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CLINICAL TRIAL

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Evaluation of a COVID-19 fundamental nursing care guideline versus usual care: The COVID-NURSE cluster randomized controlled trial

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Abstract

Aim: To evaluate the impact of usual care plus a fundamental nursing care guideline compared to usual care only for patients in hospital with COVID-19 on patient experience, care quality, functional ability, treatment outcomes, nurses' moral distress, patient health-related quality of life and cost-effectiveness.

Design: Parallel two-arm, cluster-level randomized controlled trial.

Methods: Between 18th January and 20th December 2021, we recruited (i) adults aged 18 years and over with COVID-19, excluding those invasively ventilated, admitted for at least three days or nights in UK Hospital Trusts; (ii) nurses caring for them. We randomly assigned hospitals to use a fundamental nursing care guideline and usual care or usual care only. Our patient-reported co-primary outcomes were the Relational Aspects of Care Questionnaire and four scales from the Quality from the Patient Perspective Questionnaire. We undertook intention-to-treat analyses.

Results: We randomized 15 clusters and recruited 581 patient and 418 nurse participants. Primary outcome data were available for 570–572 (98.1%–98.5%) patient participants in 14 clusters. We found no evidence of between-group differences on any patient, nurse or economic outcomes. We found between-group differences over time, in favour of the intervention, for three of our five co-primary outcomes, and a significant interaction on one primary patient outcome for ethnicity (white British vs. other) and allocated group in favour of the intervention for the 'other' ethnicity subgroup.

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Conclusion: We did not detect an overall difference in patient experience for a fundamental nursing care guideline compared to usual care. We have indications the guideline may have aided sustaining good practice over time and had a more positive impact on non-white British patients' experience of care.

Implications for the Profession and/or Patient Care: We cannot recommend the wholescale implementation of our guideline into routine nursing practice. Further intervention development, feasibility, pilot and evaluation studies are required.

Impact: Fundamental nursing care drives patient experience but is severely impacted in pandemics. Our guideline was not superior to usual care, albeit it may sustain good practice and have a positive impact on non-white British patients' experience of care.

Reporting Method: CONSORT and CONSERVE.

Patient or Public Contribution: Patients with experience of hospitalization with COVID-19 were involved in guideline development and writing, trial management and interpretation of findings.

KEYWORDS
cluster randomized controlled trial, COVID-19, fundamental nursing care, patient experience, SARS-COV-2

1 | INTRODUCTION

The SARS-COV-2 pandemic has highlighted the vital importance of nursing care for patients admitted to hospital with COVID-19. Nurses inexperienced (Gammon & Hunt, 2018) in pandemic-specific care procedures for infection prevention and control (World Health Organization, 2016) were redeployed from their usual workplaces, requiring them to nurse critically unwell patients (Bagnasco et al., 2020) and to implement practices they were unfamiliar with (Verbeek et al., 2020). In 2020, there were no guidelines available for nurses to use that would help them deliver fundamental nursing care in a pandemic (Whear et al., 2022). In our COVID-NURSE programme, we set out to remedy this omission by developing and evaluating such a guideline.

2 | BACKGROUND

Nursing care is a key driver of patient experience (Graham et al., 2018) which is correlated with patient satisfaction, safety, clinical effectiveness, care quality and treatment outcomes, including mortality and overall service use (Aiken et al., 2017; Black et al., 2014; Doyle et al., 2013). Nursing includes 'fundamental' nursing care (Kitson, 2010; Kitson et al., 2019), defined as actions on the part of the nurse to meet people's essential physical and psychosocial needs—such as oral care, toileting, nutrition, mobility, emotional and psychological well-being. This theoretical framework is underpinned by nurses developing a positive and trusting relationship with the person being cared for and their family/carers (Pentecost et al., 2019). However, reports from previous pandemics have documented reductions in nurse–patient interaction (Registered Nurses Association of Ontario, 2003) including adverse effects on communication and the nurse–patient relationship (Canadian Nurses Association, 2003), with patients reporting 'feeling abandoned'.

