

BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open

A study protocol of COCOON: Continuing Care in COVID-19 Outbreak global survey of New, expectant, and bereaved parent experiences

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-061550
Article Type:	Protocol
Date Submitted by the Author:	28-Jan-2022
Complete List of Authors:	Loughnan, Siobhan; The University of Queensland, NHMRC Centre of Research Excellence in Stillbirth, Mater Research Institute-University of Queensland Gautam, R.; NHMRC Centre of Research Excellence in Stillbirth, Mater Research Institute-University of Queensland Silverio, Sergio; King's College London, Department of Women & Children's Health; University College London, Elizabeth Garrett Anderson Institute for Women's Health Boyle, Frances; NHMRC Centre of Research Excellence in Stillbirth, Mater Research Institute-University of Queensland; Institute for Social Science Research, University of Queensland Cassidy, J.; Umamanita Ellwood, David; Griffith University, School of Medicine; NHMRC Centre of Research Excellence in Stillbirth, Mater Research Institute-University of Queensland Homer, Caroline ; Burnet Institute Horey, Dell; La Trobe University, Public Health Leisher, Susannah; International Stillbirth Alliance demontigny, Francine; Paternite Famille et Societe, University of Quebec Murphy, Margaret; University College Cork National University of Ireland, Nursing and Midwifery O'Donoghue, Keelin; Dept. of Obstetrics and Gynaecology, University College Cork Quigley, P.; International Stillbirth Alliance; DAI Global Health Ravaldi, Claudia; University of Florence; CiaoLapo Foundation for Perinatal Health Sandall, Jane; Kings College, London, Health and Social Care Research Division Storey, Claire; International Stillbirth Alliance Vannacci, Alfredo; University of Florence, NEUROFARBA; CiaoLapo Foundation for Perinatal Health Wilson, Alyce; Burnet Institute, International Development Flenady, Vicki; NHMRC Centre of Research Excellence in Stillbirth, Mater Research Institute-University of Queensland Collaborator group, COCOON Global Collaboration ; Collaborator group
Keywords:	COVID-19, PERINATOLOGY, PSYCHIATRY, OBSTETRICS, PUBLIC HEALTH

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60



1
2
3
4 **1 Study title: A study protocol of COCOON: COntinuing Care in COVID-19 Outbreak**
5 **2 global survey of New, expectant, and bereaved parent experiences**
6
7
8

9 **4 Authors:** S. A. Loughnan¹, R. Gautam¹, S. A. Silverio², F. M. Boyle^{1,3}, J. Cassidy⁴, D.
10 Ellwood^{1,5}, C. Homer⁶, D. Horey⁷, S. H. Leisher⁸, F. de Montigny⁹, M. Murphy¹⁰, K.
11 O'Donoghue¹⁰, P. Quigley¹¹, C. Ravaldi¹², J. Sandall³, C. Storey⁸, A. Vannacci¹², A. Wilson⁶,
12 & V. Flenady¹ on behalf of COCOON Global Collaboration*.
13
14
15
16

17
18 **9 Affiliations:**

19 ¹Centre of Research Excellence in Stillbirth, Mater Research Institute-University of
20 Queensland, Brisbane AUSTRALIA
21

22 ²Department of Women & Children's Health, School of Life Course & Population Sciences,
23 King's College London, UK
24

25 ³Institute for Social Science Research, The University of Queensland, Brisbane AUSTRALIA
26

27 ⁴Umamanita, Girona, SPAIN
28

29 ⁵Griffith University and Gold Coast University Hospital, Gold Coast, QLD, AUSTRALIA
30

31 ⁶Burnet Institute, Melbourne AUSTRALIA
32

33 ⁷La Trobe University, Melbourne AUSTRALIA
34

35 ⁸International Stillbirth Alliance, Millburn, NJ, USA
36

37 ⁹Paternite Famille et Societe, University of Quebec, CANADA
38

39 ¹⁰University College Cork, IRELAND
40

41 ¹¹DAI Global Health, UK
42

43 ¹²Perinatal Research Laboratory (PeaRL), University of Florence, NEUROFARBA
44 Department, CiaoLapo Foundation for Perinatal Health, Prato, ITALY
45

46
47 *See collaboration and acknowledgment section.
48
49

50 **28 Corresponding author:** Dr Siobhan Loughnan, Centre of Research Excellence in Stillbirth,
51 Level 3 Aubigny Place, Mater Health Services, South Brisbane QLD AUSTRALIA, e:
52 siobhan.loughnan@mater.uq.edu.au
53
54
55

34 **Abstract**

35 **Introduction**

36 Globally, the COVID-19 pandemic has significantly disrupted the provision of healthcare and
37 efficiency of healthcare systems and is likely to have profound implications for pregnant and
38 postpartum women and their families including those who experience the tragedy of stillbirth
39 or neonatal death. This study aims to understand the psychosocial impact of COVID-19 and
40 the experiences of parents who have accessed maternity, neonatal, and bereavement care
41 services during this time. Findings will inform strategies to improve care for women and their
42 families during this and future health crises.

44 **Methods and analysis**

45 An international, cross-sectional, online and/or telephone-based/face-to-face survey is being
46 administered across 15 countries and available in 11 languages. New, expectant, and bereaved
47 parents during the COVID-19 pandemic will be recruited. Data will be analysed descriptively
48 and by assessing multivariable associations of the outcomes with explanatory factors. In seven
49 of these countries, bereaved parents will be recruited to a nested, qualitative interview study
50 with data analysed using a grounded theory analysis (for each country) and thematic framework
51 analysis (for inter-country comparison) to gain further insights into their experiences.

53 **Ethics and dissemination**

54 Ethics approval for the global online survey: COCOON, has been granted by the Mater
55 Misericordiae Ltd Human Research Ethics Committee in Australia (ref: AM/MML/63526) and
56 local ethics committees in participating countries where required. Ethics approval for the nested
57 qualitative interview study: PUDDLES, has been granted by the King's College London
58 Biomedical & Health Sciences, Dentistry, Medicine and Natural & Mathematical Sciences
59 Research Ethics Sub-Committee [ref: HR-19/20-19455] in the UK, and local ethics committees
60 in participating countries where required. Results of the study will be published in international
61 peer-reviewed journals and through parent support organisations. Findings will contribute to
62 our understanding of delivering maternity care services, particularly bereavement care, in high-
63 income, lower-middle-income and low-income countries during this or future pandemics.

1
2
3
4 67 **Strengths and limitations of this study**
5

- 6 68 ● This study is a global collaboration across 15 countries to explore maternity care
7 experiences in both high- and lower-resourced settings following the birth or death of
8 69 a baby and the related psychosocial impact of the COVID-19 pandemic.
9
10 70
11 71 ● This study will identify areas for maternity, neonatal, and bereavement care
12 improvement, examples of best practice, and provide baseline data for ongoing
13 72 monitoring and evaluation.
14
15 73
16 74 ● Limitations of this cross-sectional study include lack of longitudinal data which limits
17 exploration of change over time, including the inability to attribute outcomes to
18 75 COVID-19 or variants, selection bias, and the inability to study outcomes in relation to
19
20 76 differential progression of the pandemic across countries, including timing of infection
21 77 peaks and public health responses (e.g., lockdowns and border closures).
22
23 78
24
25 79

26
27 80 **Keywords**
28

29 81 COVID-19, pandemic, parents, pregnancy, postpartum, stillbirth, neonatal death, service
30 delivery
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

83 **Background**

84 The COVID-19 pandemic, caused by the novel coronavirus SARS-CoV-2 [1] has led to global
85 disruptions to healthcare systems resulting in direct and indirect impacts on physical and mental
86 health outcomes, particularly for pregnant and postpartum women.[2–7] Evidence suggests
87 maternal and perinatal outcomes have worsened during the pandemic including an increase in
88 maternal deaths, stillbirth, ruptured ectopic pregnancies, and maternal stress and depression.[8–
89 10] Pregnant and postpartum women and their partners are particularly vulnerable for
90 experiencing such a significant lifecourse transition amidst a time of great uncertainty and rapid
91 change. [11,12]

92 Maternity care settings both in high- and lower-resourced settings have experienced
93 specific challenges during COVID-19 such as reduced capacity and resources to provide
94 maternal care services, care inaccessibility for parents and families, and lack of perinatal care
95 guidelines including bereavement care for parents following stillbirth and neonatal death.
96 [9,13] Social distancing restrictions have resulted in reduced health seeking behaviour, access
97 to health services and practice relating to breastfeeding, as well as postpartum and neonatal
98 care. [4,5,13–17]

99 Decreased access to normal social support systems due to travel restrictions within and
100 between countries have led to increased isolation and loneliness, with several studies
101 highlighting the increased rates of anxiety, and clinically relevant maternal depression. [4,6,18]
102 Poor maternal mental health, particularly anxiety and depression, is associated with short- and
103 long-term adverse outcomes for both the mother and infant (e.g., recurring course of maternal
104 symptoms detrimental to the mother-infant relationship, increased risk of obstetrical
105 complications, poor birth outcomes and later child developmental problems). [6,15,16] It is
106 critical we understand the clinical and psychosocial experiences of pregnancy and childbirth
107 during the pandemic if we are to improve mother, baby, and family outcomes during the current
108 global crisis as well as in response and recovery.

109 An increase in the number of preventable stillbirths and neonatal deaths is one of the
110 most crucial yet under-recognised indirect effects of the pandemic. [9,10,19] Pre-pandemic,
111 sub-standard care has been identified as contributing to up to 50% of stillbirths, with 20-30%
112 considered preventable if optimal care had been provided. [20,21] The pandemic-related
113 disruptions to maternal, newborn and child health care are known to have worsened the
114 standard of care in many instances, leading potentially to an increase in many preventable
115 losses of lives. [9] Pre-pandemic, research has shown healthcare professionals often feel

1
2
3
4 116 underprepared and unable to provide needed support to parents following the death of their
5
6 117 baby including parent-centred care plans, and bereavement-specific practices (e.g.,
7
8 118 opportunities for parenting activities such as seeing and holding their baby, bathing, and
9
10 119 dressing their baby, creating memories e.g., photographs, handprints, or footprints), and
11
12 120 memorials and commemorative rituals. [22–25] The COVID-19 pandemic may have caused
13
14 121 further disparities in service provision and care. [5,14] Hence, it is important to understand
15
16 122 bereaved parent experiences of care during this time, and the extent to which recommended
17
18 123 perinatal bereavement care practices - which are known to vary widely between countries even
19
20 124 in non-pandemic times - are being implemented. [24,26]
21
22 125

21 126 **Study aims**

23 127 This study will explore the psychosocial impact of COVID-19 and the experiences of
24
25 128 parents who have accessed maternity, neonatal, and/or bereavement care services during the
26
27 129 pandemic, to provide a comprehensive global picture of maternal healthcare during the
28
29 130 COVID-19 pandemic. We aim to explore the perspectives and experiences of parents to
30
31 131 understand:

- 32 132 ● how the COVID-19 pandemic has affected care delivery (e.g., labour and birth
33
34 133 practices) including the support services available (both formal and informal), and
35
36 134 public health limitations (e.g., visitors to hospital, presence of partners during prenatal
37
38 135 care and childbirth).
 - 39 136 ○ how these vary across countries, hospital settings, and geographical locations
40
41 137 (i.e., metropolitan vs. rural)
- 42 138 ● how bereavement care practices have been affected by the pandemic.
- 43
44 139 ● the psychosocial impact of COVID-19 including stress, social loneliness, anxiety, and
45
46 140 depression symptoms.
- 47
48 141 ● satisfaction with information provided about COVID-19 during pregnancy and
49
50 142 postpartum.
- 51
52 143 ● preventive measures taken by parents to protect themselves and others against COVID-
53
54 144 19 (e.g., decreased health service utilisation).

54 145 55 56 146 **Methods**

1
2
3
4 147 ***Study design and setting***

5
6 148 The '*Continuing Care in COVID-19 Outbreak global survey of New, expectant, and*
7 149 *bereaved parent experiences*' (COCOON) study is an international, cross-sectional online
8
9 150 survey of parents who have accessed maternity, neonatal, and/or bereavement care services
10
11 151 during the COVID-19 pandemic. The online survey is co-ordinated and managed by the
12
13 152 Stillbirth CRE based in Brisbane, Australia. Several countries have delivered the online survey
14
15 153 items via a face-to-face or telephone interview, depending on local social distancing restrictions
16
17 154 and safety, each managed by the country co-ordinating centre (see Table 1). Ethics approval
18
19 155 for this research project (reference number AM/MML/63526) has been granted by the Mater
20
21 156 Misericordiae Ltd Human Research Ethics Committee in Australia and all processes within
22
23 157 this study are compliant with Australia's National Statement on Ethical Conduct in Human
24
25 158 Research and reflect international guidance on ethical principles, with country-specific ethics
26
27 159 and governance approval gained, where required.

26 160
27
28 161

162 **Table 1. List of participating countries, survey languages, modes of survey delivery, start month and year, and survey types being**
 163 **implemented across COCOON collaboration (ordered by launch date)**

Country	Language	Mode	Planned Start	COCOON Survey								PUDDLES	
				Pregnancy/postpartum				Bereavement				Nested	
				A	B	C	D	E	F	G	H	Qualitative Study	
Australia	English	Online	May 2020	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲
UK	English	Online	July 2020	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲
Italy	Italian	Online	July 2020	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲
US	English	Online	July 2020	▲	▲	▲	▲	▲	▲	▲	▲	▲	N/A
Quebec, Canada	French	Online*	July 2020	▲	▲	▲	▲	▲	▲	▲	N/A	N/A	▲
Ireland	English	Online	Sept 2020	▲	▲	▲	▲	▲	▲	▲	▲	▲	N/A
Spain	Spanish	Online	Oct 2020	▲	▲	▲	▲	▲	▲	▲	▲	▲	N/A
Brazil	Portuguese	Online	Oct 2020	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲
India (North)	Hindi	Face-to-face and Telephonic*	Oct 2020	▲	▲	N/A	N/A	▲	▲	N/A	N/A	N/A	▲
Germany	German	Online	Nov 2020	▲	▲	▲	▲	▲	▲	▲	▲	▲	N/A
India (South)	Telugu	Online*	Dec 2020	▲	▲	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Netherlands	Dutch	Online	May 2021	▲	▲	▲	▲	▲	▲	▲	▲	▲	N/A

4	New Zealand	English	Online	May 2020	▲	▲	▲	▲	▲	▲	▲	▲
5	Vancouver,	English	Online	April 2021	N/A	N/A	N/A	N/A	▲	▲	▲	N/A
6	Canada ^a											
9	Argentina	Spanish	Online	Sept 2021	▲	▲	▲	▲	▲	▲	▲	N/A
11	Laos	Lao	Face-to-face*	Feb 2022	▲	▲	N/A	N/A	▲	▲	▲	N/A
13	Philippines	English	Online and	Feb 2022	▲	▲	▲	▲	▲	▲	▲	N/A
14		Filipino	Face-to-face									

164 Notes.; *hosting and management of own data in country; A=Pregnant women; B=Postpartum women; C=Partners of Pregnant Women;
 165 D=Partners of Postpartum Women; E=Mothers following stillbirth; F=Mothers following Neonatal Death; G=Partners following stillbirth;
 166 H=Partners following Neonatal Death; N/A=Not applicable/this aspect of the study is/was not being implemented.

1
2
3
4 167 ***Patient and Public Involvement***

5
6 168 Patients and/or public were not expressly involved in the design or conduct of the
7
8 169 current study.

9 170 ***Survey development***

10
11 171 The COCOON survey was developed at the beginning of the COVID-19 pandemic as
12
13 172 part of an international collaboration to investigate the psychosocial impact of COVID-19 and
14
15 173 parent experiences of maternity, neonatal, and perinatal bereavement care during this time .
16
17 174 A total of eight surveys were developed, each tailored for a specific parent group: (A) pregnant
18
19 175 women; (B) postpartum women; (C) partners of pregnant women; (D) partners of postpartum
20
21 176 women; (E) mothers who experienced a stillbirth; (F) mothers who experienced a neonatal
22
23 177 death; (G) partners who experienced a stillbirth; and (H) partners who experienced a neonatal
24
25 178 death. The study design and development of the core set of items for each survey was driven
26
27 179 by the Stillbirth CRE in partnership with the COCOON working group and the following
28
29 180 coordinating centres (in alphabetical order): Canada (de Montigny), Ireland (Murphy,
30
31 181 O'Donoghue), Italy (Ravaldi, Vannacci), Spain (Cassidy), UK (Silverio, Sandall), and the
32
33 182 International Stillbirth Alliance (Leisher, Storey, Quigley). This study was informed by
34
35 183 previous research conducted by investigators including the COVID-ASSESS study
36
37 184 investigating anxiety and stress in pregnant and postpartum women in Italy during the
38
39 185 pandemic [27] and international stillbirth studies published in the 2011 and 2016 *The Lancet*
40
41 186 stillbirth series. [20,21,28] The final core set of items for each survey ranged between
42
43 187 approximately 70 and 115 open- and closed-ended questions across four main sections (see
44
45 188 Table 2). Closed-ended questions were included to minimise respondent time burden, while
46
47 189 inviting extended feedback through open-ended comment response options.

48
49 190 Subsequent country co-ordinating centres which joined the COCOON collaboration
50
51 191 reviewed the core set of survey items for each survey before country-specific changes were
52
53 192 made for context and cultural acceptability, and translation into local languages. If available,
54
55 193 psychometrically validated versions of the tools were used in countries without English as the
56
57 194 main language. Investigators were also able to include additional questions related to the
58
59 195 COVID-19 pandemic in their country.

