Supplement 2
for
Guidelines for reporting trial protocols and completed trials modified due to the COVID-19 pandemic and other extenuating circumstances: The CONSERVE 2020 Statement

CONSERVE-SPIRIT Extension: [DATE] 27 September 2021					
Item	**Item Title**	**Description**			**Page No.**
I.	Extenuating Circumstances	Describe the circumstances and how they constitute extenuating circumstances.			11
II.	Important Modifications	a. Describe how the modifications are important modifications.			11
		b. Describe the impacts and mitigating strategies, including their rationale and implications for the trial.			(see below)
		c. Provide a modification timeline.			11
III.	Responsible Parties	State who planned, reviewed and approved the modifications.			11
IV.	Interim data	If modifications were informed by trial data, describe how the interim data were used, including whether they were examined by study group, and whether the individuals reviewing the data were blinded to the treatment allocation.			N/A
SPIRIT Item and Number		For each row, if important modifications occurred, check one or both of "impact" and/or "mitigating strategy" and describe the changes in the protocol. Check "no change" for items that are unaffected in the extenuating circumstance.			**Page No.**
		No Change	**Impact***	**Mitigating Strategy****	
1	Title	X			1
2	Trial registration	X			2
3	Protocol version		Updated - see item 25 for details	Online option for patient interviews	11
4	Funding		Extension to funding timelines due to recruitment delays	Ability to access grant funds to complete the trial	12
5	Roles and responsibilities	X			11
6	Background and rationale	X			3-4
7	Objectives	X			4
8	Trial design	X			4
9	Study setting	X			5
10	Eligibility criteria	X			4
11	Interventions	X			5-7
12	Outcomes	X			7-8

13	Participant timeline	X			Fig
14	Sample size	X			10
15	Recruitment		Reduced recruitment rate expected due to recruitment pauses related to COVID restrictions	Extension of timeline to complete the trial	5
16	Allocation	X			5
17	Blinding (masking)	X			5
18	Data collection methods		Goverment and hospital restrictions related to hospital visits and or home visits will result in assessments being cancelled or conducted via telephone only	Delay assessments by up to 14 days; if assessments cannot occur complete questionnaires over the phone and paper	7-8
19	Data management	X			8-9
20	Statistical methods	X			9
21	Data monitoring	X			8-10
22	Harms	X			10
23	Auditing	X			10
24	Research ethics approval	X			10
25	Protocol amendments		Protocol updated (V4) to change the patient interviews to give an online option rather than only face to face	Provides an option to conduct the participant interviews online rather than only in person	11
26	Consent or assent	X			4
27	Confidentiality	X			5 , 8
28	Declaration of interests	X			12
29	Access to data	X			N/A
30	Ancillary and post-trial care	X			N/A
31	Dissemination policy	X			10-11
32	Informed consent materials	X			
33	Biological specimens	X			N/A

*Aspects of the trial that are directly affected or changed by the extenuating circumstance and are not under the control of investigators, sponsor or funder.
**Aspects of the trial that are modified by the study investigators, sponsor or funder to respond to the extenuating circumstance or manage the direct impacts on the trial.