In our pre-trial intervention development studies over summer/autumn 2020 (Sugg et al., 2021, 2022; Whear et al., 2022), we undertook a rapid systematic review (Whear et al., 2022) and a UK-wide survey (Sugg et al., 2021, 2022) of nurses and non-registered care staff working with hospitalized patients with COVID-19 to identify the barriers to, and evidence for, fundamental nursing care procedures in patients with pandemic infectious disease. In our review (Whear et al., 2022), we were unable to identify a fundamental nursing care clinical guideline on pandemic nursing which could be used by nurses caring for patients admitted to hospital with COVID-19.

In both our survey (Sugg et al., 2021, 2022) and review (Whear et al., 2022), we found that wearing personal protective equipment (PPE), increased staffing pressures, infection prevention and control procedures, the emotional challenges caring for people in pandemics, the severity of patients' condition, lack of time, difficulties taking equipment in and out of isolation rooms, lack of interdisciplinary input, lack of knowledge about COVID-19 and fears of catching COVID-19 adversely affected nurses' non-verbal communication, their organization of care, their physical health, their workload and ability to undertake new roles. In six out of 15 care areas, the majority of respondents in our survey rated their ability to meet the needs of these patients as worse, compared to patients whom they normally care for (Sugg et al., 2021).

We presented these data to three panels of nurses caring for, and patients who had experience of hospitalization with, COVID-19 and co-created a clinical nursing guideline addressing the fundamental care needs of patients admitted to hospital with the virus. We restricted

the scope of the guideline to those patients who were non-invasively ventilated (i.e. conscious) and thus able to report on their experiences of nursing care in our subsequent 'COVID-NURSE' trial.

3 | THE STUDY

3.1 | Primary research question

What is the impact of a bespoke fundamental care guideline for patients admitted to hospital with COVID-19 on patient experience, compared to care as usual?

3.2 | Secondary research questions

(i) What is the impact of a bespoke fundamental care guideline for patients admitted to hospital with COVID-19 on care quality, functional ability and treatment outcomes, compared to care as usual?
(ii) What is the impact of the guideline for nurses caring for patients admitted to hospital with COVID-19 on nurses' moral distress, compared to care as usual?

3.3 | Health economic question

What is the cost-effectiveness of the guideline in terms of patient quality of life years, compared to care as usual?

4 | METHODS

4.1 | Study design

We undertook a multi-centre, parallel two-arm, cluster-level randomized controlled trial (RCT) (Richards et al., 2021), including clinical, economic and process evaluations, of a fundamental nursing care guideline compared to care as usual for people admitted to hospital and treated for COVID-19 consequent on a SARS-COV-2 infection, and nurses caring for them. Cluster-level randomization was necessitated by the implementation of the intervention at a health provider level. We had initially conceived the study as an adaptive pair-matched trial using a two-arm, rapid-cycle (Johnson et al., 2015) cluster RCT with three planned a priori review stages to assess intervention feasibility, integrity and acceptability, adapting the intervention accordingly. We had aimed to recruit 18 clusters in three cycles (six clusters per cycle), with 60 patient participants in each cluster, matching health providers on research intensity and population ethnicity. We had to redesign the trial to a simple cluster RCT (i.e. without pair-matching or intervention adaptation) due to three pandemic-related factors: (a) our trial was not designated a United Kingdom (UK) urgent public health (UPH) study. National Health Service (NHS) clinical research departments prioritized UPH and pharmaceutical trials meaning we were unable to recruit sites in sufficient diversity and numbers to allow matching on our a priori criteria; (b) the dynamic nature of the pandemic during 2020/21 with wildly fluctuating numbers of hospital admissions resulted in sites declining involvement when cases were high (e.g. winter 2020/21) due to clinical pressures and staff shortages, and when cases were low (e.g. summer 2021) declining to participate due to insufficient patients; (c) the difficulty of undertaking a cluster randomized controlled trial of a behavioural intervention, including practice change and staff training, in the pandemic. Nursing staff were drained and exhausted. COVID wards could be COVID 'decommissioned' at short notice, requiring us to train new intervention site ward teams at very short notice. Given these challenges, as well as redesigning the trial, we obtained a funded extension to prolong the trial by a year and revisit our sample size calculations accordingly. All amendments were reviewed and approved by the independent combined Trial Steering Committee and Data Monitoring Committee. The trial protocol is published here (Richards et al., 2021) and available as supplementary document 1. We report our trial using both the CONSORT (Schulz et al., 2010) (supplementary document 2) and CONSERVE (for completed trials modified due to the COVID-19 pandemic) (Orkin et al., 2021) (supplementary document 3) guidelines.

