ISRCTN13177364 https://doi.org/10.1186/ISRCTN13177364

The development, testing and evaluation of a COVID-19 fundamental nursing care protocol

Submission date
10/08/2020

Recruitment status
No longer recruiting

Registration date
09/09/2020

Overall study status
Completed

Last Edited
06/11/2023

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Patient experience of care is correlated with safety, clinical effectiveness, care quality, treatment outcomes and reduced overall service use. Currently, no international evidence-based guidelines exist for nursing hospitalised patients with SARS-CoV-2 who are not invasively ventilated, leading to potential variations in patient experience, treatment outcomes, care quality and costs. The aim of this study is to evaluate an evidence-based nursing protocol for patients with the SARS-CoV-2 virus, compared to care as usual, in terms of patients' reported experience of transactional and relational nursing care, care quality, treatment outcomes and costs.

Who can participate?
UK hospital trusts providing care for patients with COVID-19, patients who are not invasively ventilated admitted for care by these Trusts, and the nurses caring for these patients

What does the study involve?
Trusts will be allocated at random to one of two groups, one to implement the protocol and the other to continue to deliver nursing care as usual. In Trusts allocated to the COVID-NURSE protocol group, nurses and care assistants caring for patients with COVID-19 will need to undertake a three-hour online education programme about the protocol. Senior managers and nurse leaders will be required to support nursing teams to use the protocol. The researchers will provide support to managers and leaders together with materials supporting the protocol. The research team and clinical research nurses will collect data in both groups from non-invasively ventilated patients with COVID-19 on their experiences of care. They will also collect routine health outcomes data and questionnaires from nurses delivering care.

What are the possible benefits and risks of participating?
The study is comparing a COVID-specific nursing protocol with usual care. Participants in the experimental group of the study may benefit from receiving this protocol and no existing treatment will be withheld from any participants in either group of the study. Therefore, the researchers do not believe that participation in the study is a risk to participants. Participants may withdraw from the study at any time without prejudicing their treatment, care or employment.

Where is the study run from?
University of Exeter (UK)

When is the study starting and how long is it expected to run for?
July 2020 to January 2022 (updated 15/09/2021, previously: October 2021)

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Prof. David Richards
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
287288

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
MR/V02776X/1, IRAS 287288, CPMS 46874

Study information

Scientific Title
COVID-NURSE. The development and evaluation of a fundamental nursing care protocol for hospitalised patients with the SARS-CoV-2 virus not invasively ventilated on patients' experience of care: a cluster randomized controlled trial

Acronym
COVID-NURSE

Study objectives
Current study hypothesis as of 27/05/2021:

To undertake a cluster randomised controlled superiority trial to evaluate an evidence-based nursing protocol for patients with the SARS-CoV-2 virus, compared to care as usual, in terms of patients' reported experience of transactional and relational nursing care, care quality, treatment outcomes and costs.

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Previous study hypothesis:

To undertake a rapid cycle (Johnson et al., 2015) cluster randomised controlled superiority trial to evaluate an evidence-based nursing protocol for patients with the SARS-CoV-2 virus, compared to care as usual, in terms of patients' reported experience of transactional and relational nursing care, care quality, treatment outcomes and costs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/07/2020, University of Exeter Medical School (Knowledge Spa, Royal Cornwall Hospital, Truro, Cornwall, TR1 3HD, UK; +44 (0)1872 256460; c.barkle@exeter.ac.uk), ref: 20/07/256

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
To ensure allocation concealment, the researchers will undertake randomisation through the use of an externally administered, password-protected randomisation website independently developed and maintained by the UKCRC-registered University of Exeter Clinical Trials Unit. They will pair the 18 sites according to admission case rates, hospital type and patient ethnic diversity and, for each of the nine pairs, randomly allocate one site to the intervention group and

one site to the control group. Allocation will be conducted over three cycles of six sites (three pairs) each.