60 196

197

198

199

200 **Table 2. Core questions for different sections of the surveys**

Types of questions	Survey							
	A	B	C	D	E	F	G	H
1) Maternity care experiences								
Pregnancy, labour, birth and neonatal care (e.g., primary care provider; setting; gestation)	✓	✓	✓	✓	✓	✓	✓	✓
Postpartum and follow-up care (e.g., breastfeeding)		✓		✓				
Elements of quality, respectful care (e.g., shared decision-making)	✓	✓	✓	✓	✓	✓	✓	✓
Impact of COVID-19 pandemic (e.g., changes to care provider and mode of delivery; changes to birth plan)	✓	✓	✓	✓	✓	✓	✓	✓
Quality of care (e.g., satisfaction)	✓	✓	✓	✓	✓	✓	✓	✓
1a) Bereavement-specific care experiences								
Pregnancy, labour and birth, neonatal, postpartum and follow-up care (e.g., special nursery/intensive care unit; follow-up visits at home)					✓	✓	✓	✓
Difficulties with care due to COVID-19 restrictions and the occurrence of best practice bereavement care (e.g., opportunity to spend time with baby; creation of memories such as photos)					✓	✓	✓	✓
Investigations including autopsy or post-mortem examination (e.g., counselling; investigations received) and care around understanding the reasons behind their baby's death					✓	✓	✓	✓
2) Psychosocial outcomes								
Impact of COVID-19 (e.g., financial pressures, impact on daily life; social support)	✓	✓	✓	✓	✓	✓	✓	✓
State anxiety – STAI-S	✓	✓	✓	✓	✓	✓	✓	✓
Trait anxiety – STAI-T	✓	✓	✓	✓	✓	✓	✓	✓
Postpartum Anxiety – PSAS-RSF-C		✓						
Depression – EPDS	✓	✓	✓	✓	✓	✓	✓	✓

Perceived stress – PSS-4	✓	✓	✓	✓	✓	✓	✓	✓
Social loneliness – SLS	✓	✓	✓	✓	✓	✓	✓	✓
Perinatal grief – PGS-SF					✓	✓	✓	✓
3) Satisfaction with COVID-19 information								
Helpfulness of information	✓	✓	✓	✓	✓	✓	✓	✓
Sources of trusted information	✓	✓	✓	✓	✓	✓	✓	✓
4) Sociodemographic characteristics								
Demographic characteristics (e.g., age, education level, employment status)	✓	✓	✓	✓	✓	✓	✓	✓
Mental and physical health conditions	✓	✓	✓	✓	✓	✓	✓	✓
Family and domestic violence	✓	✓	✓	✓	✓	✓	✓	✓
COVID-19 status (e.g., diagnostic, isolation)	✓	✓	✓	✓	✓	✓	✓	✓

201

202 ***Procedures***203 ***Inclusion criteria***

204 This study will recruit women aged over 18 years of age, who were pregnant or gave
 205 birth to their baby during the COVID-19 pandemic, including women who experienced
 206 stillbirth (i.e., baby died before birth, during pregnancy or labour) or neonatal death (i.e., a live
 207 born baby dying up to 28 days after birth). For the purposes of this study, the COVID-19
 208 pandemic is defined as starting from the 30 January 2020 onwards when it was declared a
 209 Public Health Emergency of International Concern (PHEIC) by the World Health Organisation
 210 (WHO). [29] Men and women whose partner was pregnant or gave birth to their baby during
 211 the COVID-19 pandemic, or those who suffered a stillbirth or neonatal death (referred to
 212 hereafter as “partners”) will also be recruited.

213 For the bereavement surveys, country-specific changes were made to the definition of
 214 stillbirth in accordance with differing gestational age criteria in each country (e.g., in Australia
 215 stillbirth is defined as a baby dying before birth and of at least 20 weeks’ gestation [30]; UK is
 216 of at least 24 weeks’ gestation [31]; Brazil is of at least 22 weeks’ gestation [32]; India is of at
 217 least 28 weeks’ gestation [33]). Additional inclusion criteria include participants providing
 218 informed consent online and reliable access to a computer (or similar device) and internet to
 219 complete the online survey (for countries using this mode of survey delivery). For participants
 220 who reside in countries where computer and internet access is limited, additional inclusion

1
2
3
4 221 criteria includes willingness to attend a face-to-face meeting or participate in a telephone
5
6 222 interview to complete the survey items.

7 223

8
9 224 **Exclusion criteria**

10
11 225 For the bereavement surveys, parents who experienced the death of their baby prior to
12 226 the definition of stillbirth in each country, or after the definition of neonatal death in each
13 227 country will be excluded and redirected to country-specific support services.¹

14 228

15 229 **Recruitment**

16 230 For this international study an opportunity sample of self-selecting participants will be
17 231 recruited during the pandemic across the four parent groups: (1) women who are pregnant or
18 232 postpartum; (2) partners of women who are pregnant or postpartum; (3) women who have
19 233 experienced a stillbirth or neonatal death; and (4) partners who have experienced a stillbirth or
20 234 neonatal death. Participants will be predominantly recruited via online advertising including
21 235 social media and other electronic communication tools (e.g., newsletters) through each co-
22 236 ordinating centre, parent support organisation partnerships and both local and national charities
23 237 in each country, and the International Stillbirth Alliance member network. For those countries
24 238 conducting face-to-face/telephone interviews instead of the online survey (India, Laos, The
25 239 Philippines), recruitment will occur through word of mouth (e.g., obstetricians, midwives),
26 240 referral by practitioners/service providers in local service settings and advocate groups
27 241 (snowball sampling). Each COCOON co-ordinating centre has in-country partnerships with
28 242 parent organisations, maternal healthcare services, and parent bereavement organisations (see
29 243 appendix). From each participating country, we aim to recruit a minimum sample of 500
30 244 women and partners during pregnancy, 500 women and partners during the postpartum period,
31 245 and 200 bereaved parents following a stillbirth or neonatal death.

32 246

33 247 **Procedures**

34 248 Parents interested in participating access the online survey via the Stillbirth CRE
35 249 website which is delivered in seven languages (except French, Hindi, Telugu, and Lao; see
36 250 Table 1). Parents will then be required to select the country they currently reside in to enter the
37 251 survey and review the participant information and eligibility criteria for the study and provide

38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

¹For the UK, women and partners who experienced a late-term miscarriage and who are therefore not eligible to participate in the COCOON online survey, will be able to take part in the nested qualitative study (PUDDLES).

1
2
3
4 252 online consent to participate. Eligibility questions determine the logic branching of the survey
5
6 253 to ensure parents are directed to the appropriate survey (see Figure 1). Parents who do not
7
8 254 reside in any of the participating countries listed will be directed to a generic (non-country-
9
10 255 specific) survey version available in English. Those who are ineligible for participation will be
11
12 256 excluded and redirected to an end-of-survey page where country-specific support services are
13
14 257 listed (with information, webpages, e-mail addresses, and contact numbers).
15

16 259 <Insert Figure 1 Here>
17
18 260

19 261 The time required for each COCOON survey completion is approximately 30-35
20
21 262 minutes. Following completion of the survey, information on country-specific support services
22
23 263 will be provided on-screen. For concerns regarding pregnancy or postpartum care during
24
25 264 COVID-19, all participants are advised to speak with their general practitioner (family doctor)
26
27 265 or other service provider.
28

29 266

30 267 **Outcomes**

31 268 The primary outcome for this study is parent experiences of quality of care including
32
33 269 bereavement care (see Table 2). Secondary outcomes include psychosocial wellbeing and
34
35 270 satisfaction with COVID-19 information.
36

37 271

38 272 ***Experience of maternity, neonatal, and bereavement care services***

39
40 273 This section aims to understand the experiences, main concerns and perceived needs of
41
42 274 parents accessing maternity care services during the COVID-19 pandemic. Most items in this
43
44 275 section are multiple choice Likert items rated on a scale between Strongly Disagree and
45
46 276 Strongly Agree. The bereavement-specific surveys (E, F, G, H) also include questions to
47
48 277 understand the experiences of care offered to parents following stillbirth or neonatal death. [24]
49
50 278 This section also includes several open-text fields for further information.
51

52 279

53 280 ***Psychosocial impact of COVID-19***

54 281 This section includes several items to explore coping with COVID-related stressors
55
56 282 (e.g., financial pressures; worry about the health of self and baby, concerns about those at
57
58 283 greater risk of COVID-19 including elderly relatives; impact on daily life; social support) and
59
60 284 the following validated self-report outcomes measures (see Table 2).

1
2
3
4 285 **Anxiety.** The *State-Trait Anxiety Inventory for Adults (STAI)* consists of two 20-item
5
6 286 subscales assessing state and trait anxiety. [34] Items from both the state subscale (e.g., “I am
7
8 287 tense”; “I feel indecisive”) and trait subscale (e.g., “I feel satisfied with myself”; “I feel nervous
9
10 288 and restless”) are rated on a 4-point scale from 1 (Almost Never) to 4 (Almost Always) with a
11
12 289 maximum total score of 80. Higher total scores are indicative of greater anxiety. The STAI has
13
14 290 strong psychometric properties in the general adult population, has been validated in perinatal
15
16 291 populations, and has been translated into multiple languages. The *Postpartum Specific Anxiety*
17
18 292 *Scale – Research Short Form – for use in global Crises (PSAS-RSF-C)* is administered in
19
20 293 Survey B only and consists of 12 items to assess anxiety symptoms specific to the postpartum
21
22 294 period for new mothers. [7] Items (e.g., “I have repeatedly checked on my sleeping baby”; “I
23
24 295 have felt that my baby would be better cared for by someone else”) are rated on a scale from 1
25
26 296 (Not at all) to 4 (Almost always). The PSAS shows good psychometric properties. [7]

27
28 297 **Depression.** The *Edinburgh Postnatal Depression Scale (EPDS)* consists of 10 items
29
30 298 to assess both antenatal and postpartum depressive symptoms over the past seven days. [35]
31
32 299 Items (e.g., ‘I feel sad or miserable’) are rated on a scale from 0 (e.g., Not at all) to 3 (e.g., Yes,
33
34 300 most of the time) with a maximum total score of 30 (>12 indicative of possible depression).ⁱⁱ
35
36 301 The EPDS has strong psychometric properties and has been translated and validated in 20
37
38 302 different languages. [36]

39
40 303 **Stress.** The *Perceived Stress Scale-4 (PSS-4)* consists of a 4-item scale to assess the
41
42 304 degree to which individuals believe their life has been unpredictable, uncontrollable, and
43
44 305 overloaded during the past month. [36] Items (e.g., “In the last month, how often have you felt
45
46 306 that you were unable to control the important things in your life?”) are rated on a scale from 0
47
48 307 (Never) to 4 (Very often). The PSS-4 is one of the most widely used instruments for measuring
49
50 308 the perception of stress and has shown good psychometric properties in perinatal populations.
51
52 309 [37,38]

53
54 310 **Social loneliness.** The *De Jong Gierveld Loneliness Scale (SLS)* consists of six items
55
56 311 to assess loneliness [39] which is an indicator of social wellbeing and pertains to the feeling of
57
58 312 missing an intimate relationship (emotional loneliness) or missing a wider social network
59
60 313 (social loneliness). Items (e.g., “There are plenty of people I can rely on when I have
314
315 314 problems”) are rated on a scale between “no,” “more or less” and “yes”. The scale has shown
good psychometric properties. [40]

ⁱⁱAll participants who self-reported thoughts of self-harm are advised on-screen to speak with their general practitioner or other service provider for support.

1
2
3
4 316 **Perinatal grief.** The *Perinatal Grief Scale – Short Form (PGS-SF)* is administered in
5
6 317 the bereavement-specific surveys only [41] and consist of 33 items to assess behavioural and
7
8 318 affective symptoms of grief and symptoms specific to perinatal death. Items (e.g., “I find it
9
10 319 hard to get along with certain people”) are rated on a scale from “strongly agree” to “strongly
11
12 320 disagree”.ⁱⁱ Higher scores reflect more intense grief. The PGS-SF has been widely used and
13
14 321 validated for pregnancy loss and translated into multiple languages. [41]
15
16 322

16 323 ***Satisfaction with COVID-19 information***

17
18 324 We included items to explore parents’ satisfaction with COVID-19 related information
19
20 325 provided during pregnancy and postpartum including helpfulness of information, and most
21
22 326 trusted source of information. This section also includes multiple open-text fields for further
23
24 327 information.
25
26 328

26 329 ***Sociodemographic characteristics***

27
28 330 The final section of the survey includes a range of multiple-choice response items to
29
30 331 explore participant characteristics (e.g., age). Several multiple choice and Likert items were
31
32 332 also developed to assess COVID-19 status (e.g., diagnostic; isolation; availability of testing)
33
34 333 and personal measures taken by participants to protect and prevent the spread of COVID-19
35
36 334 (e.g., self-isolating). For questions on family violence, a pop-up message was displayed on-
37
38 335 screen showing support services relevant to the population and country.
39
40 336

40 337 ***Data Management***

41
42 338 The COCOON international online survey is co-ordinated and managed by the Centre
43
44 339 of Research Excellence in Stillbirth (CRE) located at Mater Research Institute within the
45
46 340 University of Queensland Faculty of Medicine in Brisbane, Australia. The online survey is
47
48 341 hosted on the Qualtrics platform and available via the Stillbirth CRE website in seven
49
50 342 languages. Several COCOON co-ordinating centres will host and manage their own data which
51
52 343 will then be collated into a central database (see Table 1).
53
54 344

54 345 ***Analytical Approach***

55 346 ***Online survey***

56
57 347 The survey data will be downloaded from Qualtrics software and further cleaned by
58
59 348 removing the entries with more than 50% missing data. The primary outcome variables will
60

1
2
3
4 349 primarily be presented using descriptive statistics and expressed in terms of frequencies,
5
6 350 averages, and proportions. Secondary outcome variables measuring psychosocial wellbeing
7
8 351 will be expressed primarily in terms of average scale scores, and categorised (e.g., high,
9
10 352 medium, low, etc.) based on recommended cut-offs (if relevant). Other secondary outcomes
11
12 353 will be presented descriptively in terms of frequencies and proportions. Aggregated
13
14 354 comparisons between countries will be made by grouping them based on policy responses by
15
16 355 governments and the difference in outcomes between them will be measured using t-tests,
17
18 356 ANOVA, or chi-square tests. We will also undertake sub-group analyses of the outcomes,
19
20 357 subject to responses being sufficient, examining sociodemographic characteristics such as
21
22 358 geographical location (e.g., urban, rural, remote) and location of birth (e.g., public vs. private
23
24 359 hospital vs. home birth). For the bereavement-specific surveys, we will also examine early vs.
25
26 360 late neonatal death and occurrence of best practice perinatal bereavement care practices. [23]
27
28 361 Inferential analyses of explanatory factors influencing the outcome variables will be carried
29
30 362 out via multivariable linear and logistic regression.

363 364 *Nested Qualitative Interview Study*

365 **Methods**

366 Several COCOON country co-ordinating centres are also participating in an international,
367
368 nested, qualitative interview study. This study is titled '*The experiences of Parents who sUffer*
369
370 *pregnancy loss and whose babies die During the panDemic: A quaLitative study of latE-term*
371
372 *miscarriage, Stillbirth and neonatal death*' (PUDDLES). The aim is to further explore the
373
374 experiences of bereaved parents following a late-term miscarriage (defined as after 14 weeks,
375
376 but before the country-specific cut-offs for stillbirth e.g., ≥ 20 weeks in Australia; ≥ 24 weeks
377
378 in the UK; etc.), stillbirth, or neonatal death during the COVID-19 pandemic. Ethics approval
379
380 for the PUDDLES study has been granted by the King's College London Biomedical & Health
381
382 Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Sub-
383
384 Committee [ref:- HR-19/20-19455] in the UK, and local ethics committees in participating
385
386 countries where required. COCOON survey respondents who experienced a bereavement will
387
388 be invited to participate in this nested qualitative study by leaving their contact details at the
389
390 end of the screen-out page. This nested study will be conducted in seven of the countries
391
392 participating in the COCOON Global Collaboration and this group is known as the PUDDLES
393
394 Global Collaboration, and is led by investigators at King's College London, UK (see Table 1).
395
396 As part of this nested qualitative study, a knowledge mapping exercise will be undertaken with
397
398
399
400

1
2
3
4 382 the view of developing a ‘maternal health system shock and resilience index’ to allow for a
5
6 383 simple comparison on deficits in care at a national, local, and individual level for data available
7
8 384 through the COCOON survey, other COVID-19 pandemic data, and for maternal health system
9
10 385 data collected in future health crises.
11
12 386

13 387 **Procedures**

14 388 At the end of the COCOON survey for participants in the UK, Australia, Brazil,
15
16 389 Canada, India, Italy, and New Zealand, parents who had experienced a stillbirth or neonatal
17
18 390 death will be invited to leave their contact details (e.g., name, email address, and/or contact
19
20 391 number) to participate in a qualitative interview (see Table 1). Likewise, those parents who
21
22 392 had experienced a late-term miscarriage and so will be screened out of the COCOON survey
23
24 393 as ineligible to participate, will also be able leave their contact details to be contacted to
25
26 394 participate in a qualitative interview. All qualitative interviews will be conducted by
27
28 395 researchers in each country co-ordinating centre, with oversight provided by the PUDDLES
29
30 396 Chief Investigator and the UK co-ordinating centre. Participants will be notified that by leaving
31
32 397 their contact details their responses to this survey no longer remain anonymous.
33
34 398

35 399 **Data Management and Analytical Approach**

36 400 The international, nested, qualitative interview study will explore parents’ lived
37
38 401 experiences of late-term miscarriage, stillbirth, and neonatal death during the pandemic, the
39
40 402 bereavement care they received, and implications for how bereavement care might be
41
42 403 optimised. Qualitative interviews will be conducted using video-conferencing software or by
43
44 404 phone (rarely: face-to-face depending on the country and public health guidance), digitally
45
46 405 recorded (with the interviewee’s permission), and transcribed verbatim. Interview transcripts
47
48 406 will be subject to a primary analysis in each country using Grounded Theory Analysis to make
49
50 407 an assessment of the country-specific experiences. Subsequently, the entire PUDDLES Global
51
52 408 dataset, comprised of seven countries’ data, will be subject to a secondary Thematic
53
54 409 Framework Analysis to identify and interpret important inter-country patterns across the
55
56 410 dataset. NVivo will be used to assist with storage, management, and coding, where appropriate.
57
58 411 At key points in this iterative process, review and discussion with members of our
59
60 412 interdisciplinary research team will take place to strengthen the credibility and validity of
413 413 findings.

414 Discussion

415 The COVID-19 pandemic has impacted the lives of millions of pregnant and
416 postpartum women and their families. [42] Globally, parents have experienced modifications
417 to care practices and endured significant health service reconfiguration which have resulted in
418 restricted access to routine healthcare, increased dependence on virtual rather than face-to-face
419 care, and limitations around labour and birth. [9] Mental health and social impacts have been
420 experienced on a global scale because of interventions to prevent and/or limit the spread of
421 COVID-19. Public health measures to reduce the spread of disease including social and
422 physical distancing have significantly affected interpersonal support and social connectedness,
423 which are robust predictors of maternal and parental mental health, in turn leading to increased
424 rates of anxiety and depression. [6,43] It is important that parent experiences of maternity care
425 during the initial stages of the COVID-19 pandemic as well as long-term are explored. Given
426 the global impact of the pandemic, it is also important that these studies are conducted on an
427 international scale to allow for cross-country comparisons. The COCOON study will help
428 identify the needs of parents globally and provide guidance to care providers and families in
429 times of social isolation and for other pandemic-related public health strategies.

430 Prior to the COVID-19 pandemic, 2 million stillbirths were reported every year globally
431 with profound economic and psychosocial burden on families and societies. [44–46] The
432 COVID-19 pandemic has contributed to an increase in stillbirths [9,19] and also resulted in
433 limitations to appropriate bereavement care and support for parents experiencing the loss of
434 their baby both in hospital and community settings. [9] The COCOON study will represent one
435 of the largest international surveys conducted during the pandemic to explore parent
436 experiences of bereavement care and the psychosocial impacts of COVID-19. Understanding
437 current practices in maternity and neonatal settings, both locally and globally, during the
438 COVID-19 outbreak is a critical first step in improving care for women and their families
439 during this current outbreak, and any similar future outbreaks.