4.2 | Study setting and sampling

We recruited patient and nurse participants between 18th January and 20th December 2021, from English NHS hospital Trusts (clusters) that identified a priori wards willing to participate in the study and, agreed to participate in the trial from October 2020 to September 2021. Patient and nurse participants were recruited from one or more hospitals and wards in each cluster. All English NHS hospital trusts were eligible for inclusion. In order to recruit patient participants, site-based research staff reviewed admission data and approached potentially suitable patients according to the eligibility criteria. Patients were given the trial participant information sheet and consent form. Those that consented were then interviewed by the same research staff to collect primary and secondary outcome data, apart from patient safety and healthcare utilization data, which were collected from routine hospital data sets.

4.3 | Inclusion criteria

Eligible patient participants were adults aged 18 years or older, not invasively ventilated, currently hospitalized and being treated for COVID-19, or recently discharged after such treatment and who had received nursing care for three or more days/nights during their admission. Eligible nursing participants were registered nurses, students and nursing care workers caring for these patients. NHS Trusts were enrolled and consented to participate in the trial before

randomization of sites to trial arm. Eligible individual participants gave written consent to data collection after cluster randomization; where possible, translation facilities were provided for participants if required.

4.4 | Randomization and masking

To ensure allocation concealment, an unblinded statistician, remote from the trial team and who had no role in site recruitment or data analysis generated the random allocation sequence and allocated sites to the intervention and control groups. We used a static list generated using random blocks (2 to 6) through an externally administered, password-protected randomization website independently developed and maintained by the UKCRC-registered University of Exeter Clinical Trials Unit. We initially allocated clusters 1:1 but with agreement from our independent steering committee; we amended this to 3:1 (intervention: control) from July 2021 to address an imbalance in our patient participant numbers. Patient participants were blinded to cluster allocation but due to the behavioural nature of the intervention it was not possible to blind research assessors or nurse participants. Trial statisticians were blind to cluster and individual participants' allocations throughout the trial and primary analyses. Blinded analyses were presented to the investigators before unblinding by the independent statistician.

4.5 | Sample size

We calculated our target patient participant sample size using an estimate of the minimum clinically important difference for the Quality from the Patients' Perspective (QPP) of 0.2 and the typical within-unit standard deviation (0.6), from the measure developers, and an intraclass correlation coefficient (ICC) of 0.02 based on indicative estimates of hospital-level variation in quality measures. We examined a number of scenarios, using alternative approaches (no small sample adjustment, Satterthwaite approximation and Kenward-Rogers (KR) approximation; cluster-level linear regression) to explore the robustness of the sample size calculations, taking into account different cluster sizes and different between-cluster standard deviation values informed by between-country differences on measures, and determined that a cluster size of 60 patient participants (derived based on expected patient numbers suggested by hospital leaders) would generate over 80% power with six clusters per arm and 90% power with seven clusters in each arm (total of 840 patient participants) at the two-sided 5% level of significance. At the planned conclusion of the study (October 2021), we had only recruited 370 patient participants from our 14 clusters. We obtained a funded extension to the trial against a projected recruitment of 590 patient participants. Using our preferred analysis method—multilevel model with KR correction for degrees of freedom (Kenward & Roger, 1997)—this generated power of 76% assuming a fixed cluster size, or 73% if accounting for cluster size variability by assuming a mean and standard deviation of cluster size of 42 and 17.6 based on the observed cluster sizes at the time of the sample size review. Due to the need to allow for the KR correction, these power calculations were undertaken using a simulation-based approach.

