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STUDY PROTOCOL



COVID-19 Unmasked Global Collaboration Protocol: longitudinal cohort study examining mental health of young children and caregivers during the pandemic

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ABSTRACT

Background: Early empirical data shows that school-aged children, adolescents and adults are experiencing elevated levels of anxiety and depression during the COVID-19 pandemic. Currently, there is very little research on mental health outcomes for young children.

Objectives: To describe the formation of a global collaboration entitled, 'COVID-19 Unmasked'. The collaborating researchers aim to (1) describe and compare the COVID-19 related experiences within and across countries; (2) examine mental health outcomes for young children (1 to 5 years) and caregivers over a 12-month period during the COVID-19 pandemic; (3) explore the trajectories/time course of psychological outcomes of the children and parents over this period and (4) identify the risk and protective factors for different mental health trajectories. Data will be combined from all participating countries into one large open access cross-cultural dataset to facilitate further international collaborations and joint publications.

Methods: COVID-19 Unmasked is an online prospective longitudinal cohort study. An international steering committee was formed with the aim of starting a global collaboration. Currently, partnerships have been formed with 9 countries (Australia, Cyprus, Greece, the Netherlands, Poland, Spain, Turkey, the UK, and the United States of America). Research partners have started to start data collection with caregivers of young children aged 1–5 years old at baseline, 3-months, 6-months, and 12-months. Caregivers are invited to complete an online survey about COVID-19 related exposure and experiences, child's wellbeing, their own mental health, and parenting.

Data analysis: Primary study outcomes will be child mental health as assessed by scales from the Patient-Reported Outcomes Measurement Information System – Early Childhood (PROMIS-EC) and caregiver mental health as assessed by the Depression Anxiety Stress Scale (DASS-21). The trajectories/time course of mental health difficulties and the impact of risk and protective factors will be analysed using hierarchical linear models, accounting for nested effects (e.g. country) and repeated measures.

Protocolo de colaboración global COVID-19 desenmascarado: estudio de cohorte longitudinal que examina la salud mental de niños pequeños y cuidadores durante la pandemia

Antecedentes: Los primeros datos empíricos muestran que los niños en edad escolar, los adolescentes y los adultos están experimentando niveles elevados de ansiedad y depresión durante la pandemia de COVID-19. Actualmente, hay muy poca investigación sobre los resultados de salud mental de los niños pequeños.

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lactante; preescolar; niño pequeño; adulto; pandemia de COVID-19; salud mental; bienestar; crianza de los hijos; factores de riesgo; colaboración global

关键词

婴儿; 学龄前; 幼儿; 成人; COVID-19 疫情; 心理健康; 身心健康; 风险因素; 全球合作


HIGHLIGHTS

- This article describes the formation of a global collaboration between 9 countries that are collecting data to examine mental health outcomes for young children (1 to 5 years) and caregivers over a 12-month period during the COVID-19 pandemic.

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Objetivos: Describir la formación de una colaboración global titulada ‘COVID-19 Desenmascarado’. Los investigadores colaboradores tienen como objetivos (1) describir y comparar las experiencias relacionadas con COVID-19 dentro y entre países; (2) examinar los resultados de salud mental de los niños pequeños (de 1 a 5 años) y los cuidadores durante un período de 12 meses durante la pandemia de COVID-19; (3) explorar las trayectorias/temporalidad de los resultados psicológicos de los niños y los padres durante este período e (4) identificar los factores de riesgo y de protección para las diferentes trayectorias de salud mental. Los datos de todos los países participantes se combinarán en un gran conjunto de datos transculturales de acceso abierto para facilitar más colaboraciones internacionales y publicaciones conjuntas.

Métodos: COVID-19 Desenmascarado es un estudio de cohorte longitudinal prospectivo en línea. Se formó un comité directivo internacional con el objetivo de iniciar una colaboración global. Actualmente, se han formado asociaciones con 9 países (Australia, Chipre, Grecia, Países Bajos, Polonia, España, Turquía, Reino Unido y Estados Unidos de América). Los socios de investigación han comenzado la recopilación de datos con los cuidadores de niños pequeños de 1 a 5 años al inicio, a los 3 meses, a los 6 meses y a los 12 meses. Se invita a los cuidadores a completar una encuesta en línea sobre la exposición y las experiencias relacionadas con COVID-19, el bienestar del niño, su propia salud mental y parentalidad.

Análisis de datos: Los resultados primarios del estudio serán la salud mental infantil según la evaluación de las escalas del Sistema De Información De medición de Resultados Informados Por El Paciente – Primera Infancia (PROMIS-EC) y la salud mental del cuidador según la evaluación de la Escala de estrés, ansiedad y depresión (DASS-21). Las trayectorias/temporalidad de las dificultades de salud mental y el impacto de los factores de riesgo y de protección se analizarán utilizando modelos lineales jerárquicos, teniendo en cuenta los efectos anidados (por ejemplo, el país) y las medidas repetidas.

COVID-19 Unmasked 全球合作协议: 考查疫情期间幼儿和看护人心理健康的纵向队列研究

背景: 早期经验数据表明, 在 COVID-19 疫情期间, 学龄儿童, 青少年和成人的焦虑和抑郁水平升高。目前, 关于幼儿心理健康结果的研究很少。

目的: 描述名为 ‘COVID-19 Unmasked’ 的全球合作的形成。合作研究者旨在 (1) 描述和比较国家内部和国家之间的 COVID-19 相关经验; (2) 考查 COVID-19 疫情期间 12 个月中幼儿 (1 至 5 岁) 和看护人的心理健康结果; (3) 探索这一时期儿童和父母心理结果的轨迹/时间进程, 以及 (4) 确定不同心理健康轨迹的风险和保护因素。来自所有参与国的数据将合并为一个大型开放访问跨文化数据集, 以促进进一步的国际合作和联合出版。