440 The PUDDLES qualitative interview study, nested within COCOON, will also allow a
441 more thorough investigation of the experiences of bereaved parents at this time, and represents
442 the largest international qualitative investigation into perinatal bereavement response to the
443 COVID-19 pandemic.

444 There are several limitations of this study. First, the cross-sectional study design makes
445 it impossible to explore change over time, or comparison with outcomes before the pandemic.
446 Despite our attempt to make cross-country comparisons, the study design may limit these

1
2
3
4 447 comparisons due to differential progression of the pandemic (i.e., timing of peaks and
5
6 448 subsequent waves) and public health responses (e.g., lockdowns, border closures) and available
7
8 449 health services which have varied globally. Second, voluntary participation and recruitment of
9
10 450 participants predominantly conducted online and via social media will result in selection bias,
11
12 451 and not account for potential participants' digital poverty (as only those with access to the
13
14 452 internet can access these surveys and such respondents are likely to be more affluent and more
15
16 453 highly educated). These factors might limit the generalisability of the findings. [47] Despite
17
18 454 such selection bias, the study will provide key insights and information that should be
19
20 455 integrated into pandemic response.

21 456 The care parents receive during pregnancy and postpartum, including the care received
22
23 457 following stillbirth or neonatal death, has important implications for immediate and longer-
24
25 458 term wellbeing. Given the emerging evidence of negative impacts of COVID-19 on the health
26
27 459 and wellbeing of parents, pandemic preparedness and the development of evidence-based
28
29 460 maternity care guidelines and practices is imperative. Findings from the COCOON study will
30
31 461 inform strategies to improve care for women and their families, provide examples of best
32
33 462 practice (both during peak times of outbreaks and during off-peak times) and provide baseline
34
35 463 data for ongoing monitoring and evaluation in high-income, and middle-income countries
36
37 464 during this pandemic, and possible future pandemic(s). This is particularly important for the
38
39 465 delivery of appropriate and respectful bereavement care to parents following stillbirth or
40
41 466 neonatal death.

42 467

43 468 **Figure legend:**

44 469 Figure 1 – Schematic depiction of participant flow through COCOON study.

45 470

1
2
3
4 471 **Involvement of parents and families:** The ISA network and the Stillbirth CRE as its Western
5 Pacific regional office are committed to ensuring that the voices of parents who have
6 472 experienced the tragedy of stillbirth are heard. Effective and meaningful parent engagement in
7 473 all Stillbirth CRE research projects is facilitated by the Stillbirth Foundation Australia, as an
8 474 integral partner of the Stillbirth CRE, and through partnerships with other parent support and
9 475 advocacy organisations such as Still Aware, Bears of Hope, Red Nose/Sands Australia,
10 476 Women's Healthcare Australasia, and others. Similarly, parent support and advocacy
11 477 organisations in other COCOON collaboration countries have also been promoting the study
12 478 through their communication channels (see acknowledgements and appendix for details).
13
14
15
16
17
18
19
20

21 480
22 481 **Study status:** The first participant of the study was enrolled on 13 May 2020 in Australia. In
23 482 the twelve months after the recruitment first began (13 May 2021), 5,668 pregnant and 8,562
24 483 postpartum women have completed the survey, and 496 partners (174 during pregnancy; 322
25 484 during postpartum period). For the bereavement surveys, 840 parents who experienced
26 485 stillbirth and 270 who experienced neonatal death have participated.
27
28
29
30

31 486
32 487 **Collaboration (listed alphabetically by surname):** Joycelyn Abiog-Filoteo, Neelam
33 488 Aggarwal, Roberto Bonaiuti, Billie Bradford, Belinda Buenafe, Robin Cronin, Rakhi Dandona,
34 489 Joanne Durham, Abigail Easter, Sanne Gordijn, Mechthild M. Gross, , Rebecca Guarino,
35 490 Wendy Hall, Katharina Hartmann, Guilherme de Jesus, Inderjeet Kaur, Joemer Calderon
36 491 Maravilla, Lesley McCowan, Lucila Castanheira Nascimento, Alonkone Phengsvanh,
37 492 Wilfredo Quijencio Jr, Larissa Rossen, Jessica Ruidiaz, Vanphanom Sychareun, Alma
38 493 Taragua, Sowmya Thota, Fatima Vera.
39
40
41
42
43
44

45 494
46 495 **Acknowledgements:** We gratefully acknowledge all parents who participated in this study and
47 496 shared their personal experiences of pregnancy and birth during the COVID-19 pandemic to
48 497 help improve future care for families around the world. We would like to thank all organisations
49 498 and partners that promoted this study (listed in appendix).
50
51
52
53

54 500 **We would also like to acknowledge the contribution of the following colleagues (listed**
55 501 **alphabetically by surname):** Christine Andrews, Naiara Barros Polita, Hannah Blencowe,
56 502 Kia-Chong Chua, Sara Crocker, Miranda Davies-Tuck, Willyane de Andrade Alvarenga, Julie
57 503 Dean, Madeline Forbes, Adrienne Gordon, Alison Griffin, Cameron Paul Hurst, Rafat Jan,
58
59
60

1
2
3
4 504 Sailesh Kumar, James Locher, Philippa Middleton, Laura Mosconi, Christine Ou, Mira Pflanz,
5 505 Tosin Popoola, Valdo Ricca, Janet Scott, Laura Singline, Jet van der Hulst, Jane Warland,
6 506 Megan Weller.
7
8

9 507
10
11 508 **Funding:** This study is funded by Investigator Flenady and Mater Research Institute,
12 509 University of Queensland, Brisbane Australia. Silverio & Sandall (King's College London) are
13 510 supported by the National Institute for Health Research Applied Research Collaboration South
14 511 London [NIHR ARC South London] at King's College Hospital NHS Foundation Trust.
15 512 Silverio is also in receipt of a Personal Doctoral Fellowship Award from the NIHR ARC South
16 513 London Capacity Building Theme; and Sandall is also supported by NIHR Senior Investigator
17 514 Awards. The views expressed are those of the authors and not necessarily those of the funders.
18 515 The training and infrastructure of the PUDDLES Global Collaboration on Perinatal
19 516 Bereavement is supported by the King's College London Global Engagement Partnership Fund
20 517 successfully awarded to Silverio[ref:- PF2021_Mar_039].
21 518
22

23 519 **Ethics approval:** This study was approved by the Mater Misericordiae Ltd Human Research
24 520 Ethics Committee (EC00332) in Australia on 13 May 2020 (reference number
25 521 AM/MML/63526) and will be carried out in accordance with Australia's National Health and
26 522 Medical Research Council Statement on Ethical Conduct in Human Research. Local ethics
27 523 committee approvals in participating countries have been granted as required.
28 524
29

30 525 **Authors' contributions:** VF and CH conceived the study. SL led the development of the study
31 526 protocol with RG, SAS, FB, JC, VF, CH, DH, SHL, FM, MM, KO, PQ, CR, CS, JS, AV, AW.
32 527 All co-authors listed in the COCOON collaboration participated in the development and design
33 528 of the COCOON study for their country co-ordinating centre. SL and RG drafted the
34 529 manuscript with SAS, FB, DE, and VF. All co-authors have contributed to the revision of the
35 530 first draft and have approved the final manuscript.
36 531
37

38 532 **Conflict of interest:** The authors declare that they currently have no competing interests.
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

533 **References**

- 534 1 WHO. Coronavirus. <https://www.who.int/westernpacific/health-topics/coronavirus>
535 (accessed 12 Oct 2021).
- 536 2 Lal A, Erondy NA, Heymann DL, *et al*. Fragmented health systems in COVID-19:
537 rectifying the misalignment between global health security and universal health coverage.
538 *The Lancet* 2020.
- 539 3 Ceulemans M, Hompes T, Foulon V. Mental health status of pregnant and breastfeeding
540 women during the COVID-19 pandemic: A call for action. *Int J Gynecol Obstet*
541 2020;**151**:146–7.
- 542 4 Jackson L, De Pascalis L, Harrold JA, *et al*. Postpartum women’s psychological
543 experiences during the COVID-19 pandemic: a modified recurrent cross-sectional
544 thematic analysis. *BMC Pregnancy Childbirth* 2021;**21**:625. doi:10.1186/s12884-021-
545 04071-2
- 546 5 Silverio SA, De Backer K, Easter A, *et al*. Women’s experiences of maternity service
547 reconfiguration during the COVID-19 pandemic: A qualitative investigation. *Midwifery*
548 2021;**102**:103116. doi:10.1016/j.midw.2021.103116
- 549 6 Fallon V, Davies SM, Silverio SA, *et al*. Psychosocial experiences of postnatal women
550 during the COVID-19 pandemic. A UK-wide study of prevalence rates and risk factors
551 for clinically relevant depression and anxiety. *J Psychiatr Res* 2021;**136**:157–66.
552 doi:10.1016/j.jpsychires.2021.01.048
- 553 7 Silverio SA, Davies SM, Christiansen P, *et al*. A validation of the Postpartum Specific
554 Anxiety Scale 12-item research short-form for use during global crises with five
555 translations. *BMC Pregnancy Childbirth* 2021;**21**:1–12.
- 556 8 Chmielewska B, Barratt I, Townsend R, *et al*. Effects of the COVID-19 pandemic on
557 maternal and perinatal outcomes: a systematic review and meta-analysis. *Lancet Glob*
558 *Health* 2021.
- 559 9 Homer CS, Leisher SH, Aggarwal N, *et al*. Counting stillbirths and COVID 19—there
560 has never been a more urgent time. *Lancet Glob Health* 2021;**9**:e10–1.
- 561 10 Khalil A, Von Dadelszen P, Draycott T, *et al*. Change in the incidence of stillbirth and
562 preterm delivery during the COVID-19 pandemic. *Jama* 2020;**324**:705–6.
- 563 11 Ollivier R, Aston DrM, Price DrS, *et al*. Mental Health & Parental Concerns during
564 COVID-19: The Experiences of New Mothers Amidst Social Isolation. *Midwifery*
565 2021;**94**:102902. doi:10.1016/j.midw.2020.102902
- 566 12 Perzow SED, Hennessey E-MP, Hoffman MC, *et al*. Mental health of pregnant and
567 postpartum women in response to the COVID-19 pandemic. *J Affect Disord Rep*
568 2021;**4**:100123. doi:<https://doi.org/10.1016/j.jadr.2021.100123>

- 1
2
3
4 569 13 Coxon K, Turienzo CF, Kweekel L, *et al.* The impact of the coronavirus (COVID-19)
5 570 pandemic on maternity care in Europe. *Midwifery* 2020.
6
7 571 14 Karavadra B, Stockl A, Prosser-Snelling E, *et al.* Women's perceptions of COVID-19
8 572 and their healthcare experiences: a qualitative thematic analysis of a national survey of
9 573 pregnant women in the United Kingdom. *BMC Pregnancy Childbirth* 2020;**20**:1–8.
11
12 574 15 Rashidi Fakari F, Simbar M. Coronavirus Pandemic and Worries during Pregnancy; a
13 575 Letter to Editor. *Arch Acad Emerg Med*
14 576 2020;**8**.<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7075675/> (accessed 29 Apr
15 577 2021).
16
17 578 16 RANZCOG. RANZCOG - COVID-19 Hub. RANZCOG - COVID-19 Hub.
18 579 2021.<https://ranzcoг.edu.au/statements-guidelines/covid-19-statement> (accessed 13 Jun
19 580 2021).
21
22 581 17 DHHS. Department of Health and Human Services Victoria | Telehealth - coronavirus
23 582 (COVID-19). 2021.<https://www.dhhs.vic.gov.au/telehealth-coronavirus-covid-19>
24 583 (accessed 13 Jun 2021).
25
26 584 18 Davenport MH, Meyer S, Meah VL, *et al.* Moms Are Not OK: COVID-19 and Maternal
27 585 Mental Health. *Front Glob Womens Health* 2020;**1**:1. doi:10.3389/fgwh.2020.00001
28
29 586 19 DeSisto CL, Wallace B, Simeone RM, *et al.* Risk for stillbirth among women with and
30 587 without COVID-19 at delivery hospitalization—United States, March 2020–September
31 588 2021. *Morb Mortal Wkly Rep* 2021;**70**:1640.
32
33 589 20 Flenady V, Middleton P, Smith GC, *et al.* Stillbirths: the way forward in high-income
34 590 countries. *The Lancet* 2011;**377**:1703–17. doi:10.1016/S0140-6736(11)60064-0
35
36 591 21 Flenady V, Wojcieszek AM, Middleton P, *et al.* Stillbirths: recall to action in high-
37 592 income countries. *The Lancet* 2016;**387**:691–702. doi:10.1016/S0140-6736(15)01020-X
38
39 593 22 Health Service Executive. National Standards for Bereavement Care Following
40 594 Pregnancy Loss and Perinatal Death.
41 595 2016.[https://www.hse.ie/eng/services/list/3/maternity/bereavement-care/national-](https://www.hse.ie/eng/services/list/3/maternity/bereavement-care/national-standards-for-bereavement-care-following-pregnancy-loss-and-perinatal-death.pdf)
42 596 [standards-for-bereavement-care-following-pregnancy-loss-and-perinatal-death.pdf](https://www.hse.ie/eng/services/list/3/maternity/bereavement-care/national-standards-for-bereavement-care-following-pregnancy-loss-and-perinatal-death.pdf)
43 597 (accessed 14 Jul 2021).
44
45 598 23 Sands. A pathway to improve bereavement care for parents in England after pregnancy or
46 599 baby loss. 2020.[https://nbcpathway.org.uk/sites/default/files/2020-](https://nbcpathway.org.uk/sites/default/files/2020-02/Stillbirth%20Full%20Guidance_Jan%202020_0.pdf)
47 600 [02/Stillbirth%20Full%20Guidance_Jan%202020_0.pdf](https://nbcpathway.org.uk/sites/default/files/2020-02/Stillbirth%20Full%20Guidance_Jan%202020_0.pdf) (accessed 14 Jul 2021).
48
49 601 24 Horey D, Boyle FM, Cassidy J, *et al.* Parents' experiences of care offered after stillbirth:
50 602 An international online survey of high and middle-income countries. *Birth* 2021;**n/a**.
51 603 doi:10.1111/birt.12546
52
53 604 25 Boyle FM, Horey D, Middleton PF, *et al.* Clinical practice guidelines for perinatal
54 605 bereavement care - An overview. *Women Birth J Aust Coll Midwives* 2020;**33**:107–10.
55 606 doi:10.1016/j.wombi.2019.01.008
56
57
58
59
60

- 1
2
3
4 607 26 Ellis A, Chebsey C, Storey C, *et al.* Systematic review to understand and improve care
5 608 after stillbirth: a review of parents' and healthcare professionals' experiences. *BMC*
6 609 *Pregnancy Childbirth* 2016;**16**:16. doi:10.1186/s12884-016-0806-2
- 8 610 27 Ravaldi C, Wilson A, Ricca V, *et al.* Pregnant women voice their concerns and birth
9 611 expectations during the COVID-19 pandemic in Italy. *Women Birth* 2021;**34**:335–43.
10 612 doi:10.1016/j.wombi.2020.07.002
- 12 613 28 de Bernis L, Kinney MV, Stones W, *et al.* Stillbirths: ending preventable deaths by 2030.
13 614 *The Lancet* 2016;**387**:703–16. doi:10.1016/S0140-6736(15)00954-X
- 15 615 29 WHO. Archived: WHO Timeline - COVID-19. 2020. [https://www.who.int/news/item/27-](https://www.who.int/news/item/27-04-2020-who-timeline---covid-19)
16 616 04-2020-who-timeline---covid-19 (accessed 12 Oct 2021).
- 18 617 30 Hilder L, Flenady V, Ellwood D, *et al.* Improving, but could do better: Trends in
19 618 gestation-specific stillbirth in Australia, 1994-2015. *Paediatr Perinat Epidemiol*
20 619 2018;**32**:487–94. doi:10.1111/ppe.12508
- 22 620 31 NHS. Stillbirth. nhs.uk. 2018. <https://www.nhs.uk/conditions/stillbirth/> (accessed 14 Jul
23 621 2021).
- 25 622 32 Carvalho TS, Pellanda LC, Doyle P. Stillbirth prevalence in Brazil: an exploration of
26 623 regional differences. *J Pediatr (Rio J)* 2018;**94**:200–6. doi:10.1016/j.jpmed.2017.05.006
- 28 624 33 Newtonraj A, Kaur M, Gupta M, *et al.* Level, causes, and risk factors of stillbirth: a
29 625 population-based case control study from Chandigarh, India. *BMC Pregnancy Childbirth*
30 626 2017;**17**:371. doi:10.1186/s12884-017-1557-4
- 32 627 34 Spielberger CD. *Manual for the State-Trait Anxiety Inventory; Palo Alto, CA, Ed.*
33 628 Consulting Psychologists Press, Inc.: Columbia, MO, USA 1983.
- 35 629 35 Cox JL, Holden JM, Sagovsky R. Detection of postnatal depression: development of the
36 630 10-item Edinburgh Postnatal Depression Scale. *Br J Psychiatry* 1987;**150**:782–6.
- 38 631 36 Hewitt CE, Gilbody SM, Mann R, *et al.* Instruments to identify post-natal depression:
39 632 which methods have been the most extensively validated, in what setting and in which
40 633 language? *Int J Psychiatry Clin Pract* 2010;**14**:72–6.
- 42 634 37 Lee E-H. Review of the psychometric evidence of the perceived stress scale. *Asian Nurs*
43 635 *Res* 2012;**6**:121–7.
- 45 636 38 Solivan AE, Xiong X, Harville EW, *et al.* Measurement of perceived stress among
46 637 pregnant women: a comparison of two different instruments. *Matern Child Health J*
47 638 2015;**19**:1910–5.
- 49 639 39 De Jong Gierveld J, Van Tilburg T. Manual of the loneliness scale 1999. *Dep Soc Res*
50 640 *Methodol Vrije Univ Amst Amst Updat Version 1801 02 1999*.
- 52 641 40 Gierveld JDJ, Tilburg TV. A 6-item scale for overall, emotional, and social loneliness:
53 642 Confirmatory tests on survey data. *Res Aging* 2006;**28**:582–98.

