TITLE (SHORT, 200 CHARACTERS MAX.):

THE IMPACT OF STAFFING MODEL AND OUT OF HOURS AVAILABILITY ON RECRUITMENT RATES IN A MULTICENTER RANDOMIZED CONTROLLED TRIAL: EXPERIENCES IN THE TTM-2 TRIAL

MAIN HYPOTHESES TESTED (2 MAX)

TTM-1 used a deferred consent model in 9 out of 10 countries and aimed to recruit patients 24/7. Whilst most randomized clinical trials in critical care struggle to recruit to target TTM-1 finished within two weeks of the proposed study period. In Cardiff the majority of patients in TTM-1 were recruited outside normal working hours because of the availability of a dedicated research staff 24/7. Optimizing recruitment is important as failure to do so often results in extended study periods, increasing costs and potentially underpowered studies. Recruiting to target over time is a key metric for NIHR funded studies in the UK but this is only met in a fraction of trials, where less than a third achieve their original recruitment target and half are awarded with an extension.

The analysis will examine recruitment out of hours (evening or weekends) and during normal office hours. It will also capture the staff infrastructure used to achieve this. We will also look at the impact of consent models if some countries do not use deferred consent. We will be able to project the impact in relation to length of study and costs of not recruiting 24/7.

MULTICENTER [YES]

All TTM2 sites

PICO

Patients:	N/A
Intervention/Exposure/Prognostic factor:	N/A
Comparison:	Consent models, procedures and staffing used to recruit patients
Outcome:	Proportion of patients recruited during normal office hours, weekends and nights and time to randomization from ROSC

DATA NEEDED FOR THE ANALYSIS (SPECIFY VARIABLES AND MOTIVATE ANY PROPOSED ADDITIONS TO THE ECRF)

Variables not directly from TTM database but from central coordinator

From the Coordinating Centre if available or data from sites:

1. Staffing model for recruitment
2. Numbers of patients screened/recruited
3. Time of day patient randomised
4. Time to randomization to ROSC according to time of day period
5. Hospital characteristics (size, teaching status, rural/urban)

LOGISTICS – HOW WILL ADDITIONAL DATA BE GATHERED?

Direct correspondence with chief investigator, national coordinators and principle investigators, eCRF, screening logs

BRIEF STATISTICAL ANALYSIS PLAN AND SAMPLE SIZE ESTIMATE

Descriptive statistics will be used to show variations across different time periods. The large number of TTM 2 sites will allow this to be adequately powered to examine these effects.

FUNDING (IF APPLICBABLE)

None

CORRESPONDING AUTHORS NAME, INSTITUTION & E-MAIL ADDRESS:

Matt Wise, University Hospital of Wales, Cardiff, mattwise@doctors.org.uk

CO-WORKERS:

Matt PG Morgan, Helena Levin, Niklas Nielsen, Josef Dankiewicz, Gisela Lilja, Tobias Cronberg, Hans Friberg