方法: COVID-19 Unmasked 是一项线上前瞻性纵向队列研究。成立了一个国际指导委员会, 旨在开展全球合作。目前, 已与 9 个国家 (澳大利亚, 塞浦路斯, 希腊, 荷兰, 波兰, 西班牙, 土耳其, 英国和美利坚合众国) 建立了伙伴关系。研究合作伙伴已开始基线, 3 个月, 6 个月和 12 个月时与 1-5 岁幼儿看护人的数据收集。邀请看护人完成一项关于 COVID-19 相关暴露和经历, 儿童身心健康, 个人心理健康和教养方式的线上调查。

数据分析: 主要研究结果将是根据患者报告结果测量信息系统——童年期早期 (PROMIS-EC) 的量表评估的儿童心理健康和由抑郁焦虑应激量表 (DASS-21) 评估的看护人心理健康。将使用考虑嵌套效应 (例如国家) 和重复测量的分层线性模型分析心理健康困难的轨迹/时间进程以及风险和保护因素的影响。

The 2019 Novel Coronavirus (COVID-19) pandemic is a globally disruptive event that has so far resulted in > 120 million confirmed cases and > 2.6 million deaths all over the world (World Health Organization, 2021 COVID-19 Dashboard, 17 March 2021). Countries have instituted mandatory lockdowns, enforced movement restrictions, and required physical distancing measures. Chronic fear and uncertainty about the widespread health risks, potential life threat, constant reappraisal and adaption to risk, ongoing financial and employment impacts, and social isolation has contributed to a sense of loss of safety and control, anger, disillusionment and escalating emotional distress (Gersons, Smid, Smit, Kazlauskas, & McFarlane, 2020). The scale, scope and enduring nature of this pandemic is unprecedented and is predicted to have long-lasting effects on society.

The unique considerations for children and youth are often forgotten in planning, preparing for and recovering from pandemics; this leaves a critical gap requiring attention from health leaders and policy makers (Bruce-Barrett, Matlow, Rafman, & Samson, 2007). Fortunately, there has been a rapid growth in research on child and adolescent physical and mental health during the pandemic. Findings to date indicate that the pandemic and the accompanying public health response have contributed to decreased physical activity and play (Moore et al., 2020), lower health related quality of life, and increased anxiety, depression, posttraumatic stress disorder (PTSD) symptoms and sleep disturbance (Marques De Miranda, Da Silva Athanasio, Sena Oliveira, & Simoes-e-Silva, 2020; Racine et al., 2020; Ravens-Sieberer et al., 2021; Yeasmin et al., 2020). In addition, the associated societal upheaval is likely to have disproportionately

affected children and families who experienced high levels of adversity prior to the pandemic, who have lower socioeconomic resources, and who had pre-existing physical and mental health vulnerabilities (Asbury, Fox, Deniz, Code, & Toseeb, 2020; Gruber et al., 2020; Patel, 2020). The threat of the virus is far from over and the uncertainty and disruption caused by social distancing restrictions and lockdowns continue to create a myriad of risk factors that may increase exposure to adverse childhood events, such as increased family violence, and thereby create or further exacerbate economic, psychosocial, and physical risks to wellbeing over time (Brown, Doom, Lechuga-Peña, Watamura, & Koppels, 2020; Griffith, 2020; Hamadani et al., 2020; Patrick et al., 2020; Usher, Bhullar, Durkin, Gyamfi, & Jackson, 2020).

So far, studies have primarily focused on the experiences of school-aged children and adolescents. Although young children may be especially vulnerable to a range of social, emotional, and behavioural difficulties following a major disruptive event such as a global pandemic (Osofsky, Kronenberg, Bocknek, & Cross Hansel, 2015; Proctor et al., 2007), the experiences and mental health needs of young children (< 6 years) in the wake of the COVID-19 pandemic have largely been neglected to date. As such, there is an urgent need for research that accounts for the unique developmental considerations which may influence the mental health outcomes for young children over time.

0.1. Impact of COVID-19 during early childhood

Early childhood is one of the most important and vulnerable periods of development across the lifespan. This developmental stage represents a time of rapid and complex growth, where a child is forming attachment relationships; progressing from basic sensorimotor functioning to emerging cognitive-linguistic capacities; and moving towards developing self-emotion regulation skills within the context of co-regulation provided by caregiver/s (Sameroff, 2010). Adverse experiences occurring during this stage can influence brain architecture, caregiving relationships, and social, emotional and physical development (Shonkoff et al., 2012).

Developmental factors will greatly influence how young children understand, respond and adjust to the pandemic (Shonkoff et al., 2012). Therefore, the impact must be considered within the context of their social, emotional and relational developmental competencies. Whilst young children are less physically susceptible to contracting or getting sick from the virus, their health and wellbeing is still at risk of being negatively affected and this may have long-term consequences for their developmental trajectories across the lifespan (Benner & Mistry, 2020).

Developmentally, children typically do not understand key aspects of death (e.g. permanent/irreversible) until around the age of 4–5 years (Panagiotaki, Hopkins, Nobes, Ward, & Griffiths, 2018). Thus, young children will be less likely to perceive COVID-19 as ‘life-threatening’ in the same way as older children and adults. Given that young children typically look to their caregivers to determine if something is dangerous or threatening and rely on them to help them feel safe, secure and protected (Humphreys, Zeanah, & Scheeringa, 2015), a caregiver’s emotional reaction and subjective appraisal of threat during the pandemic is likely to greatly influence their child’s perception of threat. Previous research has shown that parents’ fear of the Swine flu pandemic was associated with the type of verbal information they provided their children (i.e. higher transmission of threat information) which consequently led to increased fear of the disease in their children (Remmerswaal & Muris, 2011).