- 1
2
3
4 643 41 Setubal MS, Bolibio R, Jesus RC, *et al.* A systematic review of instruments measuring
5 644 grief after perinatal loss and factors associated with grief reactions. *Palliat Support Care*
6 645 2020;:1–11.
7
8 646 42 Robertson T, Carter ED, Chou VB, *et al.* Early estimates of the indirect effects of the
9 647 COVID-19 pandemic on maternal and child mortality in low-income and middle-income
10 648 countries: a modelling study. *Lancet Glob Health* 2020;8:e901–8.
11
12 649 43 Brislane Á, Larkin F, Jones H, *et al.* Access to and Quality of Healthcare for Pregnant
13 650 and Postpartum Women During the COVID-19 Pandemic. *Front Glob Womens Health*
14 651 2021;2. doi:10.3389/fgwh.2021.628625
15
16 652 44 Unicef. Stillbirths and stillbirth rates. UNICEF DATA.
17 653 2020.<https://data.unicef.org/topic/child-survival/stillbirths/> (accessed 12 Oct 2021).
18
19 654 45 Horton R, Samarasekera U. Stillbirths: ending an epidemic of grief. *The Lancet*
20 655 2016;10018:515–6.
21
22 656 46 Heazell AE, Siassakos D, Blencowe H, *et al.* Stillbirths: economic and psychosocial
23 657 consequences. *The Lancet* 2016;387:604–16.
24
25 658 47 Turienzo CF, Newburn M, Agyepong A, *et al.* Addressing inequities in maternal health
26 659 among women living in communities of social disadvantage and ethnic diversity. *BMC*
27 660 *Public Health* 2021;21:1–5.
28
29
30
31
32 661
33
34 662
35
36
37 663
38
39
40 664
41
42 665
43
44 666
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

61550 on 5 September 2022. Downloaded from <http://bmjopen.bmj.com/> on January 27, 2024 by guest. Protected by copyright.

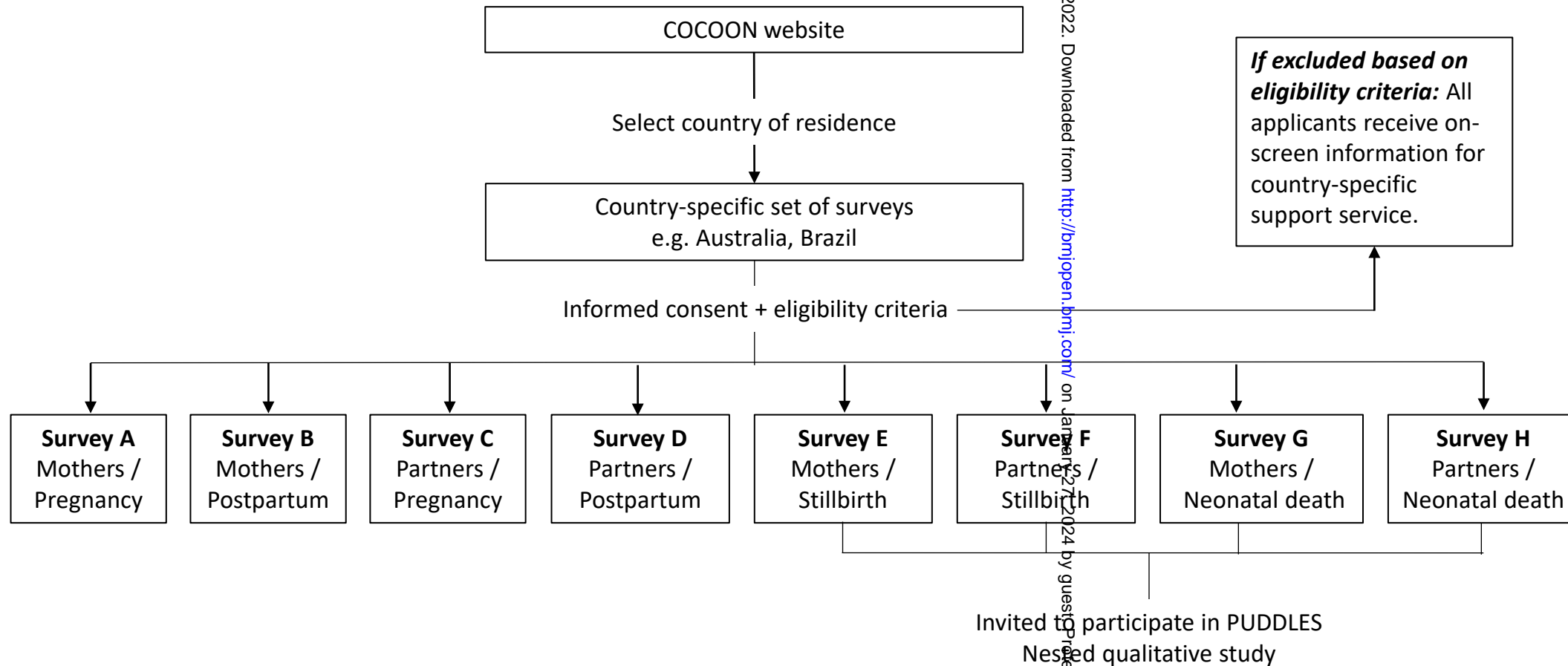


Figure 1. Schematic depiction of participant flow through COCOON study.

Appendix. COCOON country coordinating centres and partners

Country	Coordinating Centre/s	Academic and organisation partners
Argentina	<ul style="list-style-type: none"> • Era En Abril, Buenos Aires 	<ul style="list-style-type: none"> • International Stillbirth Alliance (ISA)
Australia	<ul style="list-style-type: none"> • NHMRC Centre of Research Excellence in Stillbirth, Mater Research Institute-University of Queensland (MRI-UQ), Brisbane, Queensland; Australasian Regional Office of the International Stillbirth Alliance (ISA) 	<ul style="list-style-type: none"> • Burnet Institute, Melbourne • Stillbirth Foundation Australia • Red Nose / Sands • Bears of Hope • Raising Children's Network
Brazil	<ul style="list-style-type: none"> • Hospital Universitário Pedro Ernesto • University of São Paulo, Ribeirão Preto College of Nursing 	<ul style="list-style-type: none"> • Do luto à luta: Apoio à Perda Gestacional e Neonatal • SobreViver: Apoio à Perda Gestacional ou do Recém-Nascido
Canada	<ul style="list-style-type: none"> • Paternite Famille et Societe, University of Quebec • The University of British Columbia, Vancouver Canada 	<ul style="list-style-type: none"> • International Stillbirth Alliance (ISA)
Germany	<ul style="list-style-type: none"> • Hannover Medical School • Mother Hood e.V. 	<ul style="list-style-type: none"> • Schatten & Licht e.V. • Hope's Angels • Telefonseelsorge • Verein Pustelblume • Kindsverlust.ch
India	<ul style="list-style-type: none"> • Public Health Foundation of India, Gurugram 	<ul style="list-style-type: none"> • International Stillbirth Alliance (ISA)

	<ul style="list-style-type: none"> ● Post Graduate Institute of Medical Education & Research (PGIMER) Chandigarh ● Fernandez Hospital Educational & Research Foundation, Hyderabad 	
Ireland	<ul style="list-style-type: none"> ● Pregnancy Loss Research Group, INFANT Research Centre, University College Cork 	<ul style="list-style-type: none"> ● International Stillbirth Alliance (ISA)
Italy	<ul style="list-style-type: none"> ● Ciao Lapo Foundation ● Perinatal Research Laboratory (PeaRL), University of Florence, NEUROFARBA 	<ul style="list-style-type: none"> ● International Stillbirth Alliance (ISA)
Laos	<ul style="list-style-type: none"> ● University of Health Sciences: Faculty of Medical Sciences, Vientiane, Lao People's Democratic Republic 	<ul style="list-style-type: none"> ● Queensland University of Technology (QUT)
Netherlands	<ul style="list-style-type: none"> ● University Medical Center, Groningen 	<ul style="list-style-type: none"> ● Kenniscentrum stille levens ● Steunpunt Nova
New Zealand	<ul style="list-style-type: none"> ● Te Herenga Waka Victoria University of Wellington ● University of Auckland 	<ul style="list-style-type: none"> ● Sands ● SIDS and Kids NZ
Philippines	<ul style="list-style-type: none"> ● Far Eastern University ● Filipino Nursing Diaspora Network 	<ul style="list-style-type: none"> ●
Spain	<ul style="list-style-type: none"> ● Umamanita Foundation, Girona 	<ul style="list-style-type: none"> ● El Parto es Nuestro ● La Leche League International
UK	<ul style="list-style-type: none"> ● Department of Women & Children's Health, School of Life Course & Population Sciences, King's College London 	<ul style="list-style-type: none"> ● International Stillbirth Alliance (ISA) ● Tommy's

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

		<ul style="list-style-type: none"> ● Sands ● The Lily Mae Foundation
US	<ul style="list-style-type: none"> ● NHMRC Centre of Research Excellence in Stillbirth, Mater Research Institute-University of Queensland (MRI-UQ), Brisbane, Queensland; Australasian Regional Office of the International Stillbirth Alliance (ISA) 	<ul style="list-style-type: none"> ● Star Legacy ● Miss Foundation ● First Candle

Note: Countries ordered alphabetically.

For peer review only

bmjopen-2022-061550 on September 6, 2022. Downloaded from <http://bmjopen.bmj.com/> on January 27, 2024 by guest. Protected by copyright.

BMJ Open

A multi-country study protocol of COCOON: Continuing Care in COVID-19 Outbreak global survey of New, expectant, and bereaved parent experiences

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-061550.R1
Article Type:	Protocol
Date Submitted by the Author:	19-Jun-2022
Complete List of Authors:	Loughnan, Siobhan; The University of Queensland, NHMRC Centre of Research Excellence in Stillbirth, Mater Research Institute-University of Queensland Gautam, R.; NHMRC Centre of Research Excellence in Stillbirth, Mater Research Institute-University of Queensland Silverio, Sergio; King's College London, Department of Women & Children's Health; University College London, Elizabeth Garrett Anderson Institute for Women's Health Boyle, Frances; NHMRC Centre of Research Excellence in Stillbirth, Mater Research Institute-University of Queensland; Institute for Social Science Research, University of Queensland Cassidy, J.; Umamanita Ellwood, David; Griffith University, School of Medicine; NHMRC Centre of Research Excellence in Stillbirth, Mater Research Institute-University of Queensland Homer, Caroline ; Burnet Institute Horey, Dell; La Trobe University, Public Health Leisher, Susannah; International Stillbirth Alliance demontigny, Francine; Paternite Famille et Societe, University of Quebec Murphy, Margaret; University College Cork National University of Ireland, Nursing and Midwifery O'Donoghue, Keelin; Dept. of Obstetrics and Gynaecology, University College Cork Quigley, P.; International Stillbirth Alliance; DAI Global Health Ravaldi, Claudia; University of Florence; CiaoLapo Foundation for Perinatal Health Sandall, Jane; Kings College, London, Health and Social Care Research Division Storey, Claire; International Stillbirth Alliance Vannacci, Alfredo; University of Florence, NEUROFARBA; CiaoLapo Foundation for Perinatal Health Wilson, Alyce; Burnet Institute, International Development Flenady, Vicki; NHMRC Centre of Research Excellence in Stillbirth, Mater Research Institute-University of Queensland Collaborator group, COCOON Global Collaboration ; Collaborator group
Primary Subject Heading:	Public health

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Secondary Subject Heading:	Global health, Mental health, Obstetrics and gynaecology, Health services research
Keywords:	COVID-19, PERINATOLOGY, PSYCHIATRY, OBSTETRICS, PUBLIC HEALTH



1
2
3
4 1 **Study title: A multi-country study protocol of COCOON: CONTinuing Care in COVID-**
5 2 **19 Outbreak global survey of New, expectant, and bereaved parent experiences**
6
7 3

8
9 4 **Authors:** S. A. Loughnan¹, R. Gautam¹, S. A. Silverio², F. M. Boyle^{1,3}, J. Cassidy⁴, D.
10 5 Ellwood^{1,5}, C. Homer⁶, D. Horey⁷, S. H. Leisher⁸, F. de Montigny⁹, M. Murphy¹⁰, K.
11 6 O'Donoghue¹⁰, P. Quigley¹¹, C. Ravaldi¹², J. Sandall³, C. Storey⁸, A. Vannacci¹², A. N.
12 7 Wilson⁶, & V. Flenady¹ on behalf of COCOON Global Collaboration*.
13
14
15
16 8

17
18 9 **Affiliations:**

19 10 ¹Centre of Research Excellence in Stillbirth, Mater Research Institute-University of
20 11 Queensland, Brisbane AUSTRALIA

21 12 ²Department of Women & Children's Health, School of Life Course & Population Sciences,
22 13 King's College London, UK

23 14 ³Institute for Social Science Research, The University of Queensland, Brisbane AUSTRALIA

24 15 ⁴Umamanita, Girona, SPAIN

25 16 ⁵Griffith University and Gold Coast University Hospital, Gold Coast, QLD, AUSTRALIA

26 17 ⁶Burnet Institute, Melbourne AUSTRALIA

27 18 ⁷La Trobe University, Melbourne AUSTRALIA

28 19 ⁸International Stillbirth Alliance, Millburn, NJ, USA

29 20 ⁹Paternite Famille et Societe, University of Quebec, CANADA

30 21 ¹⁰University College Cork, IRELAND

31 22 ¹¹DAI Global Health, UK

32 23 ¹²Perinatal Research Laboratory (PeaRL), University of Florence, NEUROFARBA
33 24 Department, CiaoLapo Foundation for Perinatal Health, Prato, ITALY
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50

51 26 *See collaboration and acknowledgment section.

52 28 **Corresponding author:** Dr Siobhan Loughnan, Centre of Research Excellence in Stillbirth,
53 29 Level 3 Aubigny Place, Mater Health Services, South Brisbane QLD AUSTRALIA, e:
54 30 siobhan.loughnan@mater.uq.edu.au
55
56
57
58
59
60
61
62
63

34 **Abstract**

35 **Introduction**

36 Globally, the COVID-19 pandemic has significantly disrupted the provision of healthcare and
37 efficiency of healthcare systems and is likely to have profound implications for pregnant and
38 postpartum women and their families including those who experience the tragedy of stillbirth
39 or neonatal death. This study aims to understand the psychosocial impact of COVID-19 and
40 the experiences of parents who have accessed maternity, neonatal, and bereavement care
41 services during this time.

43 **Methods and analysis**

44 An international, cross-sectional, online and/or telephone-based/face-to-face survey is being
45 administered across 15 countries and available in 11 languages. New, expectant, and bereaved
46 parents during the COVID-19 pandemic will be recruited. Validated psychometric scales will
47 be used to measure psychosocial wellbeing. Data will be analysed descriptively and by
48 assessing multivariable associations of the outcomes with explanatory factors. In seven of these
49 countries, bereaved parents will be recruited to a nested, qualitative interview study. The data
50 will be analysed using a grounded theory analysis (for each country) and thematic framework
51 analysis (for inter-country comparison) to gain further insights into their experiences.

53 **Ethics and dissemination**

54 Ethics approval for the multi-country online survey: COCOON, has been granted by the Mater
55 Misericordiae Ltd Human Research Ethics Committee in Australia (ref: AM/MML/63526).
56 Ethics approval for the nested qualitative interview study: PUDDLES, has been granted by the
57 King's College London Biomedical & Health Sciences, Dentistry, Medicine and Natural &
58 Mathematical Sciences Research Ethics Sub-Committee [ref: HR-19/20-19455] in the UK.
59 Local ethics committee approvals granted in participating countries where required. Results of
60 the study will be published in international peer-reviewed journals and through parent support
61 organisations. Findings will contribute to our understanding of delivering maternity care
62 services, particularly bereavement care, in high-income, lower-middle-income and low-income
63 countries during this or future health crises.

66 **Strengths and limitations of this study**

- 1
2
3
4 67 ● This study is a multi-country collaboration that facilitates data collection across 15
5 68 countries to explore experiences following the birth or death of a baby in a diverse range
6 69 of settings.
7
8
9 70 ● A mixed methods approach to the data analysis will contribute to the increase of
10 71 knowledge around maternity, neonatal, and bereavement care during the COVID-19
11 72 pandemic to inform future guidelines for care during a pandemic.
12
13 73 ● Limitations of this cross-sectional study include lack of longitudinal data which limits
14 74 exploration of change over time and inability to attribute outcomes to COVID-19 or
15 75 variants, selection bias, and the inability to study outcomes in relation to differential
16 76 progression of the pandemic across countries, including timing of infection peaks and
17 77 public health responses (e.g., lockdowns and border closures).
18
19
20
21
22
23
24

25 79 **Keywords**

26
27 80 COVID-19, pandemic, parents, pregnancy, postpartum, stillbirth, neonatal death, service
28
29 81 delivery
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

82 Introduction

83 The COVID-19 pandemic, caused by the novel coronavirus SARS-CoV-2 [1] has led
84 to global disruptions to healthcare systems resulting in direct and indirect impacts on physical
85 and mental health outcomes, particularly for pregnant and postpartum women.[2-7] Evidence
86 suggests maternal and perinatal outcomes have worsened during the pandemic including an
87 increase in maternal deaths, stillbirth, ruptured ectopic pregnancies, and maternal stress and
88 depression.[8–10] Pregnant and postpartum women and their partners are particularly
89 vulnerable for experiencing such a significant life course transition amidst a time of great
90 uncertainty and rapid change.[11,12]

91 Maternity care settings both in high- and lower-resourced settings have experienced
92 specific challenges during COVID-19 such as reduced capacity and resources to provide
93 maternal care services, care inaccessibility for parents and families, and lack of perinatal care
94 guidelines including bereavement care for parents following stillbirth and neonatal death.[9,13]
95 Social distancing restrictions have resulted in reduced health seeking behaviour, access to
96 health services and practice relating to breastfeeding, as well as postpartum and neonatal
97 care.[4,5,13–17] Decreased access to normal social support systems due to travel restrictions
98 within and between countries have led to increased isolation and loneliness, with several
99 studies highlighting the increased rates of anxiety, and clinically relevant maternal
100 depression.[4,6,18] Poor maternal mental health, particularly anxiety and depression, is
101 associated with short- and long-term adverse outcomes for both the mother and infant (e.g.,
102 recurring course of maternal symptoms detrimental to the mother-infant relationship, increased
103 risk of obstetrical complications, poor birth outcomes and later child developmental
104 problems).[6,15,16]

105 An increase in the number of preventable stillbirths and neonatal deaths is one of the
106 most crucial yet under-recognised indirect effects of the pandemic.[9,10,19] Pre-pandemic,
107 sub-standard care has been identified as contributing to up to 50% of stillbirths, with 20-30%
108 considered preventable if optimal care had been provided.[20,21] The pandemic-related
109 disruptions to maternal, newborn and child health care are known to have worsened the
110 standard of care in many instances, leading potentially to an increase in many preventable
111 losses of lives.[9] Pre-pandemic, research has shown healthcare professionals often feel
112 underprepared and unable to provide needed support to parents following the death of their
113 baby including parent-centred care plans, and bereavement-specific practices (e.g.,
114 opportunities for parenting activities such as seeing and holding their baby, bathing, and

