Department for Digital, Culture, Media & Sport

Events Research Programme Phase III

Development of Research Protocols

Research Study Template:

Study Name

A self-controlled case series study to measure the risk of SARS-CoV-2 infection associated with attendance at an Events Research Programme event

Event Locations for Study

All ERP events for which data are available.

Principal Investigator

Ian Douglas, London School of Hygiene & Tropical Medicine

Key research question(s)

The key research question for Phase 3 is:

> *What is the impact on risk of transmission of events held at or close to full capacity, without social distancing,*

This protocol aims to address this question. In particular it aims to assess:

- Is the risk of SARS-CoV-2 infection increased by attendance at an Events Research Programme event?
- Is any increased risk of infection modified by event type/location (outdoors/indoors)?
- Is any increased risk of infection modified by SARS-CoV-2 vaccine status?
- Is any increased risk of infection modified by entry conditional on pre-event negative LFT result?

The latter question will only be addressed if some events require a negative LFD to gain entrance.

Link to a published protocol for Phase I (if relevant)

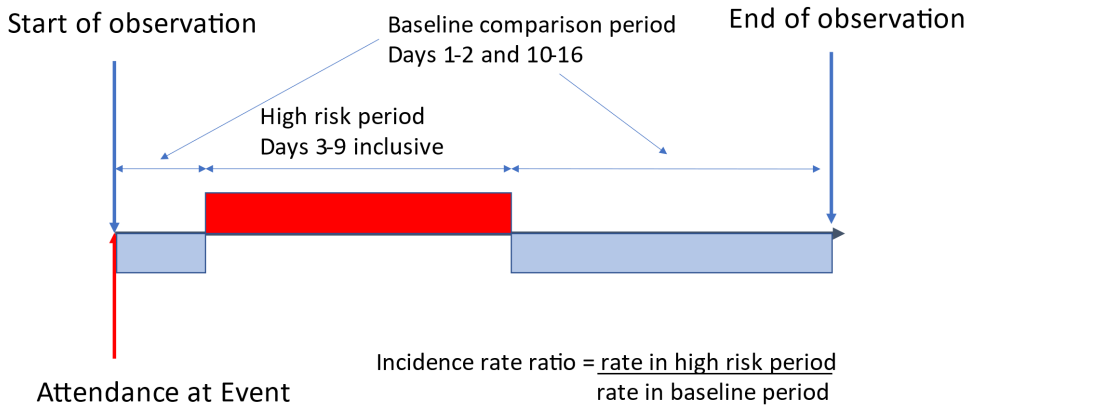
N/A

Study Design

This is a self-controlled case series, in which each person acts as their own control. Inclusion in the study is conditional on having both the exposure (attendance at an event) and the outcome (testing

positive for SARS-CoV-2). The rate of positive testing for SARS-CoV-2 is compared within person, between a 7 day high risk period beginning on day 3 following attendance at an event with the subsequent 7 day period and days 1 and 2 following the event when infection detection is assumed to be unaffected by attendance at the event. Figure 1 shows the timeline for each participant in the study. Only people who both 1) attend the event and 2) have a positive test result are included in the primary analysis. In a sensitivity analysis, the high risk period will be set from day 3-11 following the event and the baseline will be days 1,2 and 12-18.

Figure 1: Individual participant study timeline



A major strength of the study design is that it is self-controlled. This means that individual person factors that may influence risk of infection and which are constant over the observation period (e.g. occupation) are irrelevant. Factors which change over the observation period can be adjusted for if measurable (e.g. local levels of infection). The design has inherent assumptions which can be investigated in the analysis. Firstly, the likelihood of ascertaining a true positive test is assumed to be the same in the high risk and baseline weeks. This may be violated if asymptomatic testing is more likely in the high risk week following the event. To investigate any possible violation we will also measure the rate ratios for both negative tests and for positive tests restricted to those with COVID symptoms. The rate ratio for negative test results should indicate no difference in risk between the two weeks, with any difference indicating a possible bias. Differences in the rate ratios for positive tests with/without symptoms could also indicate a possible bias. Secondly the exposure is assumed to be unique and so anyone attending more than one Events Research Programme event within 2 weeks (likely to be a very small number) will be excluded from the analysis. For people attending multi-day events e.g. Silverstone, the high risk period begins on day 3 following the first day of their attendance and finishes on day 9 following the last day of attendance.

Key outcome measures

Relative risk of testing positive for SARS-CoV-2 infection associated with attendance at various types of ERP events.

NPIs being changed

NPIs will not be altered. However, we will stratify the analysis according to NPIs that are in place (e.g. whether mask wearing is required or not).

Engagement with participants and communications

Event organisers have been instructed that all attendees must be notified that participation in the SCCS analysis is a requirement for entry to the event, and be provided with a summary of what the SCCS involves. This requires that identifying information of each person attending the event is recorded in a form that can be linked to NHS Test and Trace. How this will be achieved in practice will necessarily vary from event to event due to their diverse ticketing arrangements. Every effort will be made by the event organisers to ensure all attendees provide the required information to enable their participation in the SCCS, using both pre-event and onsite registration facilities

Peer Review

This protocol was reviewed and approved by the Events Research Programme Science Board on 9th July 2021.

Ethics Approval

Approval has been obtained from the LSHTM Ethics Committee (ref 26382).