For young children, the stressors associated with COVID-19 include disruptions to routine and education (e.g. childcare/school closures, caregivers working from home), reduced physical activity and leisure activities, caregiver distress and reduced responsiveness, and loss of social interaction with extended family and friends. Early research has reported that children as young as three years old worried and felt guilty about catching and/or spreading COVID-19 and associated the virus with feeling ‘scared’, ‘nervous’, ‘lonely’, ‘sad’, ‘bored’, ‘angry’, and feeling ‘safe’, ‘calm’, and ‘happy’ when with their families (Idoiaga Mondragon, Berasategi, Eiguren, & Picaza, 2020). Studies of children from the age of three years have found they were experiencing more irritability, anxiety, emotion dysregulation and regression in already acquired tasks (Idoiaga Mondragon, Sancho, Santamaria, & Munitis, 2020; Pisano, Galimi, & Cerniglia, 2020). Research with preschool aged children ($M = 4.6$ years) has found depressive and externalizing difficulties were elevated compared to pre-COVID research using the same outcome measures (Glynn, Davis, Luby, Baram, & Sandman, 2021). In this sample, 39.9% of pre-schoolers scored above the recommended cut-off for depression and 36.1% were above the cut-off for conduct problems. Finally, an online survey conducted during the acute phase of major lockdown in German speaking countries found 7.8% of young children (1–6 years) were in the clinical range for affective problems, 4.7% for anxiety and 9.9% for oppositional defiant problems (Schmidt, Barblan, Lory, & Landolt, 2021). Caregivers reported an increase in emotional and behavioural symptoms by more than 20% during the pandemic. The increase in crying, sleep disturbance and oppositional behaviours was significantly greater for young children compared to school-aged children. In comparison,

children aged 7–10 years were significantly more fearful and adolescents (11–19 years) had higher scores for worry, being overtired, underactive and nervous.

0.2. Impact of pandemic on caregiver's mental health and parenting

Caregivers are also faced with fear and anxiety about potentially catching or spreading the virus, separation from friends and family, and concerns about the well-being of loved ones. Some caregivers are also experiencing continued stressors related to employment changes, housing insecurity, food and medication unavailability, and marital tensions. Essential personnel and healthcare workers face additional concerns about the risk of contracting or spreading COVID-19 within their family (Dubey et al., 2020). Finally, the COVID-19 pandemic has presented immediate and emerging stressors for caregivers specifically, including balancing working remotely without childcare or educating their children at home. These stressors have contributed significantly to an increased caregiver burden (Davenport, Meyer, Meah, Strynadka, & Khurana, 2020; Russell, Hutchison, Tambling, Tomkunas, & Horton, 2020), and considerable rates of parenting-related exhaustion, with higher levels for caregivers of younger children (Marchetti et al., 2020). The responsibility of providing informal care or education has been disproportionately falling to women (Wenham, Smith, & Morgan, 2020) and mothers have experienced a decrease in leisure time as well as an increased perception of work pressure compared to fathers (Yerkes et al., 2020). Broadly, these concerns, along with how caregivers and children communicate COVID-19 information, and related alterations in parenting behaviours and family cohesion, have been shown to impact both parent and child mental health (Whittle et al., 2020). Recent evidence from the UK found the prevalence of clinical levels of parental mental distress rose from 18.9% (recorded in 2018) to 27.3% (recorded in April 2020; Pierce et al., 2020). Women and people living with young children showed greater increases in mental distress. Further, results from a national survey in the United States found that since March 2020, 27% of caregivers have reported worsening mental health for themselves (Patrick et al., 2020). In a recent Mediterranean study in Spain and Italy, 35.5% of parents reported being stressed or very stressed, and 39.4% reported being somewhat stressed during the COVID-19 pandemic (Orgilés, Morales, Delvecchio, Mazzeschi, & Espada, 2020).

Evidence from the anxiety and trauma literature suggests that parental mental health difficulties can impair emotional availability and influence parenting behaviours (such as hostile discipline or modelling anxious behaviours) and contribute to higher levels of child emotional or behavioural difficulties (Cobham, McDermott, Haslam, & Sanders, 2016; Green, Chase,

Zayzay, Finnegan, & Puffer, 2018; Scheeringa & Zeanah, 2001). It is possible that increased levels of parental distress within the context of this pandemic may impair their ability to respond to their children's emotions sensitively or to model adaptive coping behaviours. Further, this could in turn have future longitudinal impacts on parent mental health and the parent-child relationship (Russell et al., 2020).

0.3. Risk and protective factors

The emerging COVID-19 research, mostly with school-aged children, has identified a number of potential risk and protective factors for mental health that may also be relevant for young children. Child specific risk factors include developmental level (e.g. age), and pre-existing mental and/or physical health conditions (e.g. emotional or neurodevelopmental disorder, sensory disability; chronic health condition; Marques De Miranda et al., 2020). Social risk factors include single-parent families, minority ethnic groups, low socio-economic status, low parental education, migration status, and limited living space (Brown et al., 2020; Ravens-Sieberer et al., 2021). Pandemic specific risk factors include mandated quarantine/isolation; caregiver/s who are frontline essential workers, a child/family member being infected; living in a highly infected area; parental job insecurity, exposure to traumatic events, perceived fear of infection/life threat, media exposure; stigma; and reduced physical activity (Brooks et al., 2020; Marques De Miranda et al., 2020; Racine et al., 2020; Yeasmin et al., 2020). Pandemic caregiver-related risk factors include caregiver mental health difficulties (e.g. anxiety, depression, stress) and harsh parenting (Brown et al., 2020; Patrick et al., 2020; Racine et al., 2020; Schmidt et al., 2021). Protective factors include greater understanding/knowledge about the pandemic, warm and responsive caregiving and adaptive coping strategies, and living in households with predictable routines (Brown et al., 2020; Domínguez-Álvarez, López-Romero, Isdahl-Troye, Gómez-Fraguela, & Romero, 2020; Glynn et al., 2021; Marques De Miranda et al., 2020). It is essential that research is conducted to identify the risk factors for mental health difficulties in young children to help identify those most risk and thus needing more psychological support over time. It is also important to identify modifiable risk and protective factors that can be targeted by prevention and intervention efforts to promote resilience, buffer the impact of potential risk-factors, and facilitate positive recovery during and after the pandemic.