Experimental intervention: care as usual plus the clinical protocol developed in stage 1. After each wave of implementation and drawing on process evaluation findings, the researchers will modify their clinical protocol accordingly and embed the new version of the protocol in each subsequent experimental intervention cycle site. They will embed the protocol in intervention sites before each cycle via staff education, reminders and leadership-directed strategies successfully used in a previous cluster randomised controlled trial to significantly increase handwashing by nurses and care staff. They will monitor protocol adherence and fidelity as part of the process evaluation, amending their educational and leadership strategies accordingly before each subsequent rapid cycle wave.

Control: care as usual only

The intervention duration will be a minimum of 72 hours. Follow up will be also after a minimum of 72 hours, ensuring that patient-participants are able to report their experience of being nursed using the nursing protocol for a minimum of 72 hours.

Intervention Type
Behavioural

Primary outcome(s)
Patient experience measured using the Quality from the Patient's Perspective, and the Relational Aspects of Care Questionnaires at a minimum of 72 hours after exposure to the nursing care protocol

Key secondary outcome(s))
Current secondary outcome measures as of 19/10/2020:
Measured after a minimum of 72 hours after protocol exposure:
1. Care quality (prevalence of level 3 and 4 pressure sores, frequency of patient falls, frequency of medication errors) measured using the United Kingdom National Health Service Ward to Board dashboard
2. Functional ability measured using the Barthell Index
3. Treatment outcomes measured using the WHO Clinical Progression Scale
4. Depression measured using the PHQ-2
5. Anxiety measured using the GAD-2
6. Health utility measured using the EQ5D
7. Nurse outcomes measured using the Measure of Moral Distress for Health Care Professionals

Previous secondary outcome measures:
Measured after a minimum of 72 hours after protocol exposure:
1. Care quality measured using the United Kingdom National Health Service Ward to Board dashboard
2. Functional ability measured using the Barthell Index
3. Treatment outcomes measured using the WHO Clinical Progression Scale
4. Nurse outcomes measured using the Measure of Moral Distress for Health Care Professionals
5. Health utility measured using the EQ5D

Completion date
31/01/2022

Eligibility

Key inclusion criteria
1. Patients who are not invasively ventilated
2. Aged ≥18 years
3. Currently hospitalised and treated for infection with the SARS-CoV-2 virus
4. Received nursing care for a minimum of 72 hours during their current admission

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
999

Key exclusion criteria
1. Patients who are invasively ventilated
2. Participants unable to give informed consent

Date of first enrolment
01/11/2020

Date of final enrolment
24/12/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Devon and Exeter NHS Foundation Trust
Royal Devon and Exeter Hospital
Barrack Road
Exeter

United Kingdom
EX2 5DW

Sponsor information

Organisation
University of Exeter

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Participants will be identified by a unique study ID. Personal identifiable data including date of birth and NHS number may be collected but will be stored separately to research data and will be destroyed as per applicable regulations when the project is concluded. Data will be managed by the UKCRC registered Exeter Clinical Trials Unit (ExeCTU) following GDPR and data protection guidelines and all relevant Clinical Trial Regulations. All data will be anonymised prior to publication. Data will be collected and stored electronically in accordance with the Data Protection Act 2018 and ICH GCP E6 R2. ExeCTU will use Redcap Cloud Electronic Data Capture

System to collect all case report data. This system is validated to ISO27001 standards, backed up and maintained in Europe. This system is fully compliant to GDPR regulations and managed by ExeCTU. Any additional study data will be stored and backed up on the secure ExeCTU servers, maintained by ExeCTU. Data will be cleaned and validated appropriately and a full Data Protection Impact Assessment (DPIA) will be undertaken along with the development of a comprehensive Data Management Plan (DMP) before the first participant is recruited.
Where data are disseminated (e.g. via report, presentation or publication), they will be anonymised. The researchers will align all confidentiality and data handling with the Caldicott Principles. Anonymised data will be stored indefinitely on a research data storage system provided by the University of Exeter called Open access Research Exeter (ORE) for archiving (http://www.exeter.ac.uk/research/openresearch/policies/ore/).

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/11/2021	14/02/2022	Yes	No
Protocol article		26/05/2021	28/05/2021	Yes	No
Participant information sheet	Consent form version 4.0	12/01/2021	06/11/2023	No	Yes
Participant information sheet	Consent form version 5.0	25/01/2021	06/11/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes