. This disparity was evident early in the pandemic when discussions arose regarding the potential exclusion of this population to critical care.

**Methods:** An anonymous online survey will be conducted with caregivers, both family members and paid staff, to explore the impact of COVID-19 on this population in terms of demographics, living arrangements, access to services, the impact of social distancing, and also carer wellbeing. The survey will be developed by the research team, many of whom are experts in intellectual disability within their own jurisdictions. Using back-translation our team will translate the survey for distribution in 16 countries worldwide for international comparison. The survey team have extensive personal and professional networks in intellectual disability and will promote the survey widely on social media with the support of local disability and advocacy agencies. Statistical descriptive and comparative analyses will be conducted. Ethical approval has been obtained for this study from University College Dublin's Human Research Ethics Committee (HS-20-28-Linehan).

**Dissemination:** Study findings will be prepared in a number of formats in order to meet the needs of different audiences. Outputs will include academic papers, lessons learned paper, practice guidelines, reports, infographics and video content. These outputs will be directed to families, frontline and management delivering disability services, national-level policy makers, healthcare quality and delivery authorities, national pandemic organisations and international bodies.

**Keywords**
Caregivers, Carers, Coronavirus, COVID-19, Health Disparity, Intellectual and Developmental Disability, Intellectual Disability, Pandemic

This article is included in the Coronavirus (COVID-19) collection.
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Introduction

Intellectual and developmental disability is a term, growing in usage, which acknowledges that intellectual disability is often accompanied by other disabilities including, but not limited to, sensory disability, speech and language difficulties, seizures, behavioural disorder, or difficulties with movement\(^1\). Intellectual disability is diagnosed as deficits in intellectual functioning, deficits in adaptive behaviour, and onset during the developmental period\(^2\). An estimated 1% of the world’s population has intellectual disability with higher proportions living in low income countries\(^3\). Using a global population of 7.7 billion\(^4\), it can be estimated that approximately 77 million persons worldwide live with intellectual disability, many of whom will present with additional disabilities such as those listed above.

A paradigm shift in models of disability emphasises the critical need for appropriate support to be available to people with intellectual disability. This position advances previous understandings of disability as either a medical condition requiring a ‘treatment’ or ‘cure’\(^7\), or as a social concept requiring attitudinal and environmental change\(^8\). Developed by the American Association on Intellectual and Developmental Disabilities, the support needs model argues that good quality outcomes for people with intellectual disabilities are a function of the support they receive, or ‘put another way, if supports were removed, people with ID (intellectual disability) would not be able to function as successfully in typical activities and settings’\(^9\). The COVID-19 pandemic has disrupted access to supports typically received by people with intellectual and developmental disability and has placed additional challenges on mainstream systems to make adjustments to accommodate need. The impact of these challenges has yet to be empirically assessed.

The United Nation’s Convention on the Rights of Persons with Disabilities affirms the right of persons with disabilities to full inclusion and participation in all aspects of life, charging signatories to the Convention with organising, strengthening and extending support services. Addressing the need for full inclusion, global efforts in deinstitutionalisation have resulted in growing numbers of individuals with intellectual and developmental disability being moved from institutional settings to the community to live in their own home, or in small dispersed community housing often owned by agents such as disability services or mainstream social services\(^10,11\). Paid staff provide various levels of support from drop-in to 24/7. Across all settings, including the family home, there is evidence that appropriate support, drawing on practices such as Active Support, are necessary to promote good quality of life outcomes\(^12,13\). Caregivers therefore play a critical role in the current pandemic. Among many concerns are the impact of caregivers contracting the virus, the challenge of ensuring continuity of care for those who live in community settings, and the situations of those who live and work within large institutional settings.