0.4. Current study: COVID-19 Unmasked Global Collaboration

The COVID-19 pandemic is a global event impacting children and caregivers all over the world. However, the degree and duration of exposure to potential threat,

experience of enforced lockdowns and physical distancing restrictions (e.g. more vs less restrictive), racialization of the coronavirus, and level of access to financial and mental health supports have varied widely within and across communities and countries. Therefore, as the COVID-19 pandemic continues to unfold, psychological responses may vary greatly depending on developmental level, cultural background as well as the community and country in which children and families are living. To date, there is little known about how disruptive events affect early childhood mental health over time or across cultures and as such, there is an urgent need for global collaboration that aligns core outcome measures and aims to be inclusive and equitable (Alisic et al., 2020). It is critical to understand how stress responses present in young children (1 to 5 years) so that developmentally appropriate, inclusive, equitable, and well-timed assessment tools and interventions can be developed and delivered across the continuum of care from mental health promotion, prevention and tertiary level intervention. To address some of the aforementioned gaps in our empirical and clinical knowledge base, the COVID-19 Unmasked Global Collaboration was formed during April 2020.

The primary purpose of this paper is to describe the formation of this Global Collaboration and the initial execution of the COVID-19 Unmasked research study, which aims to bring a broad perspective of young child and caregiver well-being in the context of COVID-19. More specifically, the collaborating researchers aim to (1) describe and compare the COVID-19 related experiences within and across countries; (2) examine mental health outcomes for young children (1 to 5 years) and caregivers over a 12-month period during the COVID-19 pandemic; (3) explore the trajectories/time course of psychological outcomes of the children and parents over this period and (4) identify the risk and protective factors for different mental health trajectories. Data from all participating countries will be combined into one large open access cross-cultural dataset to facilitate international collaborations and joint publications. Based on the emerging literature, it is hypothesized that during the pandemic young children and their caregivers will show higher levels of mental health difficulties compared to pre-pandemic normative data. It is further hypothesized that pre-existing psychosocial risk factors (e.g. prior mental health difficulties, adverse childhood experiences, chronic health condition, neurodevelopmental disorder, physical/sensory disability, ethnic minority), COVID-19 specific stressors (e.g. COVID-19 diagnosis, death of a loved one, lockdown duration, impact on caregiver employment/finances, increased family tension, separation from loved ones) and caregiving factors (e.g. mental health difficulties, COVID-19 specific worries, high parental rejection, avoidance, low social support), will be significantly associated with elevated and/or worsening child mental health difficulties (i.e. anger/irritability,

anxiety, depression, sleep disturbance) over time. Finally, it is hypothesized that protective factors for children showing a resilient trajectory (i.e. consistently low or recovery from initial elevated mental distress) will include higher child self-regulation abilities, positive parent-child relationships, low parent stress, warm caregiving style, higher positive family experiences (e.g. increased closeness), and routine during the pandemic.

1. Methods

1.1. Formation of COVID-19 unmasked global collaboration

The COVID-19 Unmasked project was first conceptualized and launched in Australia. To better understand the different experiences and impact of the pandemic on young children around the world, the lead investigator (ADY) sought out international partnerships. To recruit research partners, the study was advertised as a project on the Global Collaboration on Traumatic Stress Global COVID-19-related projects website (COVID-19 projects | Global Collaboration) and on COVID-MINDS: <https://www.covidminds.org/longitudinal-studies>. Researchers are invited to contact the lead investigator (ADY) to explore options for collaboration (i.e. collect data in their own country, provide research support to the global collaboration team, analyse data or work on joint publications). When a critical mass of collaborators was reached (i.e. 4 countries), we (ADY, MV, MM, HC, ME) created a steering committee to guide project decisions and implementation. The steering committee meets monthly to discuss, plan and solve study-related procedures and process issues. To date, researchers from the following countries, in addition to Australia, have joined the collaboration: Cyprus, Greece, the Netherlands, Poland, Spain, Turkey, the UK, and the United States of America.

Once an investigator from a new country joins the project, the Australian team shares all study materials (i.e. study protocol, measures, ethics application, recruitment flyers, REDCap files, SPSS syntax) so that each team can adapt and/or translate as appropriate for their own country and available resources. Separate ethics applications are submitted in each country. Each country is asked to set-up and manage their own secure online survey web platforms, such as REDCap, Limesurvey or Qualtrics.

To ensure timely dissemination of results, data from each participating country will be analysed and published separately in reports, online blogs and articles, journal publications, and conference presentations. Data will then be combined to form a large cross-cultural dataset for joint publications. In line with the 'FAIR' guiding principles for scientific data stewardship which states that data should be Findable, Accessible, Inter-operable, and Re-usable (<https://www.global-psychotrauma.net/fair>), we plan to contribute to the Prospective studies of

Acute Child Trauma and Recovery (PACT/R) Data Archive (Kassam-Adams & Olf, 2020).

1.2. Design

COVID-19 Unmasked is a prospective longitudinal cohort study consisting of an online survey completed at four time-points (baseline, 3, 6 and 12 months) by participants from partnering countries. The baseline study assessment will vary across countries; all baseline assessments will start after each country has identified COVID-19 within their population and will depend on when each research team joined the collaboration and the length of time it takes to translate study materials, receive ethics approvals, and have all research procedures finalized. Refer to Supplementary Table S1 for a summary of the actual and/or anticipated data collection dates for each participating site. This research aims to recruit participants from the general population. The study will be conducted in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement (von Elm et al., 2007).