1
2
3
4 115 dressing their baby, creating memories e.g., photographs, handprints, or footprints), and
5
6 116 memorials and commemorative rituals.[22–25]

7 117 The COVID-19 pandemic may have caused further disparities in service provision and
8
9 118 care for women and families world-wide, particularly parents who have experienced the death
10
11 119 of their baby.[5,14] It is critical we understand the clinical and psychosocial experiences of
12
13 120 pregnancy and childbirth during the pandemic if we are to improve mother, baby, and family
14
15 121 outcomes during this current global crisis and other future health events. It is particularly
16
17 122 important to understand bereaved parent experiences of care during this time, and the extent to
18
19 123 which recommended perinatal bereavement care practices - which are known to vary widely
20
21 124 between countries even in non-pandemic times - are being provided.[24,26]
22

23 126 **Study aims**

24
25 127 This study will explore the psychosocial impact of COVID-19 and the experiences of
26
27 128 parents who have accessed maternity, neonatal, and/or bereavement care services during the
28
29 129 pandemic, to provide an international picture of maternal healthcare during the COVID-19
30
31 130 pandemic. We aim to explore the perspectives and experiences of parents to understand:

- 32 131 ● maternity and perinatal bereavement care practices during the COVID-19 pandemic
33 132 (e.g., labour and birth practices) including the support services available (both formal
34 133 and informal), and public health limitations (e.g., visitors to hospital, presence of
35 134 partners during prenatal care and childbirth); and how these vary across countries,
36 135 hospital settings, and geographical locations (i.e., metropolitan vs. rural)
- 37 136 ● the psychosocial impact of COVID-19 including stress, social loneliness, anxiety, and
38 137 depression symptoms.
- 39 138 ● satisfaction with information provided about COVID-19 during pregnancy and
40 139 postpartum.
- 41 140 ● preventive measures taken by parents to protect themselves and others against COVID-
42 141 19 (e.g., decreased health service utilisation).
43
44
45
46
47
48
49
50
51

52 143 **Methods**

53 144 ***Study design and setting***

54 145 The *multi-country 'Continuing Care in COVID-19 Outbreak global survey of New,*
55
56 146 *expectant, and bereaved parent experiences'* (COCOON) study is an international, cross-
57
58 147 sectional online survey of parents who have accessed maternity, neonatal, and/or bereavement
59
60

1
2
3
4 148 care services during the COVID-19 pandemic. The online survey is co-ordinated and managed
5
6 149 by the Stillbirth CRE based in Brisbane, Australia. Several countries have delivered the online
7
8 150 survey items via a face-to-face or telephone interview, depending on local social distancing
9
10 151 restrictions and safety, each managed by the country co-ordinating centre (see Table 1). Ethics
11
12 152 approval for this research project (reference number AM/MML/63526) has been granted by
13
14 153 the Mater Misericordiae Ltd Human Research Ethics Committee in Australia and all processes
15
16 154 within this study are compliant with Australia's National Statement on Ethical Conduct in
17
18 155 Human Research and reflect international guidance on ethical principles, with country-specific
19
20 156 ethics and governance approval gained, where required.
21
22 157
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

159 **Table 1. List of participating countries, survey languages, modes of survey delivery, start month and year, and survey types being**
 160 **implemented across COCOON collaboration (ordered by launch date)**

Country	Language	Mode	Survey Administration Period	COCOON Survey								PUDDLES Nested Qualitative Study	
				Pregnancy/postpartum				Bereavement					
				A	B	C	D	E	F	G	H		
Australia	English	Online	May 2020 – Oct 2021	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲
UK	English	Online	July 2020 – Jan 2021	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲
Italy	Italian	Online	July 2020 – Oct 2021	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲
US	English	Online	July 2020 – Oct 2021	▲	▲	▲	▲	▲	▲	▲	▲	▲	N/A
Quebec, Canada	French	Online*	July 2020 – Oct 2021	▲	▲	▲	▲	▲	▲	▲	N/A	N/A	▲
Ireland	English	Online	Sept 2020 – Oct 2021	▲	▲	▲	▲	▲	▲	▲	▲	▲	N/A
Spain	Spanish	Online	Oct 2020 – Oct 2021	▲	▲	▲	▲	▲	▲	▲	▲	▲	N/A

Brazil	Portuguese	Online	Oct 2020 – Oct 2021	▲	▲	▲	▲	▲	▲	▲	▲	▲
India (North)	Hindi	Face-to-face/ Telephonic*	Oct 2020 – Oct 2021	▲	▲	N/A	N/A	▲	N/A	N/A	N/A	▲
Germany	German	Online	Nov 2020 – Oct 2021	▲	▲	▲	▲	▲	▲	▲	▲	N/A
India (South)	Telugu	Online*	Dec 2020 – Oct 2021	▲	▲	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Netherlands	Dutch	Online	May 2021 – Oct 2021	▲	▲	▲	▲	▲	▲	▲	▲	N/A
New Zealand	English	Online	May 2020 – Oct 2021	▲	▲	▲	▲	▲	▲	▲	▲	▲
Vancouver, Canada ^a	English	Online	April 2021 – May 2022	N/A	N/A	N/A	N/A	▲	▲	▲	▲	N/A
Argentina	Spanish	Online	Sept 2021 – May 2022	▲	▲	▲	▲	▲	▲	▲	▲	N/A
Laos	Lao	Face-to-face*	May 2022 – July 2022	▲	▲	N/A	N/A	▲	▲	▲	N/A	N/A
Philippines	English Filipino	Online and Face-to-face	July 2022 – Dec 2022	▲	▲	▲	▲	▲	▲	▲	▲	N/A

1
2
3
4 161 Notes. *hosting and management of own data in country; A=Pregnant women; B=Postpartum women; C=Partners of Pregnant Women; D=Partners
5
6 162 of Postpartum Women; E=Mothers following stillbirth; F=Mothers following Neonatal Death; G=Partners following stillbirth; H=Partners
7
8 163 following Neonatal Death; N/A=Not applicable/this aspect of the study is/was not being implemented.
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

For peer review only

bmjopen-2022-061550 on 5 September 2022. Downloaded from <http://bmjopen.bmj.com/> on January 27, 2024 by guest. Protected by copyright.

164 ***Patient and Public Involvement***

165 Patients and/or public were not expressly involved in the design or conduct of the
166 current study.

167 ***Survey development***

168 The COCOON survey was developed at the beginning of the COVID-19 pandemic as
169 part of an international collaboration to investigate the psychosocial impact of COVID-19 and
170 parent experiences of maternity, neonatal, and perinatal bereavement care during this time .
171 A total of eight surveys were developed, each tailored for a specific parent group: (A) pregnant
172 women; (B) postpartum women; (C) partners of pregnant women; (D) partners of postpartum
173 women; (E) mothers who experienced a stillbirth; (F) mothers who experienced a neonatal
174 death; (G) partners who experienced a stillbirth; and (H) partners who experienced a neonatal
175 death. The study design and development of the core set of items for each survey was driven
176 by the Stillbirth CRE in partnership with the COCOON working group and the following
177 coordinating centres (in alphabetical order): Canada (de Montigny), Ireland (Murphy,
178 O'Donoghue), Italy (Ravaldi, Vannacci), Spain (Cassidy), UK (Silverio, Sandall), and the
179 International Stillbirth Alliance (Leisher, Storey, Quigley). This study was informed by
180 previous research conducted by investigators including the COVID-ASSESS study
181 investigating anxiety and stress in pregnant and postpartum women in Italy during the
182 pandemic [27] and international stillbirth studies published in the 2011 and 2016 *The Lancet*
183 stillbirth series.[20,21,28] The final core set of items for each survey ranged between
184 approximately 70 and 115 open- and closed-ended questions across four main sections (see
185 Table 2). Closed-ended questions included to minimise respondent time burden, while inviting
186 extended feedback through open-ended comment response options. Validated psychometric
187 scales were included to explore psychosocial outcomes.

188 All country co-ordinating centres which joined the COCOON collaboration reviewed
189 the core set of survey items for each survey before minor contextual changes were made around
190 terminology (e.g. health practitioner terms) and translated into local languages. All study
191 information (including consent) and survey items were translated from English to the local
192 language (including independent review for accuracy) by each country coordinating centre.
193 Where validated translations of psychometric scales were not available, these scales were
194 translated from English to by each country coordinating team. In addition to the core set of
195 survey items and psychometric scales, each country coordinating centre was able to include

196 additional survey items relevant to understanding the impact of the pandemic in their country
197 and will be reported separately.

198

199 **Table 2. Core questions for different sections of the surveys**

Types of questions	Survey							
	A	B	C	D	E	F	G	H
1) Maternity care experiences								
Pregnancy, labour, birth and neonatal care (e.g., primary care provider; setting; gestation)	✓	✓	✓	✓	✓	✓	✓	✓
Postpartum and follow-up care (e.g., breastfeeding)		✓		✓				
Elements of quality, respectful care (e.g., shared decision-making)	✓	✓	✓	✓	✓	✓	✓	✓
Impact of COVID-19 pandemic (e.g., changes to care provider and mode of delivery; changes to birth plan)	✓	✓	✓	✓	✓	✓	✓	✓
Quality of care (e.g., satisfaction)	✓	✓	✓	✓	✓	✓	✓	✓
1a) Bereavement-specific care experiences								
Pregnancy, labour and birth, neonatal, postpartum and follow-up care (e.g., special nursery/intensive care unit; follow-up visits at home)					✓	✓	✓	✓
Difficulties with care due to COVID-19 restrictions and the occurrence of best practice bereavement care (e.g., opportunity to spend time with baby; creation of memories such as photos)					✓	✓	✓	✓
Investigations including autopsy or post-mortem examination (e.g., counselling; investigations received) and care around understanding the reasons behind their baby's death					✓	✓	✓	✓
2) Psychosocial outcomes								
Impact of COVID-19 (e.g., financial pressures, impact on daily life; social support)	✓	✓	✓	✓	✓	✓	✓	✓
State anxiety – STAI-S	✓	✓	✓	✓	✓	✓	✓	✓

Trait anxiety – STAI-T	✓	✓	✓	✓	✓	✓	✓	✓
Postpartum Anxiety – PSAS-RSF-C		✓						
Depression – EPDS	✓	✓	✓	✓	✓	✓	✓	✓
Perceived stress – PSS-4	✓	✓	✓	✓	✓	✓	✓	✓
Social loneliness – SLS	✓	✓	✓	✓	✓	✓	✓	✓
Perinatal grief – PGS-SF					✓	✓	✓	✓
3) Satisfaction with COVID-19 information								
Helpfulness of information	✓	✓	✓	✓	✓	✓	✓	✓
Sources of trusted information	✓	✓	✓	✓	✓	✓	✓	✓
4) Sociodemographic characteristics								
Demographic characteristics (e.g., age, education level, employment status)	✓	✓	✓	✓	✓	✓	✓	✓
Mental and physical health conditions	✓	✓	✓	✓	✓	✓	✓	✓
Family and domestic violence	✓	✓	✓	✓	✓	✓	✓	✓
COVID-19 status (e.g., diagnostic, isolation)	✓	✓	✓	✓	✓	✓	✓	✓

Notes. A=Pregnant women; B=Postpartum women; C=Partners of Pregnant Women; D=Partners of Postpartum Women; E=Mothers following stillbirth; F=Mothers following Neonatal Death; G=Partners following stillbirth; H=Partners following Neonatal Death.

Procedures

Inclusion criteria

This study will recruit women aged over 18 years of age, who were pregnant or gave birth to their baby during the COVID-19 pandemic, including women who experienced stillbirth (i.e., baby died before birth, during pregnancy or labour) or neonatal death (i.e., a live born baby dying up to 28 days after birth). For the purposes of this study, the COVID-19 pandemic is defined as starting from the 30 January 2020 onwards when it was declared a Public Health Emergency of International Concern (PHEIC) by the World Health Organisation (WHO).[29] Men and women whose partner was pregnant or gave birth to their baby during the COVID-19 pandemic, or those who suffered a stillbirth or neonatal death (referred to hereafter as “partners”) will also be recruited.

For the bereavement surveys, country-specific changes were made to the definition of stillbirth in accordance with differing gestational age criteria in each country (e.g., in Australia stillbirth is defined as a baby dying before birth and of at least 20 weeks’ gestation;[30] UK is

1
2
3
4 218 of at least 24 weeks' gestation;[31] Brazil is of at least 22 weeks' gestation;[32] India is of at
5
6 219 least 28 weeks' gestation).[33] Additional inclusion criteria include participants providing
7
8 220 informed consent online and reliable access to a computer (or similar device) and internet to
9
10 221 complete the online survey (for countries using this mode of survey delivery). For participants
11
12 222 who reside in countries where computer and internet access is limited, additional inclusion
13
14 223 criteria include willingness to attend a face-to-face meeting or participate in a telephone
15
16 224 interview to complete the survey items.

17 225

18 226 **Exclusion criteria**

19
20 227 For the bereavement surveys, parents who experienced the death of their baby prior to
21
22 228 the definition of stillbirth in each country, or after the definition of neonatal death in each
23
24 229 country will be excluded and redirected to country-specific support services.¹

25 230

27 231 **Recruitment**

28
29 232 For this international study an opportunity sample of self-selecting participants will be
30
31 233 recruited during the pandemic across the four parent groups: (1) women who are pregnant or
32
33 234 postpartum; (2) partners of women who are pregnant or postpartum; (3) women who have
34
35 235 experienced a stillbirth or neonatal death; and (4) partners who have experienced a stillbirth or
36
37 236 neonatal death. Participants will be predominantly recruited via online advertising including
38
39 237 social media and other electronic communication tools (e.g., newsletters) through each co-
40
41 238 ordinating centre, parent support organisation partnerships and both local and national charities
42
43 239 in each country, and the International Stillbirth Alliance member network. For those countries
44
45 240 conducting face-to-face/telephone interviews instead of the online survey (India, Laos, The
46
47 241 Philippines), recruitment will occur through word of mouth (e.g., obstetricians, midwives),
48
49 242 referral by practitioners/service providers in local service settings and advocate groups
50
51 243 (snowball sampling). Each COCOON co-ordinating centre has in-country partnerships with
52
53 244 parent organisations, maternal healthcare services, and parent bereavement organisations (see
54
55 245 appendix). From each participating country, we aim to recruit a minimum sample of 500
56
57 246 women and partners during pregnancy, 500 women and partners during the postpartum period,
58
59 247 and 200 bereaved parents following a stillbirth or neonatal death.

248

59 ¹For the UK, women and partners who experienced a late-term miscarriage and who are therefore not eligible to
60 participate in the COCOON online survey, will be able to take part in the nested qualitative study (PUDDLES).

249 **Procedures**

250 Parents interested in participating access the online survey via the Stillbirth CRE
251 website which is delivered in seven languages (except French, Hindi, Telugu, and Lao; see
252 Table 1). Parents will then be required to select the country they currently reside in to enter the
253 survey and review the participant information and eligibility criteria for the study and provide
254 online consent to participate. Eligibility questions determine the logic branching of the survey
255 to ensure parents are directed to the appropriate survey (see Figure 1). Parents who do not
256 reside in any of the participating countries listed will be directed to a generic (non-country-
257 specific) survey version available in English. Those who are ineligible for participation will be
258 excluded and redirected to an end-of-survey page where country-specific support services are
259 listed (with information, webpages, e-mail addresses, and contact numbers).

260

261 <Insert Figure 1 Here>

262

263 The time required for each COCOON survey completion is approximately 30-35
264 minutes. Following completion of the survey, information on country-specific support services
265 will be provided on-screen. For concerns regarding pregnancy or postpartum care during
266 COVID-19, all participants are advised to speak with their general practitioner (family doctor)
267 or other service provider.

268

269 **Outcomes**

270 The primary outcome for this study is parent experiences of quality of care including
271 bereavement care (see Table 2). Secondary outcomes include psychosocial wellbeing and
272 satisfaction with COVID-19 information.

273

274 ***Experience of maternity, neonatal, and bereavement care services***

275 This section aims to understand the experiences, main concerns and perceived needs of
276 parents accessing maternity care services during the COVID-19 pandemic. Most items in this
277 section are multiple choice Likert items rated on a scale between Strongly Disagree and
278 Strongly Agree. The bereavement-specific surveys (E, F, G, H) also include questions to
279 understand the experiences of care offered to parents following stillbirth or neonatal death. [24]
280 This section also includes several open-text fields for further information.

281

282 *Psychosocial impact of COVID-19*

283 This section includes several items to explore coping with COVID-related stressors
284 (e.g., financial pressures; worry about the health of self and baby, concerns about those at
285 greater risk of COVID-19 including elderly relatives; impact on daily life; social support) and
286 the following validated self-report outcomes measures (see Table 2).

287 **Anxiety.** The *State-Trait Anxiety Inventory for Adults (STAI)* consists of two 20-item
288 subscales assessing state and trait anxiety.[34] Items from both the state subscale (e.g., “I am
289 tense”; “I feel indecisive”) and trait subscale (e.g., “I feel satisfied with myself”; “I feel nervous
290 and restless”) are rated on a 4-point scale from 1 (Almost Never) to 4 (Almost Always) with a
291 maximum total score of 80. Higher total scores are indicative of greater anxiety. The STAI has
292 strong psychometric properties in the general adult and perinatal populations and has been
293 translated into multiple languages including Dutch,[35] French,[36] German,[37] Hindi,[38]
294 Italian,[39] Portuguese,[40] and Spanish.[41] The *Postpartum Specific Anxiety Scale –*
295 *Research Short Form – for use in global Crises (PSAS-RSF-C)* is administered in Survey B
296 only and consists of 12 items to assess anxiety symptoms specific to the postpartum period for
297 new mothers, across four factors.[7] It was developed in rapid response to the pandemic with
298 translations provided in Italian, French, Spanish, Chinese, and Dutch. Items (e.g., “I have
299 repeatedly checked on my sleeping baby”; “I have felt that my baby would be better cared for
300 by someone else”) are rated on a scale from 1 (Not at all) to 4 (Almost always). The PSAS
301 shows good psychometric properties [7] and the research long-form [42] has been subject to
302 multiple translations including French,[43] with ongoing translations and validations taking
303 place in Italian, Spanish, Dutch and more. A research short-form has also been developed.[44]

304 **Depression.** The *Edinburgh Postnatal Depression Scale (EPDS)* consists of 10 items
305 to assess both antenatal and postpartum depressive symptoms over the past seven days.[45]
306 Items (e.g., ‘I feel sad or miserable’) are rated on a scale from 0 (e.g., Not at all) to 3 (e.g., Yes,
307 most of the time) with a maximum total score of 30 (>12 indicative of possible depression).²
308 The EPDS has strong psychometric properties [46] and has been translated and validated in 20
309 different languages including Dutch,[47] French,[48] German,[49] Hindi,[50] Italian,[51]
310 Portuguese,[52] and Spanish.[53]

311 **Stress.** The *Perceived Stress Scale-4 (PSS-4)* consists of a 4-item scale to assess the
312 degree to which individuals believe their life has been unpredictable, uncontrollable, and

²All participants who self-reported thoughts of self-harm are advised on-screen to speak with their general practitioner or other service provider for support.