Article 25 of the Convention specifically affirms the right of persons with disabilities to enjoy the highest attainable standard of health without discrimination on the basis of disability. Despite this protection, many individuals with intellectual and developmental disability experience significant disparities in the prevalence of adverse health conditions and behavioural disorder, attention to healthcare needs, preventative care/health promotion activities, and access to health care\(^14\). These disparities were brought into sharp focus by a UK confidential inquiry into mortality which revealed that avoidable deaths from causes amenable to change by good quality healthcare are twice as likely among this population when compared to the general population\(^15\). As the COVID-19 pandemic evolves, questions have arisen in the US regarding the legality of specifically withholding COVID-19 treatment from individuals with severe intellectual disability\(^16\). Questions have also arisen in the UK where COVID-19 guidelines produced by the National Institute for Health & Care Excellence were deemed to reduce access to critical care for those with intellectual and developmental disabilities, forcing an immediate modification\(^17\).

The present study aims to collect survey data on the experiences of individuals with intellectual and developmental disability and their caregivers during the COVID-19 pandemic throughout 16 international jurisdictions. To the authors’ knowledge this will be the first international dataset documenting the situation of this population during a pandemic.

Protocol

This research study comprises an international survey of caregivers of individuals with intellectual and developmental disability conducted by an international network of academics and practitioners. The research team will develop and disseminate an anonymous online survey for completion by caregivers addressing two core questions. Firstly, what is the impact of the COVID-19 pandemic on individuals with intellectual and developmental disability and their caregivers, for example, in access to healthcare and impact of restrictive practices? Secondly, do differences exist in the experiences of those living in different living arrangements and in different international jurisdictions?

The Principal Investigator is Chair of the Comparative Policy and Practice (CPP) special interest group of IASSIDD, the International Association for the Scientific Study of Intellectual and Developmental Disabilities, the leading professional association in the intellectual and developmental disability field. The CPP membership includes some of the foremost intellectual disability researchers in their respective countries who have previous experience collaborating on research. This group has been supplemented by non-CPP members who bring other expertise to the project including data management, data analysis and translation skills.

To promote clear communication and understanding among the study team, a logic model has been developed outlining the study’s inputs, activities, outputs, short-term outcomes and long-term outcomes. The model provides a useful graphic to concisely encapsulate key areas of the study. The logic model is presented in Figure 1 below.
Design
This study is a cross-sectional, anonymous, online survey of adult caregivers, comprising family members and paid staff, who support individuals with intellectual and developmental disabilities. This open survey will be hosted online using the platform Qualtrics Core XM™. The study team, representing 16 countries - Australia, Brazil, China, Czech Republic, France, Greece, India, Ireland, Japan, Netherlands, Norway, Portugal, Spain, UK, US, and Zambia - will play a key role in creating awareness of the survey in their countries. It is hoped that additional countries may participate if representatives with expertise in this field can be sourced. Additional ethical approval will be sought, as required, for their inclusion.

An advisory group, comprised of a number of study team members, will be established to ensure standardisation in the promotion of the survey. A promotional pack will be developed to include a note outlining the background of study, its purpose and global reach, survey inclusion criteria, ethical approval as well as the study team and funder. A link and a QR code to the survey will also be provided.

Recruitment of study participants
The participants in this study will self-select to complete the online survey. To facilitate recruitment the study team will engage in a number of activities to promote awareness of the survey and consequently notify caregivers about the survey. Firstly, members of the study team will compile a list of relevant disability and advocacy organisations within their countries. The target organisations include those that provide services and support to individuals who have intellectual and developmental disabilities or their family members, ranging from formal state services to informal social media support groups. Promotional information will be shared by the team members in their respective countries and following this, organisations will be invited to disseminate a survey link to staff and more widely through their communication and social media channels. As the study team includes intellectual disability experts in their respective countries, it is anticipated that they can encourage disability and advocacy agencies within their jurisdictions to promote the survey. The study team also anticipates the survey will ‘go viral’ whereby information will snowball beyond the immediate efforts of the team. Similar online surveys of the general population’s experiences during the pandemic have successfully employed this methodology, enjoying high response rates.