1.3. Participants

Participants are caregivers of young children between 1–5 years. To be included in the study, participating caregivers need to be at least 18 years old, have access to the internet and be able to complete the survey in the main language for each participating country (i.e. English, Polish, Dutch, Turkish, Spanish, Greek). Caregivers living in the Netherlands have the option to complete the survey in Dutch or English.

1.4. Measures

The COVID-19 Unmasked Survey has a core set of measures to address the primary aims of the global collaboration. An additional (optional) set of measures were also made available to be considered for inclusion in each study based on country specific research aims and questions. The core and optional set of measures for all countries and variations in measures at each time point between study sites are outlined below and in Table 1. Detailed information and a copy of each survey that was developed for the study can be accessed via the Supplementary Material link.

1.5. Core measures

1.5.1. Demographic characteristics & pre-existing health conditions

This section of the survey includes questions, tailored as relevant for each country, to collect information on pre-pandemic sociodemographic variables and physical and mental health conditions for the child, caregiver and

family. *Child* sociodemographic variables include age, gender, ethnicity, country of birth and normal child-care/school arrangements (e.g. home care, childcare centre, school). *Caregiver* variables include gender, age, ethnicity/culture, country of birth, relationship to child, relationship status, highest level of education, and employment status for participating caregiver (and co-parent if applicable). *Family* related variables include combined family income, region family lives in (state/territory, urban vs rural), number of children and adults living in household, number of children younger than 5 years, residence type (e.g. apartment versus house with yard).

Caregivers are also asked if they have previously been told by a health professional that their child has had any of the following: emotional, behavioural, or self-regulatory difficulties (e.g. anxiety, depression, traumatic stress, sleep/feeding/crying disorder), neurodevelopmental disorder (e.g. ADHD, autism spectrum disorder), sensory disability (e.g. blindness, hearing loss), physical disability (e.g. epilepsy, cerebral palsy) and/or chronic health condition (e.g. asthma, diabetes, cancer). Participants are also asked if they or a co-parent (if applicable) have a history of mental health or chronic health conditions.

1.5.2. COVID-19 pandemic exposure, loss, and impact

The *COVID-19 Pandemic Exposure and Loss Questions* were included in the study to understand and track the level of direct exposure and loss experienced by young children and their families during the COVID-19 pandemic. This was to identify risk-factors as well as allow for comparisons regarding the degree of threat, exposure and loss experienced within and across countries. Specifically, this section of the survey includes items assessing the potential threat of exposure to COVID-19 (e.g. child or family member diagnosed with COVID-19), loss of loved ones during the pandemic, frequency of exposure to COVID-19 related information (i.e. media) and if caregiver/s were frontline or essential workers. See Supplementary Material for questions.

The *Pandemic Impact Questionnaire: Early Childhood* (PIC-EC; De Young & Vasileva, 2020c) was developed for the study to measure, track and compare the impact that indirect COVID-19 related experiences have on young children, caregivers and families during the course of the pandemic. The questionnaire has 2 scales that assess the degree of negative impact and positive change experienced during the COVID-19 pandemic. In total, the questionnaire includes 22 items that participants rate on a 5-point Likert-scale from 0 (not at all) to 4 (very much). Fifteen questions assess COVID-19 pandemic related negative impact on daily routines, lifestyle and activities experienced by the child, the caregiver and the family.

Table 1. Measures used by each country at each time point.

| Measure | Study time point | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------------|---------------------------|---------|-----|-----|-----|-----|---------------------------|-----|-----|---------|-----|-----|---------------------------|-----|-----|-----|-----|---------|----------------------------|-----|-----|-----|-----|-----|-----|---------|-----|-----|-----|-----|-----|-----|
| | T ₀ : Baseline | | | | | | T ₁ : 3 months | | | | | | T ₂ : 6 months | | | | | | T ₃ : 12 months | | | | | | | | | | | | | |
| | AUS | CYP/GRC | GBR | ESP | NLD | POL | TUR | USA | AUS | CYP/GRC | GBR | ESP | NLD | POL | TUR | USA | AUS | CYP/GRC | GBR | ESP | NLD | POL | TUR | USA | AUS | CYP/GRC | GBR | ESP | NLD | POL | TUR | USA |
| *Demographics | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| *Pandemic related^a | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Child Outcomes | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| *PROMIS-EC | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Anger | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Anxiety | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Depression | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Self-regulation | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Positive affect | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Parent relationship | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Sleep Disturbance | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Attachment-seeking ^b | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Posttraumatic stress ^c | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Parent Distress | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| *DASS-21 | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Risk & Protective | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Caregiver worries ^d | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Parenting responses ^e | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Parenting practices ^f | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Warmth | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Rejection | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Child worries ^g | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |

AUS: Australia; CYP/GRC: Cyprus and Greece; GBR: UK; ESP: Spain; NLD: the Netherlands; POL: Poland; TUR: Turkey; USA: United States of America. ^aCore outcome measures: PROMIS-EC; Patient-Reported Outcome Measurement Information System – Early Childhood scales; DASS-21: Depression Anxiety and Stress Scale. ^bPandemic related: Pandemic exposure, loss and impact questions ^cAttachment-seeking: Young Child Stress-related Attachment-Seeking Scale; ^dPosttraumatic stress: Posttraumatic stress disorder Scale for Young Children; ^eCaregiver worries: Caregiver COVID-19 Worries Scale; ^fParenting responses: COVID-19 Pandemic Parenting Survey; ^gParenting as a Social Construct Questionnaire; ^hChild worries: Preschooler Stressor-related Thoughts and Worries.

Seven questions assess COVID-19 related positive changes and are based on the five domains of posttraumatic growth including new possibilities, relating to others, personal strength, spiritual change and appreciation of life (Tedeschi & Calhoun, 2004). See Supplementary Material for more background and a copy of the survey.