1
2
3
4 313 overloaded during the past month.[54] Items (e.g., “In the last month, how often have you felt
5 314 that you were unable to control the important things in your life?”) are rated on a scale from 0
6 315 (Never) to 4 (Very often). The PSS-4 is one of the most widely used instruments for measuring
7 316 the perception of stress; has shown good psychometric properties in perinatal populations; [55]
8 317 and has been translated into multiple languages including French,[56] German,[57] Hindi,[58]
9 318 Italian,[59] Portuguese,[60] and Spanish.[61]

10
11 319 **Social loneliness.** The *De Jong Gierveld Loneliness Scale* (SLS) consists of six items
12 320 to assess loneliness [62] which is an indicator of social wellbeing and pertains to the feeling of
13 321 missing an intimate relationship (emotional loneliness) or missing a wider social network
14 322 (social loneliness). Items (e.g., “There are plenty of people I can rely on when I have
15 323 problems”) are rated on a scale between “no,” “more or less” and “yes”. The scale has shown
16 324 good psychometric properties,[63] and has been translated into multiple languages including
17 325 Dutch,[64] French,[65] German,[66] and Spanish.[67]

18 326 **Perinatal grief.** The *Perinatal Grief Scale – Short Form (PGS-SF)* is administered in
19 327 the bereavement-specific surveys only [68] and consist of 33 items to assess behavioural and
20 328 affective symptoms of grief and symptoms specific to perinatal death. Items (e.g., “I find it
21 329 hard to get along with certain people”) are rated on a scale from “strongly agree” to “strongly
22 330 disagree”.ⁱⁱ Higher scores reflect more intense grief. The PGS-SF has been widely used and
23 331 validated for pregnancy loss and translated into multiple languages including Dutch,[69]
24 332 French,[70] German,[71] Italian,[72] and Portuguese.[70]

25 333

26 334 ***Satisfaction with COVID-19 information***

27 335 We included items to explore parents’ satisfaction with COVID-19 related information
28 336 provided during pregnancy and postpartum including helpfulness of information, and most
29 337 trusted source of information. This section also includes multiple open-text fields for further
30 338 information.

31 339

32 340

33 341

34 342 ***Sociodemographic characteristics***

35 343 The final section of the survey includes a range of multiple-choice response items to
36 344 explore participant characteristics (e.g., age). Several multiple choice and Likert items were
37 345 also developed to assess COVID-19 status (e.g., diagnostic; isolation; availability of testing)

1
2
3
4 346 and personal measures taken by participants to protect and prevent the spread of COVID-19
5
6 347 (e.g., self-isolating). For questions on family violence, a pop-up message was displayed on-
7
8 348 screen showing support services relevant to the population and country.
9

349

350 ***Data Management***

351 The COCOON international online survey is co-ordinated and managed by the Centre
352 of Research Excellence in Stillbirth (CRE) located at Mater Research Institute within the
353 University of Queensland Faculty of Medicine in Brisbane, Australia. The online survey is
354 hosted on the Qualtrics platform and available via the Stillbirth CRE website in seven
355 languages. Several COCOON co-ordinating centres will host and manage their own data which
356 will then be collated into a central database (see Table 1).
357

357

358 ***Analytical Approach***

359 ***Online survey***

360 All survey data will be downloaded from Qualtrics software into a single dataset
361 including all surveys. We will analyse and report findings for two groups: (1) Pregnancy and
362 postpartum (surveys: A, B, C, D); and (2) bereaved parents (surveys: E, F, G, H). The primary
363 outcome variables for each group will be presented primarily using descriptive statistics and
364 expressed in terms of frequencies, averages, and proportions. Secondary outcome variables
365 measuring psychosocial wellbeing will be expressed primarily in terms of average scale scores,
366 and categorised (e.g., high, medium, low, etc.) based on recommended cut-offs (if relevant).
367 Other secondary outcomes will be presented descriptively in terms of frequencies and
368 proportions. Comparisons of responses between countries will be undertaken subject to
369 sufficient numbers in each country. Comparison of responses by sociodemographic groupings
370 such as geographical location (e.g., urban, rural, remote) and location of birth (e.g., public vs.
371 private hospital vs. home birth) will also be undertaken, subject to sufficient numbers in each.
372 Univariable associations will be assessed using t-tests, ANOVA, chi-square or Fisher's exact
373 tests. Inferential analyses of explanatory factors influencing the outcome variables will be
374 carried out via multivariable linear and logistic regression. Mixed effects models will be used
375 to account for clustering by country when evaluating the association between potential
376 explanatory factors other than country on outcomes. To account for variation in COVID-19
377 severity in each country, we will calculate and explore in multivariable models a stringency
378 index for each participant based on country and survey completion date using the *Oxford*

379 *Coronavirus Government Response Tracker (OxCGRT)* dataset available online
380 (<https://ourworldindata.org/coronavirus>) and provides a COVID-19: Stringency Index.[73]

381

382 *Nested Qualitative Interview Study*

383 **Methods**

384 Several COCOON country co-ordinating centres are also participating in an international,
385 nested, qualitative interview study. This study is titled '*The experiences of Parents who suffer
386 pregnancy loss and whose babies died During the pandemic: A qualitative study of late-term
387 miscarriage, Stillbirth and neonatal death*' (PUDDLES). The aim is to further explore the
388 experiences of bereaved parents following a late-term miscarriage, stillbirth, or neonatal death
389 during the COVID-19 pandemic. Ethics approval for the PUDDLES study has been granted by
390 the King's College London Biomedical & Health Sciences, Dentistry, Medicine and Natural &
391 Mathematical Sciences Research Ethics Sub-Committee [ref:- HR-19/20-19455] in the UK,
392 and local ethics committees in participating countries where required. COCOON survey
393 respondents who experienced a bereavement will be invited to participate in this nested
394 qualitative study by leaving their contact details at the end of the screen-out page. This nested
395 study will be conducted in seven of the countries participating in the COCOON Global
396 Collaboration and this group is known as the PUDDLES Global Collaboration, and is led by
397 investigators at King's College London, UK (see Table 1). As part of this nested qualitative
398 study, a knowledge mapping exercise will be undertaken with the view of developing a
399 'maternal health system shock and resilience index' to allow for a simple comparison on
400 deficits in care at a national, local, and individual level for data available through the COCOON
401 survey, other COVID-19 pandemic data, and for maternal health system data collected in future
402 health crises.

403

404 **Procedures**

405 At the end of the COCOON survey for participants in the UK, Australia, Brazil,
406 Canada, India, Italy, and New Zealand, parents who had experienced a stillbirth or neonatal
407 death will be invited to leave their contact details (e.g., name, email address, and/or contact
408 number) to participate in a qualitative interview (see Table 1). Likewise, those parents who
409 had experienced a late-term miscarriage and so will be screened out of the COCOON survey
410 as ineligible to participate, will also be able leave their contact details to be contacted to
411 participate in a qualitative interview. All qualitative interviews will be conducted by

1
2
3
4 412 researchers in each country co-ordinating centre, with oversight provided by the PUDDLES
5 413 Chief Investigator and the UK co-ordinating centre. Participants will be notified that by leaving
6 414 their contact details their responses to this survey no longer remain anonymous.
7
8
9

415

416 **Data Management and Analytical Approach**

417 The international, nested, qualitative interview study will explore parents' lived
418 experiences of late-term miscarriage, stillbirth, and neonatal death during the pandemic, the
419 bereavement care they received, and implications for how bereavement care might be
420 optimised. Qualitative interviews will be conducted using video-conferencing software or by
421 phone (rarely: face-to-face depending on the country and public health guidance), digitally
422 recorded (with the interviewee's permission), and transcribed verbatim. Interview transcripts
423 will be subject to a primary analysis in each country using Grounded Theory Analysis [74,75]
424 (for investigation into psychological experiences) or Template Analysis [76,77] (for an
425 assessment of the reconfiguration of maternal, neonatal, and bereavement services) to make an
426 assessment of the country-specific experiences. Subsequently, the entire PUDDLES Global
427 dataset, comprised of participating countries' data, will be subject to a secondary Thematic
428 Framework Analysis [78,79] to identify and interpret important inter-country patterns across
429 the dataset. NVivo will be used to assist with storage, management, and coding, where
430 appropriate. At key points in this iterative process, review, and discussion with members of our
431 interdisciplinary research team will take place to strengthen the credibility and validity of
432 findings.
433

434

434 **Discussion**

435 The COVID-19 pandemic has impacted the lives of millions of pregnant and
436 postpartum women and their families.[80] Globally, parents have experienced modifications
437 to care practices and endured significant health service reconfiguration which have resulted in
438 restricted access to routine healthcare, increased dependence on virtual rather than face-to-face
439 care, and limitations around labour and birth.[9] Mental health and social impacts have been
440 experienced on a global scale because of interventions to prevent and/or limit the spread of
441 COVID-19. Public health measures to reduce the spread of disease including social and
442 physical distancing have significantly affected interpersonal support and social connectedness,
443 which are robust predictors of maternal and parental mental health, in turn leading to increased
444 rates of anxiety and depression.[6,81] It is important that parent experiences of maternity care

1
2
3
4 445 during the initial stages of the COVID-19 pandemic as well as long-term are explored. Given
5
6 446 the global impact of the pandemic, it is also important that these studies are conducted on an
7
8 447 international scale to allow for cross-country comparisons. Findings from the COCOON study
9
10 448 will provide a snapshot of parent experiences during the pandemic in multiple countries and
11
12 449 will add to the growing literature to inform guidance to care providers and families in times of
13
14 450 social isolation and for other pandemic-related public health strategies.

15 451 Prior to the COVID-19 pandemic, 2 million stillbirths were reported every year globally
16
17 452 with profound economic and psychosocial burden on families and societies.[82-84] The
18
19 453 COVID-19 pandemic has contributed to an increase in stillbirths [9,19] and also resulted in
20
21 454 limitations to appropriate bereavement care and support for parents experiencing the loss of
22
23 455 their baby both in hospital and community settings. [9] The COCOON study will represent one
24
25 456 of the largest international cross-sectional surveys conducted during the pandemic to explore
26
27 457 parent experiences of bereavement care following the death of a baby. Understanding current
28
29 458 practices in maternity and neonatal settings, both locally and across countries, during the
30
31 459 COVID-19 outbreak is a critical first step in improving care for women and their families
32
33 460 during this current outbreak, and any similar future outbreaks. The PUDDLES qualitative
34
35 461 interview study, nested within COCOON, will also allow a more thorough investigation of the
36
37 462 experiences of bereaved parents at this time, and represents the largest international qualitative
38
39 463 investigation into perinatal bereavement response to the COVID-19 pandemic.

40 464 There are several limitations of this study. First, this cross-sectional study will provide
41
42 465 an overall description of the sample during different stages of the COVID pandemic but will
43
44 466 not be able to identify reasons for individual outcomes or attribute outcomes to COVID-19 or
45
46 467 variants. The cross-sectional study design makes it impossible to explore change over time, or
47
48 468 comparison with outcomes before the pandemic. Despite our attempt to make cross-country
49
50 469 comparisons, the study design may limit these comparisons due to differential progression of
51
52 470 the pandemic (i.e., timing of peaks and subsequent waves) and public health responses (e.g.,
53
54 471 lockdowns, border closures) and available health services which have varied globally. Our
55
56 472 study is also limited due to lack of low-income settings where unequal socioeconomic impacts
57
58 473 of the COVID-19 pandemic have been experienced.[84] Voluntary participation and
59
60 474 recruitment of participants predominantly conducted online and via social media will result in
475
476 selection bias, and not account for potential participants' digital poverty (as only those with
477
478 access to the internet can access these surveys and such respondents are likely to be more
479
480 affluent and more highly educated). These factors might limit the generalisability of the

1
2
3
4 478 findings.[85] Further, different sampling methods will be used in this study with several
5
6 479 countries conducting telephone surveys/interviews, rather than online surveys, which may
7
8 480 result in lower face validity of items. Finally, all survey items and where validated
9
10 481 psychometric scales were not available, translation from English to local languages (e.g.
11
12 482 Italian) was completed by each countries coordinating centre and independently reviewed;
13
14 483 however back-translation was not conducted potentially impacting accuracy, consistency, and
15
16 484 quality. These factors may limit the generalisability of findings, particularly for low-income
17
18 485 settings.[49] There is a need for further longitudinal studies to investigate the psychosocial
19
20 486 impact of the pandemic over time, especially in low-income settings.

21
22 487 The care parents receive during pregnancy and postpartum, including the care received
23
24 488 following stillbirth or neonatal death, has important implications for immediate and longer-
25
26 489 term wellbeing. Given the emerging evidence of negative impacts of COVID-19 on the health
27
28 490 and wellbeing of parents, pandemic preparedness and the development of evidence-based
29
30 491 maternity care guidelines and practices is imperative. Findings from the COCOON study will
31
32 492 inform strategies to improve care for women and their families, provide examples of best
33
34 493 practice (both during peak times of outbreaks and during off-peak times), and provide baseline
35
36 494 data for ongoing monitoring and evaluation in high-income, and middle-income countries
37
38 495 during this pandemic, and possible future pandemic(s). This is particularly important for the
39
40 496 delivery of appropriate and respectful bereavement care to parents following stillbirth or
41
42 497 neonatal death.

43
44 498
45
46 499 **Ethics and dissemination:** This study was approved by the Mater Misericordiae Ltd Human
47
48 500 Research Ethics Committee (EC00332) in Australia on 13 May 2020 (reference number
49
50 501 AM/MML/63526) and will be carried out in accordance with Australia's National Health and
51
52 502 Medical Research Council Statement on Ethical Conduct in Human Research. The nested
53
54 503 qualitative interview study: PUDDLES, obtained ethical approval from the King's College
55
56 504 London Biomedical & Health Sciences, Dentistry, Medicine and Natural & Mathematical
57
58 505 Sciences Research Ethics Sub-Committee [ref: HR-19/20-19455] in the UK. Local ethics
59
60 506 committee approvals for each country coordinating centre were obtained where required:
507
508 507 Brazil: Ethics Research Committee of Pedro Ernesto University Hospital Rio de Janeiro State
509
510 508 University; Canada: The University of British Columbia Office of Research Services
Behavioural Research Ethics Board (Anglophone surveys), Research Ethics Committee of the
Université du Québec en Outaouais (Francophone surveys); Germany: Ethikkommission

1
2
3
4 511 Medizinische Hochschule Hannover; India (North): Post Graduate Institute of Medical
5
6 512 Education & Research (PGIMER) Ethics Committee; India (South): Institutional Ethics
7
8 513 Committee, Fernandez Foundation; Ireland: Clinical Research Ethics Committee of Cork
9
10 514 Teaching Hospitals; Italy: Florence University Ethics Committee; Laos: The University of
11
12 515 Health Sciences of Lao PDR; Netherlands: Universitair Medisch Centrum Groningen; New
13
14 516 Zealand: Victoria University of Wellington Human Ethics Committee; Philippines: Far Eastern
15
16 517 University-Nicanor Reyes Medical Foundation (FEU-NRMF) Institutional Ethics Review
17
18 518 Committee; Spain: The University of Alicante Research Ethics Committee; United Kingdom;
19
20 519 King's College London Biomedical and Health Sciences, Dentistry, Medicine and Natural and
21
22 520 Mathematical Sciences Research Ethics Sub-Committee. Results will be submitted for
23
24 521 publication in international peer-reviewed journals and through parent support organisations.
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

524 **References**

- 525 1 WHO. Coronavirus. <https://www.who.int/westernpacific/health-topics/coronavirus>
526 (accessed 12 Oct 2021).
- 527 2 Lal A, Erondy NA, Heymann DL, *et al.* Fragmented health systems in COVID-19:
528 rectifying the misalignment between global health security and universal health coverage.
529 *The Lancet* 2021;**397**(10268):61-7. [https://doi.org/10.1016/S0140-6736\(20\)32228-5](https://doi.org/10.1016/S0140-6736(20)32228-5)
- 530 3 Ceulemans M, Hompes T, Foulon V. Mental health status of pregnant and breastfeeding
531 women during the COVID-19 pandemic: A call for action. *Int J Gynecol Obstet*
532 2020;**151**:146–7. <https://doi.org/10.1002/ijgo.13295>
- 533 4 Jackson L, De Pascalis L, Harrold JA, *et al.* Postpartum women’s psychological
534 experiences during the COVID-19 pandemic: a modified recurrent cross-sectional
535 thematic analysis. *BMC Pregnancy Childbirth* 2021;**21**(1):625. doi:10.1186/s12884-021-
536 04071-2
- 537 5 Silverio SA, De Backer K, Easter A, *et al.* Women’s experiences of maternity service
538 reconfiguration during the COVID-19 pandemic: A qualitative investigation. *Midwifery*
539 2021;**102**:103116. doi:10.1016/j.midw.2021.103116
- 540 6 Fallon V, Davies SM, Silverio SA, *et al.* Psychosocial experiences of postnatal women
541 during the COVID-19 pandemic. A UK-wide study of prevalence rates and risk factors
542 for clinically relevant depression and anxiety. *J Psychiatr Res* 2021;**136**:157–66.
543 doi:10.1016/j.jpsychires.2021.01.048
- 544 7 Silverio SA, Davies SM, Christiansen P, *et al.* A validation of the Postpartum Specific
545 Anxiety Scale 12-item research short-form for use during global crises with five
546 translations. *BMC Pregnancy Childbirth* 2021;**21**:1–12. [https://doi.org/10.1186/s12884-](https://doi.org/10.1186/s12884-021-03597-9)
547 021-03597-9
- 548 8 Chmielewska B, Barratt I, Townsend R, *et al.* Effects of the COVID-19 pandemic on
549 maternal and perinatal outcomes: a systematic review and meta-analysis. *Lancet Glob*
550 *Health* 2021;**9**(6):e759-72. [https://doi.org/10.1016/S2214-109X\(21\)00079-6](https://doi.org/10.1016/S2214-109X(21)00079-6)