Sample size calculation
Attempts to determine sample size are challenging. Firstly, to the authors’ knowledge no international online survey of caregivers
has previously been undertaken during a pandemic which might provide a reliable estimate. Secondly, in many countries the numbers of persons with intellectual and developmental disabilities and the numbers of caregivers is unknown. Ireland, as the lead country in this research, has data available on the numbers of persons with intellectual disability and caregivers from the national census, which in 2016 were recorded as 66,611 and 195,263 respectively, albeit the latter figure is for all caregivers, not just those supporting people who have intellectual and developmental disabilities. Figures for those employed in disability services are equally challenging as, in Ireland, they are reported as Whole Time Equivalent posts rather than individual staff members. To December of 2019, a total of 18,515 Whole Time Equivalent posts were reported working in disability services in Ireland. Attempting to determine the proportions of caregivers who provide support for persons with intellectual and developmental disabilities, and the actual number of personnel who provide staff support to this population is speculative and therefore has not been determined. Given that sample size calculations are required to determine if sufficient statistical power is available to researchers, it can be argued that if an average of 200 individuals participate in this survey from each of the jurisdictions, the combined sample of 3,200 responses would be more than sufficient to provide the statistical power for any analyses.

Survey Instrument
The anonymous online survey will use only closed quantitative items. While the survey is presented to participants in different languages, the survey software, Qualtrics, enables participants to enter their data onto one global dataset. The survey will comprise seven sections, exploring: characteristics of respondents (e.g. gender, age, status of family member or staff); characteristics of person(s) supported (e.g. level of intellectual disability, presence of additional disability, living arrangements); local practices during the pandemic in family home or workplace (e.g. restrictions to typical activity, introduction of new practices, equipment); access to information and training; experience of symptoms, testing, treatment; impact of social distancing; two standardised scales for caregivers measuring mood and the impact of pandemic. Piloting will determine if the format and length of survey is appropriate. Using a process of back translation, the study team will translate the survey into local languages.

Outcome Measures
The primary outcome of interest in this survey is the impact of the pandemic on individuals with intellectual disability and their caregivers. Outcomes for people with intellectual and developmental disability are explored generally throughout the survey, but specifically in questions relating to access to health services and protective equipment, continuity of care, adverse impact of restrictions and questions relating to their experiences of symptoms, testing and treatment. Outcomes for caregivers are also explored generally throughout the survey, but specifically in questions relating to mood and impact, using the DASS 21 and Coronavirus Anxiety Scale, and questions relating to their experiences of symptoms, testing and treatment.

Data analysis and statistical plan
All data will be analysed using IBM SPSS Version 26 statistical software. Descriptive, comparative, bivariate and multivariate analysis will be conducted to document the circumstances of the respondents and the people they support. Of particular interest are comparative analyses to explore trends by different living arrangement and different jurisdictions.

Ethics
Ethical approval for the study has been obtained from the host institution University College Dublin [HS 20-28-Linehan]. The study team will each assess the requirement for ethical approval within their own jurisdiction. It is not envisaged that the study team will apply for ethical approval from individual disability agencies as to do so would take considerable time and would likely create a circle of amendments which would collectively need to be agreed by all parties. It is also important to note that this research is an anonymous survey. There is no opportunity for participants to identify either themselves or the organisations they work for or engage with.

The study team acknowledge the sensitive nature of this topic and identified a number of ethical issues to the ethical approval body with actions to respond to each issue. Individuals who have intellectual and developmental disability, or support a person or persons with intellectual and developmental disability, may have experienced adverse effects to social distancing, may have contracted the virus or know of family and/or friends who did, and indeed may have experienced the death of family and/or friends to the virus. Reflecting on their experiences, and the experiences of those they support, it is possible that some participants may become distressed when completing the survey. For this reason, participants are directed to national and/or local support services should they wish to avail of support.