1.5.3. Child mental health and wellbeing

The primary outcome measures chosen for this study are the *Patient-Reported Outcomes Measurement Information System Early Childhood Parent Report* measures (PROMIS EC; Blackwell et al., 2020). The PROMIS EC are a set of developmentally sensitive parent-report outcome measures for young children (1–5 years). PROMIS EC has four overarching domains that align with the existing PROMIS paediatric and adult measure domains, which are based on the World Health Organization framework: (a) Global Health; (b) Mental Health; (c) Social Health; and (d) Physical Health (Cella et al., 2007). From the Global Health domain, three single items that each give an overall rating of the child's mental health, overall physical health and achievement of developmental milestones were included. To assess mental health outcomes, the following PROMIS EC measures were chosen: (1) *Anger/Irritability* (4-item short form) to assess angry moods (e.g. irritability) and behaviours (e.g. temper tantrums); (2) *Anxiety* (8-item short form) to assess symptoms related to fear, worry, tension, and separation anxiety, (3) *Depressive Symptoms* (4-item short-form) to measure depressive symptoms such as sad, withdrawn, and lack of enjoyment; (4) *Self-Regulation – Frustration Tolerance* (6-items) to assess the child's ability to regulate and manage emotions (e.g. frustration); and (5) *Positive Affect* (4-item short form) to assess positive emotions including happiness, joy, and playfulness. The *Child/Caregiver Interactions* (5-items) short form from the *Social Relationships* item bank in the Social Health domain was used to measure the quality of the parent-child relationship (e.g. child seeks comfort from parent, child is affectionate with parent). Finally, the *Sleep Health – Disturbance* measure (5-item custom short form) was chosen from the *Sleep Health* item bank in the Physical Health domain to assess problems with delayed sleep onset and disrupted sleep.

The Global Health items are rated on a 5-point Likert Scale (5 = Excellent to 1 = Poor). The other items are rated on a 5-point Likert scale ranging from 1 to 5 (1 = Never to 5 = Always). The sum total scores for each short-form will be calculated, compared to normative reference tables (USA pre-pandemic national sample) and transformed into T-scores (Mean = 50, SD = 10, Range = 0–100). Transformed scores for the anger/irritability, anxiety, depressive symptoms and sleep disturbance forms will be recoded to indicate if children are 'within normal limits' (< +1 SD from the normative mean) or have moderate

(+1.0–2.0 SD from the normative mean) to severe (>2 SD above the normative mean) mental health difficulties. Transformed scores for the self-regulation – frustration tolerance and positive affect scales will be recoded to assess if children are falling within the average range (± 1 SD from the normative mean), low/high range (± 1.0 – 2.0 SD from the normative mean) or very low/very high range ($\pm >2$ SD above the normative mean). Higher scores indicate better wellbeing. Transformed scores for the child-caregiver relationship short-form will be recoded to determine if the relationship is rated as poor, fair, good or excellent (-2 SD, -1 SD, 1 – 2 SD, and >1 SD).

When needed, researchers worked with the PROMIS EC translation team to obtain permission to translate into their preferred language (i.e. Dutch, Polish, Spanish, Turkish). Due to the time-sensitive nature of the study, it wasn't possible for teams to go through the rigorous translation process required to meet PROMIS translation standards (Devine et al., 2018). Therefore, with permission, the PROMIS EC measures were translated and back-translated by each research team and, following approvals, were used in the COVID-19 Unmasked global collaboration and will be referred to as a 'precursor to the official final version' of the PROMIS EC translated measures. In the Dutch study, the PROMIS EC were translated in collaboration with the Dutch-Flemish PROMIS National Center and went through a process of forward translation, back-translation and cognitive debriefing with five parents. For validation purposes, at baseline, full measures were used for Anger/Irritability, Depressive Symptoms, Anxiety and Sleep Health – Disturbance (instead of short forms).

1.5.4. Parent mental health

The *Depression, Anxiety and Stress Scale (DASS-21) short-form* is 21-item, self-report measure assessing symptoms of depression, anxiety and stress in caregivers with acceptable to excellent reliability, and convergent and discriminant validity for the English, Dutch, Spanish, Polish and Turkish versions (Bados, Solanas, & Andrés, 2005; de Beurs, Van Dyck, Marquenie, Lange, & Blonk, 2001; Henry & Crawford, 2005; Lovibond & Lovibond, 1995; Pezirkianidis, Karakasidou, Lakioti, Stalikas, & Galanakis, 2018; Sariçam, 2018; Scholten, Velten, Bieda, Zhang, & Margraf, 2017). Items on the DASS are summed and multiplied by 2 to provide a Total score and totals for the Depression, Anxiety, and Stress scales. Scores will also be re-coded to identify caregivers experiencing moderate to extremely severe depression, anxiety and stress symptoms according to the DASS manual (Lovibond & Lovibond, 1995).

1.6. Optional measures

The *Preschooler Stressor-related Thoughts and Worries* (PSTW; Vasileva & De Young, 2020a) questionnaire was

developed for this study to assess caregiver report of their child's (3–5 years) degree of understanding, thoughts and worries related to COVID-19. The questions are based on theoretical models of posttraumatic stress (Ehlers & Clark, 2000) and empirical evidence of preschoolers' thoughts associated with anxiety or depression (Creswell, Shildrick, & Field, 2011; Hutchison, Beresford, Robinson, & Ross, 2010). Items are rated on a 4-point Likert scale from 0 (not at all) to 4 (very much) and assess preschooler's confusion, worries, and unhelpful cognitions related to COVID-19. Refer to Supplementary material for more background and a copy of the PSTW.

The *Posttraumatic Stress Disorder Scale for Young Children* (PSYC; De Young, 2020) was developed for this study to assess caregiver report of young children's exposure to potentially traumatic events (PTE) prior to and/or during the pandemic (Part 1), to assess the frequency of PTSD symptoms in response to the PTE/s (Part 2) and determine the impact on everyday functioning (Part 3). Refer to Supplementary material for background and copy of the PSYC.

The *Young Child Stress-related Attachment-Seeking Scale* was developed for this study based on qualitative analysis of preliminary data obtained from the Australian sample describing common attachment-seeking behaviours reported by caregivers (Vasileva & De Young, 2020b). The 10-item questionnaire asks caregivers to rate the frequency of attachment-seeking behaviours they have observed in their child since the pandemic started (e.g. 'My child seeks physical closeness', 'My child needs constant reassurance', 'My child has difficulties sleeping alone') on a 4-point Likert scale from 1 (Equal or less often) to 4 (Very much more often). Refer to Supplementary material.

The toddler version of the *Parenting as Social Construct Questionnaire* (PSCQ-T, Zimmer-Gembeck, Webb, Thomas, & Klag, 2015) was included to measure parenting practices during the COVID-19 pandemic. The Warmth and Rejection subscales were chosen for this study to measure positive and negative parenting practices that may either buffer or exacerbate child mental health difficulties. Each subscale includes 4-items which asks caregivers to rate their parenting practices (e.g. 'I can always find time for my child' [warmth] and 'I don't understand my child very well' [rejection]), on a 5-point Likert scale from 1 (not true at all) to 4 (very true). The PSCQ-T has demonstrated acceptable validity and reliability (Zimmer-Gembeck et al., 2015).

The *COVID-19 Pandemic Parenting Survey* (CPPS, De Young & Vasileva, 2020) was developed for this study to explore parenting responses during the COVID-19 pandemic and understand how these behaviours influence child mental health outcomes over time (i.e. protective or risk factor). Refer to Supplementary material for more background and a copy of the questionnaire.

The *Caregiver COVID-19 Worries Scale* (CCWS; De Young & Vasileva, 2020a) was adapted for this study to assess the type and intensity of COVID-19 related worries caregivers have during the pandemic and to determine if they are predictive of outcomes over time. The questionnaire has 8-items that ask caregivers to rate the degree of worry they have felt on a 5-point Likert scale from 0 (Not at all) to 4 (Very much). Refer to Supplementary material for background and a copy of CCWS.

Preferred Mental Health Supports. Caregivers are asked to rate their preferences for the following mental health support options: in-person therapy, therapy via video or telephone call, online therapy, structured online programmes with or without therapist support, informational/educational websites, self-help books, podcasts or telephone helplines. Participants rate each support option on a 3-point Likert scale (0 = unlikely; 1 = maybe I would consider it; 2 = likely) based on the likelihood of accessing each option if they were concerned about their child's emotional well-being. Refer to Supplementary Material for questions.

1.7. Procedure

Using a convenience sampling approach and snowballing, each research site distributes study information (e.g. via a flyer with the link to the survey) through study authors' partner organizations and professional networks (e.g. university and health service mailing lists and newsletters, local councils), study websites (i.e. <https://www.childrens.health.qld.gov.au/covid-19-unmasked/>) social media (i.e. Facebook, Twitter, LinkedIn), early childhood organizations (e.g. early child care centres, parenting groups), parenting experts, blogs, and media interviews advertising the study for participation. Teams aimed to be as inclusive and representative as possible by actively targeting recruitments efforts towards groups that are often missed by research (e.g. paid Facebook campaigns targeting fathers and caregivers with a migration background and disseminating recruitment flyers through community-based groups, organizations and networks for Culturally and Linguistically Diverse families, Aboriginal and Torres Strait Islander families, families living in socially-disadvantaged communities, mental health consumers etc). Recruitment flyers and study websites aimed to be visually appealing and representative of different family backgrounds. Participants are invited to complete the online survey, at baseline (T_0) and followed up at 3 months (T_1), 6 months (T_2) and 12 months (T_3). See Supplementary Table S1 for a summary of the actual/anticipated survey start dates for each country.

After those interested click on the study link, they are taken to the first page of the survey platform, which includes an information sheet and consent form. Once participants consent, they can immediately complete the

T₀ assessment. Caregivers have an option to consent to follow-up surveys (by providing an email address) at 3-, 6-, and 12 months later. The survey is created so that participants are able to opt out of completing questions by clicking 'prefer not to say' or choosing not to answer. At the completion of the survey, participants receive information about support services and online resources to support their child, themselves, or other family members (e.g. domestic violence hotlines, evidence based mental health information websites, COVID-19 specific resources). The first survey takes approximately 20–45 minutes to complete. At each subsequent time point, the participant will receive emails to prompt them to complete a shorter follow-up survey (approximately 10–20 minutes) with up to two reminders. Data will be linked for each child/family across timepoints.

1.8. Statistical analysis

1.8.1. Missing data

For the global collaboration manuscripts, raw data from each site will be merged before imputing missing values. Missing data at the subscale level will then be imputed using mean imputation per participant (pro-rating) if the participant had at least 50% of each scale of interest completed before imputation so that a total score can be obtained. Mean imputation will only be used when missing data in a given scale across the sample is <10%. Analysis of incomplete or missing data using comparisons between key demographic variables will be examined using chi-square tests and t-tests.

1.8.2. Data analysis

To address aims 1–2 for the global collaboration manuscripts, descriptive analyses will be performed to describe participant sociodemographic variables and compare COVID-19 pandemic exposure, loss, and impact experiences across countries. Means and standard deviations will be presented for continuous data normally distributed or median and inter-quartile range (IQR) when continuous data are not normally distributed. Categorical variables will be presented using frequencies and proportions. To explore psychosocial outcomes during the COVID-19 pandemic across the different countries, the same descriptive analyses will also be performed for each of the PROMIS-EC short forms as well as the DASS-21 total and subscales. Proportions of participants exceeding the recommended category thresholds for each of these measures will also be reported. T-tests (with unequal variance; Welch test) or Mann Whitney-U tests will be used (depending on whether the assumption of normality is met) to determine whether there are differences in mean scores for the PROMIS-EC and DASS-21 outcome measures completed during the pandemic compared to pre-pandemic normative data.