- 1
2
3
4 551 9 Homer CS, Leisher SH, Aggarwal N, *et al.* Counting stillbirths and COVID 19—there
5 has never been a more urgent time. *Lancet Glob Health* 2021;**9**(1):e10–1.
6 552
7 553 [https://doi.org/10.1016/S2214-109X\(20\)30456-3](https://doi.org/10.1016/S2214-109X(20)30456-3)
8
9
10 554 10 Khalil A, Von Dadelszen P, Draycott T, *et al.* Change in the incidence of stillbirth and
11 preterm delivery during the COVID-19 pandemic. *Jama* 2020;**324**(7):705–
12 555
13 556 6.doi:10.1001/jama.2020.12746
14
15
16 557 11 Ollivier R, Aston DrM, Price DrS, *et al.* Mental Health & Parental Concerns during
17 COVID-19: The Experiences of New Mothers Amidst Social Isolation. *Midwifery*
18 558 2021;**94**:102902.doi:10.1016/j.midw.2020.102902
19 559
20
21
22 560 12 Perzow SED, Hennessey E-MP, Hoffman MC, *et al.* Mental health of pregnant and
23 postpartum women in response to the COVID-19 pandemic. *J Affect Disord Rep*
24 561 2021;**4**:100123.<https://doi.org/10.1016/j.jadr.2021.100123>
25 562
26
27
28 563 13 Coxon K, Turienzo CF, Kweekel L, *et al.* The impact of the coronavirus (COVID-19)
29 pandemic on maternity care in Europe.
30 564
31 *Midwifery*2020;**88**:102779.doi:10.1016/j.midw.2020.102779
32 565
33
34
35 566 14 Karavadra B, Stockl A, Prosser-Snelling E, *et al.* Women’s perceptions of COVID-19
36 and their healthcare experiences: a qualitative thematic analysis of a national survey of
37 pregnant women in the United Kingdom. *BMC Pregnancy Childbirth* 2020;**20**:1–
38 568
39 8.<https://doi.org/10.1186/s12884-020-03283-2>
40 569
41
42
43 570 15 Rashidi Fakari F, Simbar M. Coronavirus Pandemic and Worries during Pregnancy; a
44 Letter to Editor. *Arch Acad Emerg Med* 2020;**8**(1):e21-
45 571
46 572 e21.<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7075675/> (accessed 29 Apr 2021).
47
48
49 573 16 RANZCOG. RANZCOG - COVID-19 Hub. RANZCOG - COVID-19 Hub.
50 574 2021.<https://ranzcoг.edu.au/statements-guidelines/covid-19-statement> (accessed 13 Jun
51 575
52 575 2021).
53
54
55 576 17 DHHS. Department of Health and Human Services Victoria | Telehealth - coronavirus
56 (COVID-19). 2021.<https://www.dhhs.vic.gov.au/telehealth-coronavirus-covid-19>
57 577
58 578 (accessed 13 Jun 2021).
59
60

- 1
2
3
4 579 18 Davenport MH, Meyer S, Meah VL, *et al.* Moms Are Not OK: COVID-19 and Maternal
5 580 Mental Health. *Front Glob Womens Health* 2020;**1**:1. doi:10.3389/fgwh.2020.00001
6
7
8 581 19 DeSisto CL, Wallace B, Simeone RM, *et al.* Risk for stillbirth among women with and
9 582 without COVID-19 at delivery hospitalization—United States, March 2020–September
10 583 2021. *Morb Mortal Wkly Rep* 2021;**70**:1640. doi: 10.15585/mmwr.mm7047e1
11
12
13
14 584 20 Flenady V, Middleton P, Smith GC, *et al.* Stillbirths: the way forward in high-income
15 585 countries. *The Lancet* 2011;**377**:1703–17. doi:10.1016/S0140-6736(11)60064-0
16
17
18
19 586 21 Flenady V, Wojcieszek AM, Middleton P, *et al.* Stillbirths: recall to action in high-
20 587 income countries. *The Lancet* 2016;**387**:691–702. doi:10.1016/S0140-6736(15)01020-X
21
22
23 588 22 Health Service Executive. National Standards for Bereavement Care Following
24 589 Pregnancy Loss and Perinatal Death.
25 590 2016. [https://www.hse.ie/eng/services/list/3/maternity/bereavement-care/national-](https://www.hse.ie/eng/services/list/3/maternity/bereavement-care/national-standards-for-bereavement-care-following-pregnancy-loss-and-perinatal-death.pdf)
26 591 [standards-for-bereavement-care-following-pregnancy-loss-and-perinatal-death.pdf](https://www.hse.ie/eng/services/list/3/maternity/bereavement-care/national-standards-for-bereavement-care-following-pregnancy-loss-and-perinatal-death.pdf)
27 592 (accessed 14 Jul 2021).
28
29
30
31
32
33 593 23 Sands. A pathway to improve bereavement care for parents in England after pregnancy or
34 594 baby loss. 2020. [https://nbcpathway.org.uk/sites/default/files/2020-](https://nbcpathway.org.uk/sites/default/files/2020-02/Stillbirth%20Full%20Guidance_Jan%202020_0.pdf)
35 595 [02/Stillbirth%20Full%20Guidance_Jan%202020_0.pdf](https://nbcpathway.org.uk/sites/default/files/2020-02/Stillbirth%20Full%20Guidance_Jan%202020_0.pdf) (accessed 14 Jul 2021).
36
37
38
39 596 24 Horey D, Boyle FM, Cassidy J, *et al.* Parents’ experiences of care offered after stillbirth:
40 597 An international online survey of high and middle-income countries. *Birth*
41 598 2021;**48**(3):366-74. doi:10.1111/birt.12546
42
43
44
45 599 25 Boyle FM, Horey D, Middleton PF, *et al.* Clinical practice guidelines for perinatal
46 600 bereavement care - An overview. *Women Birth J Aust Coll Midwives* 2020;**33**:107–10.
47 601 doi:10.1016/j.wombi.2019.01.008
48
49
50
51 602 26 Ellis A, Chebsey C, Storey C, *et al.* Systematic review to understand and improve care
52 603 after stillbirth: a review of parents’ and healthcare professionals’ experiences. *BMC*
53 604 *Pregnancy Childbirth* 2016;**16**:16. doi:10.1186/s12884-016-0806-2
54
55
56
57
58
59
60

- 1
2
3
4 605 27 Ravaldi C, Wilson A, Ricca V, *et al.* Pregnant women voice their concerns and birth
5 expectations during the COVID-19 pandemic in Italy. *Women Birth* 2021;**34**:335–43.
6 606
7 607 doi:10.1016/j.wombi.2020.07.002
8
9
10 608 28 de Bernis L, Kinney MV, Stones W, *et al.* Stillbirths: ending preventable deaths by 2030.
11 *The Lancet* 2016;**387**:703-16. doi:10.1016/S0140-6736(15)00954-X
12 609
13
14 610 29 WHO. Archived: WHO Timeline - COVID-19. 2020.[https://www.who.int/news/item/27-](https://www.who.int/news/item/27-04-2020-who-timeline---covid-19)
15 611 [04-2020-who-timeline---covid-19](https://www.who.int/news/item/27-04-2020-who-timeline---covid-19) (accessed 12 Oct 2021).
16
17
18 612 30 Hilder L, Flenady V, Ellwood D, *et al.* Improving, but could do better: Trends in
19 613 gestation-specific stillbirth in Australia, 1994-2015. *Paediatr Perinat Epidemiol*
20 614 2018;**32**:487–94. doi:10.1111/ppe.12508
21
22
23 615 31 NHS. Stillbirth. nhs.uk. 2018.<https://www.nhs.uk/conditions/stillbirth/> (accessed 14 Jul
24 616 2021).
25
26
27 617 32 Carvalho TS, Pellanda LC, Doyle P. Stillbirth prevalence in Brazil: an exploration of
28 618 regional differences. *J Pediatr (Rio J)* 2018;**94**:200-6. doi:10.1016/j.jped.2017.05.006
29
30
31 619 33 Newtonraj A, Kaur M, Gupta M, *et al.* Level, causes, and risk factors of stillbirth: a
32 620 population-based case control study from Chandigarh, India. *BMC Pregnancy Childbirth*
33 621 2017;**17**:371. doi:10.1186/s12884-017-1557-4
34
35
36 622 34 Spielberger CD. *Manual for the State-Trait Anxiety Inventory; Palo Alto, CA, Ed.*
37 623 Consulting Psychologists Press, Inc.: Columbia, MO, USA 1983.
38
39
40 624 35 Van der Ploeg, HM. The development and validation of the dutch state-trait anxiety
41 625 inventory. *Stress and anxiety* 1985;**9**:129-139.
42
43
44 626 36 Turgeon L, Chartrand É. Psychometric properties of the French Canadian version of the
45 627 state-trait anxiety inventory for children. *Educational and Psychological Measurement*
46 628 2003;**63**(1):174-85. <https://doi.org/10.1177/0013164402239324>
47
48
49 629 37 Reck C, Zimmer K, Dubber S, *et al.* The influence of general anxiety and childbirth-
50 630 specific anxiety on birth outcome. *Archives of women's mental health* 2013;**16**(5):363-
51 631 9.<https://doi.org/10.1007/s00737-013-0344-0>
52
53
54
55
56
57
58
59
60

- 1
2
3
4 632 38 Aneja J, Chavan BS, Huria A, *et al.* Perceived stress and its psychological correlates in
5 633 pregnant women: an Indian study. *International Journal of Culture and Mental Health*
6 634 2018;**11**(3):268-79. <https://doi.org/10.1080/17542863.2017.1364284>
7
8
9
10 635 39 Prete G, Fontanesi L, Porcelli P, *et al.* The psychological impact of COVID-19 in Italy:
11 636 worry leads to protective behavior, but at the cost of anxiety. *Frontiers in Psychology*
12 637 2020;**11**:566659.<https://doi.org/10.3389/fpsyg.2020.566659>
13
14
15
16 638 40 Biaggio AM, Natalicio L. Manual para o Inventario de Ansiedade Traço-Estado
17 639 (IDATE)[State-Trait Anxiety Inventory Manual]. Rio De Janeiro: Centro de Psicologia
18 640 Aplicada. 1979.
19
20
21
22 641 41 Bados A, Gómez-Benito J, Balaguer G. The state-trait anxiety inventory, trait version:
23 642 does it really measure anxiety?. *Journal of personality assessment* 2010;**92**(6):560-7.
24 643 <https://doi.org/10.1080/00223891.2010.513295>
25
26
27
28 644 42 Fallon V, Halford JC, Bennett KM, *et al.* The postpartum specific anxiety scale:
29 645 development and preliminary validation. *Archives of women's mental health*
30 646 2016;**19**(6):1079-90. <https://doi.org/10.1007/s00737-016-0658-9>
31
32
33
34 647 43 Infante-Gil L, Silverio SA, Fallon V, *et al.* Postpartum specific anxiety in a French
35 648 population: Validation of the French version of the Postpartum Specific Anxiety Scale
36 649 [PSAS-FR]. *Perspectives in Psychiatric Care* 2022;**58**(1):418-
37 650 28.<https://doi.org/10.1111/ppc.12808>
38
39
40
41
42 651 44 Davies SM, Christiansen P, Harrold JA, *et al.* Creation and validation of the Postpartum
43 652 Specific Anxiety Scale Research Short-Form (PSAS-RSF). *Archives of women's mental*
44 653 *health* 2021;**24**(6):957-69.<https://doi.org/10.1007/s00737-021-01114-7>
45
46
47
48 654 45 Cox JL, Holden JM, Sagovsky R. Detection of postnatal depression: development of the
49 655 10-item Edinburgh Postnatal Depression Scale. *Br J Psychiatry* 1987;**150**:782–
50 656 6.DOI: <https://doi.org/10.1192/bjp.150.6.782>
51
52
53
54 657 46 Hewitt CE, Gilbody SM, Mann R, *et al.* Instruments to identify post-natal depression:
55 658 which methods have been the most extensively validated, in what setting and in which
56
57
58
59
60

- 1
2
3
4 659 language? *Int J Psychiatry Clin Pract* 2010;**14**:72–
5
6 660 6.<https://doi.org/10.3109/13651500903198020>
7
8
9 661 47 Pop VJ, Komproe IH, Van Son MJ. Characteristics of the Edinburgh post natal
10 662 depression scale in The Netherlands. *Journal of affective disorders* 1992;**26**(2):105-10.
11 663 [https://doi.org/10.1016/0165-0327\(92\)90041-4](https://doi.org/10.1016/0165-0327(92)90041-4)
12
13
14 664 48 Guedeney N, Fermanian J. Validation study of the French version of the Edinburgh
15 665 Postnatal Depression Scale (EPDS): new results about use and psychometric properties.
16 666 *European psychiatry* 1998;**13**(2):83-9.[https://doi.org/10.1016/S0924-9338\(98\)80023-0](https://doi.org/10.1016/S0924-9338(98)80023-0)
17
18
19 667 49 Bergant AM, Nguyen T, Heim K, *et al.* German language version and validation of the
20 668 Edinburgh postnatal depression scale. *Deutsche medizinische Wochenschrift* (1946)
21 669 1998;**123**(3):35-40.
22
23
24 670 50 Joshi U, Lyngdoh T, Shidhaye R. Validation of Hindi version of Edinburgh postnatal
25 671 depression scale as a screening tool for antenatal depression. *Asian Journal of Psychiatry*
26 672 2020;**48**:101919.<https://doi.org/10.1016/j.ajp.2019.101919>
27
28
29 673 51 Carpinello B, Pariante CM, Serri F, *et al.* Validation of the Edinburgh postnatal
30 674 depression scale in Italy. *Journal of Psychosomatic Obstetrics & Gynecology*
31 675 1997;**18**(4):280-5. <https://doi.org/10.3109/01674829709080700>
32
33
34 676 52 Areias ME, Kumar R, Barros H, *et al.* Comparative incidence of depression in women
35 677 and men, during pregnancy and after childbirth: validation of the Edinburgh Postnatal
36 678 Depression Scale in Portuguese mothers. *The British journal of psychiatry*
37 679 1996;**169**(1):30-5.[doi:10.1192/bjp.169.1.30](https://doi.org/10.1192/bjp.169.1.30)
38
39
40 680 53 Garcia-Esteve L, Ascaso C, Ojuel J, *et al.* Validation of the Edinburgh postnatal
41 681 depression scale (EPDS) in Spanish mothers. *Journal of affective disorders*
42 682 2003;**75**(1):71-6.[https://doi.org/10.1016/S0165-0327\(02\)00020-4](https://doi.org/10.1016/S0165-0327(02)00020-4)
43
44
45 683 54 Lee EH. Review of the psychometric evidence of the perceived stress scale. *Asian*
46 684 *nursing research*. 2012;**6**(4):121-7.<https://doi.org/10.1016/j.anr.2012.08.004>
47
48
49
50
51
52
53
54
55
56
57
58
59
60

- 1
2
3
4 685 55 Solivan AE, Xiong X, Harville EW, *et al.* Measurement of perceived stress among
5 pregnant women: a comparison of two different instruments. *Maternal and child health*
6 686 *journal* 2015;**19**(9):1910-5.<https://doi.org/10.1007/s10995-015-1710-5>
7 687
8
9
10 688 56 Lesage FX, Berjot S, Deschamps F. Psychometric properties of the French versions of the
11 Perceived Stress Scale. *International journal of occupational medicine and*
12 689 *environmental health* 2012;**25**(2):178-84. <https://doi.org/10.2478/S13382-012-0024-8>
13 690
14
15
16 691 57 Klein EM, Brähler E, Dreier M, *et al.* The German version of the Perceived Stress Scale–
17 psychometric characteristics in a representative German community sample. *BMC*
18 692 *psychiatry* 2016;**16**(1):1-0.<https://doi.org/10.1186/s12888-016-0875-9>
19 693
20
21
22 694 58 Pangtey R, Basu S, Meena GS, *et al.* Perceived stress and its epidemiological and
23 behavioral correlates in an Urban Area of Delhi, India: A community-based cross-
24 695 sectional study. *Indian journal of psychological medicine* 2020;**42**(1):80-
25 696 6.https://doi.org/10.4103/IJPSYM.IJPSYM_528_18
26 697
27
28
29
30 698 59 Mondo M, Sechi C, Cabras C. Psychometric evaluation of three versions of the Italian
31 Perceived Stress Scale. *Current Psychology* 2021;**40**(4):1884-
32 699 92.<https://doi.org/10.1007/s12144-019-0132-8>
33 700
34
35
36 701 60 Siqueira Reis R, Ferreira Hino AA, Romélio Rodriguez Añez C. Perceived stress scale:
37 reliability and validity study in Brazil. *Journal of health psychology* 2010;**15**(1):107-
38 702 14.<https://doi.org/10.1177/1359105309346343>
39 703
40
41
42 704 61 Vallejo MA, Vallejo-Slocker L, Fernández-Abascal EG, *et al.* Determining factors for
43 stress perception assessed with the Perceived Stress Scale (PSS-4) in Spanish and other
44 705 European samples. *Frontiers in psychology*
45 706 2018;**9**:37.<https://doi.org/10.3389/fpsyg.2018.00037>
46 707
47
48
49
50 708 62 De Jong Gierveld J, Van Tilburg T. Manual of the loneliness scale 1999. *Dep Soc Res*
51 709 *Methodol Vrije Univ Amst Amst Updat Version 1801 02 1999*.
52
53
54
55 710 63 Gierveld JD, Tilburg TV. A 6-item scale for overall, emotional, and social loneliness:
56 Confirmatory tests on survey data. *Research on aging* 2006;**28**(5):582-
57 711 98.<https://doi.org/10.1177/0164027506289723>
58 712
59
60

- 1
2
3
4 713 64 Uysal-Bozkir Ö, Fokkema T, MacNeil-Vroomen JL, *et al.* Translation and validation of
5
6 714 the De Jong Gierveld loneliness scale among older migrants living in the Netherlands.
7
8 715 *The Journals of Gerontology: Series B* 2017;**72**(1):109-
9
10 716 19.<https://doi.org/10.1093/geronb/gbv044>
- 11
12 717 65 de Jong Gierveld J, Keating N, Fast JE. Determinants of loneliness among older adults in
13
14 718 Canada. *Canadian Journal on Aging/La Revue canadienne du vieillissement*
15
16 719 2015;**34**(2):125-36.DOI: <https://doi.org/10.1017/S0714980815000070>
- 17
18 720 66 De Jong Gierveld J, Van Tilburg T. The De Jong Gierveld short scales for emotional and
19
20 721 social loneliness: tested on data from 7 countries in the UN generations and gender
21
22 722 surveys. *European journal of ageing* 2010;**7**(2):121-30.[https://doi.org/10.1007/s10433-](https://doi.org/10.1007/s10433-010-0144-6)
23
24 723 010-0144-6
- 25
26 724 67 Tomás JM, Pinazo-Hernandis S, Donio-Bellegarde M, *et al.* Validity of the de Jong
27
28 725 Gierveld Loneliness Scale in Spanish older population: Competitive structural models
29
30 726 and item response theory. *European journal of ageing* 2017;**14**(4):429-37.
- 31
32 727 68 Setubal MS, Bolibio R, Jesus RC, *et al.* A systematic review of instruments measuring
33
34 728 grief after perinatal loss and factors associated with grief reactions. *Palliative &*
35
36 729 *Supportive Care* 2021;**19**(2):246-56.
- 37
38 730 69 Hunfeld JA, Wladimiroff JW, Passchier J, *et al.* Reliability and validity of the Perinatal
39
40 731 Grief Scale for women who experienced late pregnancy loss. *British Journal of Medical*
41
42 732 *Psychology* 1993;**66**(3):295-8.<https://doi.org/10.1111/j.2044-8341.1993.tb01753.x>
- 43
44 733 70 Paris GF, Montigny FD, Pelloso SM. Adaptação transcultural e evidências de validação
45
46 734 da Perinatal Grief Scale. *Texto & Contexto-Enfermagem* 2017;**26**.
- 47
48
49 735 71 Toedter LJ, Lasker JN, Janssen HJ. International comparison of studies using the
50
51 736 perinatal grief scale: a decade of research on pregnancy loss. *Death studies*
52
53 737 2001;**25**(3):205-28. <https://doi.org/10.1080/07481180125971>
- 54
55 738 72 Ravaldi C, Bettiol A, Crescioli G, *et al.* Italian translation and validation of the Perinatal
56
57 739 Grief Scale. *Scandinavian Journal of Caring Sciences* 2020;**34**(3):684-
58
59 740 9.<https://doi.org/10.1111/scs.12772>
- 60

- 1
2
3
4 741 73 Ritchie H, Mathieu E, Rodés-Guirao L, *et al.* Coronavirus Pandemic (COVID-19).
5
6 742 *Published online at OurWorldInData.org.* 2020. Retrieved from:
7
8 743 'https://ourworldindata.org/coronavirus' [Online Resource]
9
10 744 74 Glaser BG, Strauss AL. Discovery of grounded theory: strategies for qualitative research.
11
12 745 Aldine. 1967.
13
14 746 75 Silverio SA, Gauntlett W, Wallace H, *et al.* (Re) discovering grounded theory for cross-
15
16 747 disciplinary qualitative health research. In *Myths, methods, and messiness:: Insights for*
17
18 748 *qualitative research analysis.* 2019 (pp. 41-59). University of Bath.
19
20
21 749 76 King N. Doing template analysis. *Qualitative organizational research: Core methods and*
22
23 750 *current challenges* 2012;**426**(10.4135):9781526435620.
24
25 751 77 Brooks J, McCluskey S, Turley E, *et al.* The utility of template analysis in qualitative
26
27 752 psychology research. *Qualitative research in psychology.*2015;**12**(2):202-22.
28
29
30 753 78 Ritchie J, Spencer L, O'Connor W. Carrying out qualitative analysis. In *Qualitative*
31
32 754 *research practice: A guide for social science students and researchers.* sage 2003:219-
33
34 755 62.
35
36 756 79 Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for
37
38 757 the analysis of qualitative data in multi-disciplinary health research. *BMC medical*
39
40 758 *research methodology* 2013;**13**(1):1-8.<https://doi.org/10.1186/1471-2288-13-117>
41
42 759 80 Robertson T, Carter ED, Chou VB, *et al.* Early estimates of the indirect effects of the
43
44 760 COVID-19 pandemic on maternal and child mortality in low-income and middle-income
45
46 761 countries: a modelling study. *The Lancet Global Health* 2020;**8**(7):e901-8.
47
48 762 81 Brislane Á, Larkin F, Jones H, *et al.* Access to and quality of healthcare for pregnant and
49
50 763 postpartum women during the COVID-19 pandemic. *Frontiers in Global Women's*
51
52 764 *Health* 2021;**2**:628625.
53
54 765 82 Unicef. Stillbirths and stillbirth rates. UNICEF DATA.
55
56 766 2020.<https://data.unicef.org/topic/child-survival/stillbirths/> (accessed 12 Oct 2021).
57
58
59
60

- 1
2
3
4 767 83 Horton R, Samarasekera U. Stillbirths: ending an epidemic of grief. *The Lancet*
5 768 2016;**10018**(387):515-6.DOI:
6 769 10.1016/S0140-6736(15)01276-3
7
8
9
10 770 84 Heazell AE, Siassakos D, Blencowe H, *et al.* Stillbirths: economic and psychosocial
11 771 consequences. *The Lancet* 2016;**387**(10018):604-16.<https://doi.org/10.1016/S0140->
12 772 [6736\(15\)00836-3](https://doi.org/10.1016/S0140-6736(15)00836-3)
13
14
15
16 773 85 Josephson A, Kilic T, Michler JD. Socioeconomic impacts of COVID-19 in low-income
17 774 countries. *Nature Human Behaviour* 2021;**5**(5):557-65.<https://doi.org/10.1038/s41562->
18 775 [021-01096-7](https://doi.org/10.1038/s41562-021-01096-7)
19
20
21
22 776 85 Fernandez Turienzo C, Newburn M, Agyepong A, *et al.* Addressing inequities in maternal
23 777 health among women living in communities of social disadvantage and ethnic diversity.
24 778 *BMC Public Health* 2021;**21**(1):1-5. <https://doi.org/10.1186/s12889-021-10182-4>
25
26
27
28
29
30

31 780 **Figure legend:**

32
33 781 Figure 1 – Schematic depiction of participant flow through COCOON study.
34
35 782

36
37 783 **Involvement of parents and families:** The ISA network and the Stillbirth CRE as its Western
38 784 Pacific regional office are committed to ensuring that the voices of parents who have
39 785 experienced the tragedy of stillbirth are heard. Effective and meaningful parent engagement in
40 786 all Stillbirth CRE research projects is facilitated by the Stillbirth Foundation Australia, as an
41 787 integral partner of the Stillbirth CRE, and through partnerships with other parent support and
42 788 advocacy organisations such as Still Aware, Bears of Hope, Red Nose/Sands Australia,
43 789 Women’s Healthcare Australasia, and others. Similarly, parent support and advocacy
44 790 organisations in other COCOON collaboration countries have also been promoting the study
45 791 through their communication channels (see acknowledgements and appendix for details).
46
47
48
49
50

51 792
52
53 793 **Study status:** The first participant of the study was enrolled on 13 May 2020 in Australia. In
54 794 the twelve months after the recruitment first began (13 May 2021), 5,668 pregnant and 8,562
55 795 postpartum women have completed the survey, and 496 partners (174 during pregnancy; 322
56
57
58
59
60

1
2
3
4 796 during postpartum period). For the bereavement surveys, 840 parents who experienced
5 797 stillbirth and 270 who experienced neonatal death have participated.

6 798
7
8
9 799 **Collaboration (listed alphabetically by surname):** Joycelyn Abiog-Filoteo, Neelam
10 800 Aggarwal, Roberto Bonaiuti, Billie Bradford, Belinda Buenafe, Sara Crocker, Robin Cronin,
11 801 Rakhi Dandona, Joanne Durham, Abigail Easter, Madeline Forbes, Alison Griffin, Sanne
12 802 Gordijn, Mechthild M. Gross, Rebecca Guarino, Wendy Hall, Katharina Hartmann, Guilherme
13 803 de Jesus, Inderjeet Kaur, Joemer Calderon Maravilla, Lesley McCowan, Lucila Castanheira
14 804 Nascimento, Alonkone Phengsvanh, Wilfredo Quijencio Jr, Larissa Rossen, Jessica Ruidiaz,
15 805 Vanphanom Sychareun, Alma Taragua, Sowmya Thota, Fatima Vera.

16 806
17
18 807 **Acknowledgements:** We gratefully acknowledge all parents who participated in this study and
19 808 shared their personal experiences of pregnancy and birth during the COVID-19 pandemic to
20 809 help improve future care for families around the world. We would like to thank all organisations
21 810 and partners that promoted this study (listed in appendix).

22 811
23 812 **We would also like to acknowledge the contribution of the following colleagues (listed**
24 813 **alphabetically by surname):** Christine Andrews, Naiara Barros Polita, Hannah Blencowe,
25 814 Kia-Chong Chua, Miranda Davies-Tuck, Willyane de Andrade Alvarenga, Julie Dean, ,
26 815 Adrienne Gordon, Cameron Paul Hurst, Rafat Jan, Sailesh Kumar, James Locher, Philippa
27 816 Middleton, Laura Mosconi, Christine Ou, Mira Pflanz, Tosin Popoola, Valdo Ricca, Janet
28 817 Scott, Laura Singline, Jet van der Hulst, Jane Warland, Megan Weller.

29 818
30 819 **Authors' contributions:** VF and CH conceived the study. SL led the development of the study
31 820 protocol with RG, SAS, FB, JC, VF, CH, DH, SHL, FM, MM, KO, PQ, CR, CS, JS, AV, AW.
32 821 All co-authors listed in the COCOON collaboration participated in the development and design
33 822 of the COCOON study for their country co-ordinating centre. SL and RG drafted the
34 823 manuscript with SAS, FB, DE, and VF. All co-authors have contributed to the revision of the
35 824 first draft and have approved the final manuscript.

36 825
37 826 **Funding:** This study is funded by Investigator Flenady and Mater Research Institute,
38 827 University of Queensland, Brisbane Australia. Silverio & Sandall (King's College London) are
39 828 supported by the National Institute for Health Research Applied Research Collaboration South
40 829 London [NIHR ARC South London] at King's College Hospital NHS Foundation Trust.

1
2
3
4 830 Silverio is also in receipt of a Personal Doctoral Fellowship Award from the NIHR ARC South
5
6 831 London Capacity Building Theme; and Sandall is also supported by NIHR Senior Investigator
7
8 832 Awards. The views expressed are those of the authors and not necessarily those of the funders.
9
10 833 The training and infrastructure of the PUDDLES Global Collaboration on Perinatal
11
12 834 Bereavement is supported by the King's College London Global Engagement Partnership Fund
13
14 835 successfully awarded to Silverio[ref:- PF2021_Mar_039].
15

836

16 837 **Competing interests:** The authors declare that they currently have no competing interests.
17
18

838

839

840

841

842

843
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

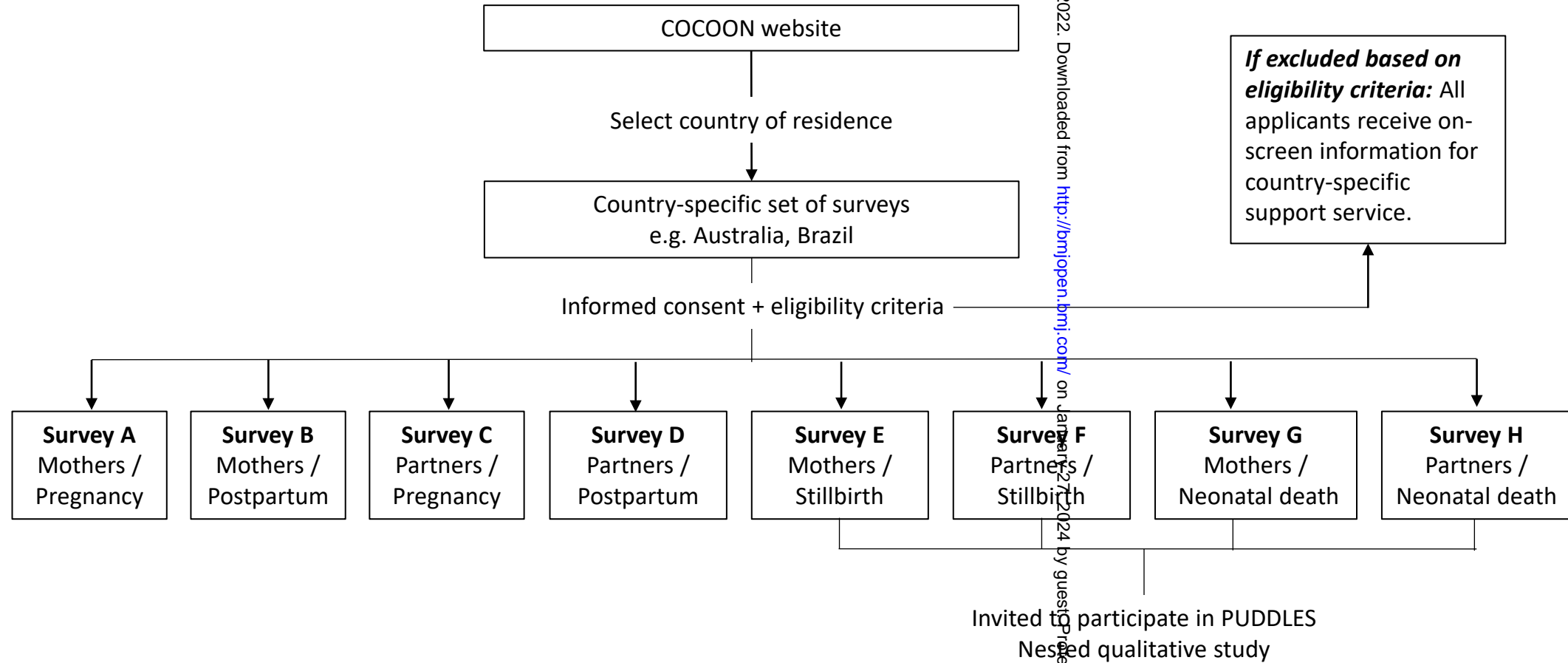


Figure 1. Schematic depiction of participant flow through COCOON study.

615150 on 5 September 2022. Downloaded from <http://bmjopen.bmj.com/> on January 27, 2024 by guest. Protected by copyright.

Appendix. COCOON country coordinating centres and partners

Country	Coordinating Centre/s	Academic and organisation partners
Argentina	<ul style="list-style-type: none"> Era En Abril, Buenos Aires 	<ul style="list-style-type: none"> International Stillbirth Alliance (ISA)
Australia	<ul style="list-style-type: none"> NHMRC Centre of Research Excellence in Stillbirth, Mater Research Institute-University of Queensland (MRI-UQ), Brisbane, Queensland; Australasian Regional Office of the International Stillbirth Alliance (ISA) 	<ul style="list-style-type: none"> Burnet Institute, Melbourne Stillbirth Foundation Australia Red Nose / Sands Bears of Hope Raising Children's Network
Brazil	<ul style="list-style-type: none"> Hospital Universitário Pedro Ernesto University of São Paulo, Ribeirão Preto College of Nursing 	<ul style="list-style-type: none"> Do luto à luta: Apoio à Perda Gestacional e Neonatal SobreViver: Apoio à Perda Gestacional ou do Recém-Nascido
Canada	<ul style="list-style-type: none"> Paternite Famille et Societe, University of Quebec The University of British Columbia, Vancouver Canada 	<ul style="list-style-type: none"> International Stillbirth Alliance (ISA)
Germany	<ul style="list-style-type: none"> Hannover Medical School Mother Hood e.V. 	<ul style="list-style-type: none"> Schatten & Licht e.V. Hope's Angels Telefonseelsorge Verein Pustelblume Kindsverlust.ch
India	<ul style="list-style-type: none"> Public Health Foundation of India, Gurugram 	<ul style="list-style-type: none"> International Stillbirth Alliance (ISA)

	<ul style="list-style-type: none"> ● Post Graduate Institute of Medical Education & Research (PGIMER) Chandigarh ● Fernandez Hospital Educational & Research Foundation, Hyderabad 	
Ireland	<ul style="list-style-type: none"> ● Pregnancy Loss Research Group, INFANT Research Centre, University College Cork 	<ul style="list-style-type: none"> ● International Stillbirth Alliance (ISA)
Italy	<ul style="list-style-type: none"> ● Ciao Lapo Foundation ● Perinatal Research Laboratory (PeaRL), University of Florence, NEUROFARBA 	<ul style="list-style-type: none"> ● International Stillbirth Alliance (ISA)
Laos	<ul style="list-style-type: none"> ● University of Health Sciences: Faculty of Medical Sciences, Vientiane, Lao People's Democratic Republic 	<ul style="list-style-type: none"> ● Queensland University of Technology (QUT)
Netherlands	<ul style="list-style-type: none"> ● University Medical Center, Groningen 	<ul style="list-style-type: none"> ● Kenniscentrum stillle levens ● Steunpunt Nova
New Zealand	<ul style="list-style-type: none"> ● Te Herenga Waka Victoria University of Wellington ● University of Auckland 	<ul style="list-style-type: none"> ● Sands ● SIDS and Kids NZ
Philippines	<ul style="list-style-type: none"> ● Far Eastern University ● Filipino Nursing Diaspora Network 	<ul style="list-style-type: none"> ●
Spain	<ul style="list-style-type: none"> ● Umamanita Foundation, Girona 	<ul style="list-style-type: none"> ● El Parto es Nuestro ● La Leche League International
UK	<ul style="list-style-type: none"> ● Department of Women & Children's Health, School of Life Course & Population Sciences, King's College London 	<ul style="list-style-type: none"> ● International Stillbirth Alliance (ISA) ● Tommy's

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

		<ul style="list-style-type: none"> ● Sands ● The Lily Mae Foundation
US	<ul style="list-style-type: none"> ● NHMRC Centre of Research Excellence in Stillbirth, Mater Research Institute-University of Queensland (MRI-UQ), Brisbane, Queensland; Australasian Regional Office of the International Stillbirth Alliance (ISA) 	<ul style="list-style-type: none"> ● Star Legacy ● Miss Foundation ● First Candle

Note: Countries ordered alphabetically.

STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation	Pg No	Line No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	2	45
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2	35-64
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4,5	83-125
Objectives	3	State specific objectives, including any prespecified hypotheses	5 18	128-142 385-390
Methods				
Study design	4	Present key elements of study design early in the paper	5-6 (online survey) 18 (qualitative nested study)	144-157 383-403
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-6 7-8 18-19 (qualitative study)	144-157 160-164 405-415
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	12-14, 18-19 (qualitative study)	205-268 405-415
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	10-11 14-17	168-203 270-349
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	14	250-268
Bias	9	Describe any efforts to address potential sources of bias	20	474-479
Study size	10	Explain how the study size was arrived at	13-14	246-248
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	17	359-381
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	17 19	359-381 417-433
		(b) Describe any methods used to examine subgroups and interactions	17	369-372
		(c) Explain how missing data were addressed	17	359-381
		(d) If applicable, describe analytical methods taking account of sampling strategy	Not applicable (N/A)	N/A

		(e) Describe any sensitivity analyses	N/A	N/A
Results				
n/a	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	N/A	N/A
		(b) Give reasons for non-participation at each stage	N/A	N/A
		(c) Consider use of a flow diagram	N/A	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	N/A	N/A
		(b) Indicate number of participants with missing data for each variable of interest	N/A	N/A
Outcome data	15*	Report numbers of outcome events or summary measures	N/A	N/A
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	N/A	N/A
		(b) Report category boundaries when continuous variables were categorized	N/A	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A	N/A
Discussion				
Key results	18	Summarise key results with reference to study objectives	N/A	N/A
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	20	465-487
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	N/A	N/A
Generalisability	21	Discuss the generalisability (external validity) of the study results	N/A	N/A
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	33-34	827-836

1
2
3 *Give information separately for exposed and unexposed groups.
4
5

6 **Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and
7 published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely
8 available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at
9 <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is
10 available at www.strobe-statement.org.
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60