The study team is also cognisant of the fact that participants may be aware of cases of abuse, neglect and/or exploitation during this period. Given the anonymous nature of the survey, and the use of closed items, participants will be unable to detail these experiences to the study team. Instead, participants will be advised to direct any such concerns to the appropriate relevant authorities which will be identified for their attention.

The study team acknowledge that the study does not involve people with intellectual and developmental disabilities in its design or collection of data instead relying on proxy perspectives and experiences of family members and staff. This is a limiting factor as critical experiences and views will be missing from the findings. The study team is aware of the perceptual and experiential differences between individuals and their caregivers; however, due to the complexity of the study, the challenges of collecting data from individuals with low literacy and often limited access to digital technology; and the short time frame, this study is unable to satisfactorily address this issue.

Finally, ethical issues arise regarding the security and anonymity of the online survey, notably as participants are informed that the dataset will be uploaded to an open data portal for use by other
researchers. To address these issues, the study team will develop an anonymous survey, without collecting IP addresses that may provide a link to participation, and will use closed response items to ensure that no communication that may be identifiable can be received from participants. The survey is hosted on the Qualtrics platform which has been successfully used in previous large-scale surveys by the lead institution, University College Dublin in Ireland.

**Data management and dissemination**

A comprehensive data management plan will be developed by the study team and all data gathered will be shared on an approved data repository. The data management plan is due for publication on the HRB Open Research in Month 3 of the project. In preparation for this, the study team used an adapted version of the Data Value Map\(^2\), as a discursive template to facilitate a conversation about the data management requirements for this study. In line with the HRB Data Management Planning template, issues relate to data collection, data storage, data analysis, data sharing and preservation, and ethical and legal requirements, as well as who will be responsible for each stage. This discussion helped to forge an appreciation of the open research lifecycle among the study team and the value that will accrue from this process. A visualisation of this plan, developed by Gail Birkbeck (co-author), is presented in Figure 2.

When completed, this study will be reported using CHERRIES: Eysenbach G. Improving the quality of Web surveys: the Checklist for Reporting Results of Internet E-Surveys (CHERRIES). J Med Internet Res. 2004; 6(3):e34.

**Study status**

This study has not yet commenced data collection.

**Conclusion**

Despite the protections of the UN Convention on the Rights of Persons with Disability, people with intellectual and developmental disabilities are at risk of health disparities when compared with the general population. This study aims to gather international data on the experiences of individuals with intellectual and developmental disabilities and their caregivers during

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**Figure 2.** Visualised data management plan for coronavirus disease 2019 (COVID-19) intellectual and developmental disabilities (IDD) research project.
the COVID-19 pandemic. These data will provide a first glimpse of the challenges which arose for this population and their caregivers during the pandemic. Of particular interest is whether experiences varied by living arrangement and by country, and whether lessons can be learned to inform policy and practice for future pandemics. By depositing the anonymous dataset on an open forum, other researchers are encouraged to continue the exploration of these data.

Data availability
Underlying data
No data are associated with this article.

References

Open Peer Review

Current Peer Review Status: ✔️ ✗

Version 1

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The research protocol as described is well planned and organized. The topic is of eminent relevance with regard to health provision and equal opportunities for people with intellectual disability in a period of pandemic. Though the authors do not mention it, the research as planned refers directly to article 11 of the UN-CRPD.

Having said this, we have to address one major concern and several additional issues listed below:

Major concern:

- Authors state that the main goal of the study is to assess the experience and the impact of the pandemic of and on persons with ID and their caregivers. However, persons with ID are not directly included in the study. We highly recommend the consortium to respect the requirements of the UN-CRPD and adhere to the principle “nothing about us without us”. We agree that it will take special effort to include persons with ID as direct participants in the study. However, the pandemic is not a good reason to exclude persons with ID from the study. Without the direct experience as expressed by persons with ID the study findings will be of limited impact. We therefor demand the consortium for a change and include people with ID in an acceptable way in the sample. In countries like the UK, Ireland, Australia, the Netherlands, Norway and France with substantial advances and supports for self-advocates this inclusion is more than realistic!