To address aim 3, hierarchical linear models will be used to explore the trajectories/time course of the psychological outcomes of the children and parents (PROMIS and DASS-21). These will consist of linear mixed models which allow for repeated measures over time and nesting effects (e.g. country) via the incorporation of random effects. To address aim 4, risk and protective factors will also be incorporated as fixed effects in the models; interactions of these factors with time (modelled as fixed effects) may also be explored.

Qualitative data will be analysed using thematic analyses to identify and examine common themes that arise from caregivers' responses on the open-ended questions throughout the survey.

1.9. Ethics Approval

Ethical approval was sought and obtained at each of the respective study sites. Australia: Children's Health Queensland Hospital and Health Service Human Research Ethics Committee HREC/20/QCHQ/63,632, University of Melbourne Medicine and Dentistry HESC ID 2,057,001; Cyprus and Greece: Social Sciences Department, University of Nicosia (SSERB 00111); the Netherlands: Ethics Committee of the Faculty of Social and Behavioural Sciences of Utrecht University (20–408); Poland: Ethics Committee of the Faculty of Psychology, University of Warsaw (5/7/2020); Spain: Ethics Committee for Research in Humans of the Ethics Commission in Experimental Research (1519154), University of Valencia; Turkey: Ethics Committee of Istanbul Rumeli University; UK: STAFF193; United States of America: #59685).

1.10. Data management, protection and quality assurance

Data is/will be collected using secure web applications, such as REDCap (Research Electronic Data Capture; Harris et al., 2009), Limesurvey, SurveyMonkey or Qualtrics and stored on a secure server at each study site. Each site will be responsible for handling data in compliance with international standards for data protection and will be stored for as long as required by state and university guidelines and policies for the retention and disposal of records collected during research.

1.11. Data availability

Each country will be responsible for collecting, managing, storing data and disseminating findings. Participants have consented to this research knowing that de-identified information will be stored on public repositories for the purposes of data sharing. Following the

completion of data sharing agreements, original data will be combined into one core COVID-19 Unmasked global collaboration dataset. Following the completion of data collection and the publication of the results related to the primary study aims, the data will be made publicly available via PACT/R.

1.12. Dissemination of outcomes

Findings will be disseminated via peer-reviewed publications; reports to the general public, major professional groups, education and health services; online newsletters and blogs; media, and conference and webinar presentations. Findings will also be shared on research websites and social media platforms:

- <https://www.childrens.health.qld.gov.au/covid-19-unmasked/>;
- <https://www.global-psychotrauma.net/covid-19-projects>;
- <https://www.covidminds.org>;
- <https://www.uu.nl/onderzoek/covid-19-en-het-jonge-gezin-aandacht-voor-de-allerkleinsten>
- <https://covidunmaskedspain.weebly.com>

Where possible, research teams will rapidly translate their research findings into evidence-based resources targeted towards children, caregivers, educators and health care providers to enhance positive coping and resilience. Resources disseminated to date include educational tip sheets and the Birdie's Tree resources (i.e. Birdie and the Virus therapeutic storybooks, Relaxing with Birdie flip-book and animation <https://www.childrens.health.qld.gov.au/natural-disaster-recovery/>).

1.13. Recruitment progress

All countries have now started at least their baseline data collection. Overall, at the time of submission, >6010 families have been recruited into the COVID-19 Unmasked study and completed primary outcome measures. Refer to Supplementary Table S1 for a summary of recruitment dates and numbers for each country to date.

2. Discussion

The COVID-19 Unmasked global collaboration was formed between research teams in 9 countries to better understand and compare the different experiences and impact of the pandemic on young children (1–5 years) and families. This project will help to identify if and how the COVID-19 pandemic is affecting the mental health trajectories of young children and parents from different countries over a 12-month period as well as identify risk and protective factors. Since this age group has been overlooked thus far, it is critical to understand how stress responses present in this

population so that developmentally appropriate and well-timed interventions are designed and delivered across the continuum of care to prevent a cascade of secondary mental health symptoms and chronic diseases in later childhood.

The findings from the COVID-19 Unmasked global will directly translate into mental health promotion and prevention models for the early years by (1) providing public health advice to inform future preparedness and response efforts by identifying the typical responses and characteristics of young children and their caregivers over a 12-month period; (2) promoting resilience and emotional wellbeing by identifying factors which contribute to positive outcome trajectories; and (3) providing accurate and comprehensive information to determine developmentally sensitive, ethically, culturally and economically effective strategies that are best suited to the mental health needs and context for each child/family. Specifically, this information will inform the workforce required and lead to programme and service development and new policies both during and beyond the crisis.

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Author contributions

Except for the first two authors, authors have contributed equally and have been ordered alphabetically. ADY conceptualized the project and started the global collaboration by engaging with previous international collaborators and advertising the project on the Global Collaboration on Traumatic Stress Global COVID-19-related projects website. ADY and MV worked closely together to design the study and develop study specific measures and documents that were shared with all research teams. The steering committee (ADY, MV, MM, HC, ME) meets monthly to discuss, plan and solve study-related procedures and process issues. Each of the authors are the primary investigators of their country specific research projects. The research teams in the Netherlands, Cyprus and Greece, Poland, Spain and Turkey translated study measures and materials. ADY, MV, RP*, MM, HC, ME planned, drafted and revised the manuscript of the study protocol; and all authors reviewed and approved the final version of the manuscript. All authors in the global consortium* are the research investigators that have contributed to the design and conduct of the studies in each of the respective countries and have critically reviewed and approved the final version of the manuscript.

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