Further aspects:

1. We suggest to reflect on sample representativeness in a differentiate way. Even if in most countries, there is only fragmented knowledge about the characteristics of the sample, data collection should aim at some kind of representativeness. Otherwise, results cannot be generalised, and their full potential will remain unfolded. A representative sample might be randomly selected from a larger dataset after data collection, resulting in a stratified
sample. Further, authors are not quite consistent when offering general epidemiological data on people with ID data in the first section of the introduction, and stating later in the section of sample size that the number of people with ID remains unknown in many countries.

2. Considering the statistical analysis, the fact that the total sample in this study will be far beyond 1,000 persons has to be addressed in the study protocol. We highly recommend authors not to use p-values for any interpretation. Using p-values for interpreting results is never advisable with this sample size though unfortunately still frequently done. With such a large sample size, every test will be “statistically significant” with p-values < 0.01. However, this would be an artefact resulting from the large samples size. Thus, we strongly recommend making use of effect sizes for interpretation, as they are independent of sample size.

3. We have some concerns with using only closed questions for data collection. The study design has the potential to explore all kinds of matters arising in relation to the pandemic, even aspects that may not have been on the authors’ minds. Thus, including open-ended questions will provide the opportunity to address aspects not specifically selected primary to data collection.

4. Finally, we advise authors to go more into detail with dissemination. The impact of the study will be highly dependent on a dissemination plan including various stakeholders. Many dissemination frameworks available can guide dissemination activities. Thank you for offering us the opportunity to review this study protocol. May the consortium understand our concerns and recommendation in the way to transform a good study protocol in an excellent one!

Is the rationale for, and objectives of, the study clearly described?  
Partly

Is the study design appropriate for the research question?  
Partly

Are sufficient details of the methods provided to allow replication by others?  
Yes

Are the datasets clearly presented in a useable and accessible format?  
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Psychology and intellectual Disability. Health promotion and disability. Disability and inclusive research.

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however we have significant reservations, as outlined above.
The proposed study is critically important and timely; the authors/survey planners are commended for their speed in developing an approach to assess the impact of COVID-19 on a population that often gets forgotten. The article is well-written, incorporates many of the concerns that are being voiced now, and proposes to generate data that will provide valuable information.

Questions re: Appropriate Design relate to:

1. What efforts will be made to reflect any degree of representativeness in the sample (e.g., comparison with what is known about persons with IDD in each country)? Without some understanding of representativeness, how will findings be interpreted, and interpreted across countries? Will any options be available for responses from persons who do not have internet access?

2. The respondents will necessarily be those who have not become ill or very ill or died due to COVID-19. Will any data be available on hospitalizations or deaths to complement the survey findings?

3. The issue of only carer responses is a concern, as noted by the authors. Was thought given to supplementing with case studies with persons with IDD to capture some of their expressed experiences?

Questions re: Sufficient Details relate to the survey questionnaire still under development.

Because this is a prospective proposal, several comments are added for consideration:

1. Potential impact - in addition to the outcomes to be measured, will there be any questions related to value of training or materials for persons with IDD and carers in learning how to understand and cope with COVID.

2. Any other opportunities for collecting information on “valuable practices”?

3. The public health, medical, and general communities are learning so much about the disease as we gain more experience with it. Will information for each country be “time-stamped” in some way (e.g., date? Or time relative to when the virus became more prevalent in their country?)

4. What information will be collected about their current situation, such as access to clean water in low and middle income countries, or opportunities for social distancing in densely populated urban settings?
Thank you for the opportunity to comment.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Partly

Are sufficient details of the methods provided to allow replication by others?
Partly

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Disability and public health; disability epidemiology and policy; data for health equity and IDD.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.