4.6 | Study intervention and comparator

The intervention was usual care plus our clinical nursing guideline (supplementary document 4) consisting of 26 fundamental care strategies, grouped thematically into actions to address: (a) communication with patients, with patients' significant others, between patients and their significant others, between nurses, and between nurses and other members of the care team; (b) organization of fundamental nursing care activities; (c) addressing the values of patients and significant others; (d) specific fundamental nursing care interventions; (e) identifying and responding to mental health and well-being needs of patients' and their significant others; (f) actions for nurse managers and leaders to organize, educate and support their staff. The guideline was delivered using elements adapted from the methods used successfully in a previous cluster randomized controlled trial: (Huis et al., 2013): the guideline itself, trigger reminder posters, and a two-hour bespoke online staff education programme hosted by FutureLearn (www.futurelearn.com). In each intervention cluster, we identified ward managers and senior nurses to lead delivery. The control clusters provided usual care according to their individual Trust's existing care processes.

4.7 | Intervention fidelity

We assessed adherence to our clinical guideline using a bespoke questionnaire completed by nurse participants in the intervention group, which listed each element of the guideline. Nurse participants rated how much they used each element on a scale from 0 (never) to 4 (all of the time).

4.8 | Data collection

We collected all patient-reported outcomes apart from Trust-level safety and economic data after participants had received or provided nursing care for three or more days/nights. We collected Trust-level safety data for wards recruiting participants during the whole of each site's data collection period and follow-up data on health service utilization at patient participant discharge.

4.8.1 | Co-primary outcomes

Patient-reported experience measures addressing transactional nursing care, using (i) the four perceived reality scales of the Quality from the Patients' Perspective (QPP) questionnaire (Wilde Larsson & Larsson, 2002) and (ii) relational nursing care, using the Relational

Aspects of Care Questionnaire (RACQ) (Graham et al., 2018; Kelly et al., 2018).

4.8.2 | Secondary outcomes

Measures of patient safety and quality of care (pressure injuries, falls, medication errors) from routine hospital data; Barthel Index for functional ability (Mahoney & Barthel, 1965); WHO Clinical Progression Scale (Marshall, 2020); PHQ-2 for depression (Kroenke et al., 2003); GAD-2 for anxiety (Kroenke et al., 2007). Our nurse outcome was the Measure of Moral Distress for Health Care Professionals (MMD-HP) (Corley et al., 2001). Sites reported all serious adverse events (SAEs), which were reviewed by the chief investigator (DAR) and overseen by the independent trial steering committee to determine relatedness to trial intervention or procedures. We also collected semi-structured qualitative interview data from a purposive sample of nurses and care staff, to explore their views on the mechanisms, impact and acceptability of the clinical protocol, to be reported elsewhere.

4.8.3 | Economic outcomes

We took the UK NHS and personal social services NICE reference perspective (National Institute for Health Care Excellence, 2013), measuring patient participants' health utility using the EQ-5D-5L (EuroQol Research Foundation, 2019) and collecting cost data including length of stay, and COVID-19-specific interventions from baseline to discharge using a bespoke hospital care use inventory. We derived unit costs using a price year of 2019/20 from national sources including the Personal Social Services Research Unit and the NHS Reference Cost. We estimated the cost of training based on staff attending a two-hour training session, not included in the cost-effectiveness analysis assuming this would be incorporated within their working time.

4.9 | Data analysis

We undertook analysis according to a pre-specified statistical analysis plan signed off by the trial statistician, chief investigator and independent statistician from the Trial Steering Committee prior to database lock (supplementary document 5). Any analysis not pre-specified is clearly labelled as *post-hoc*. We analysed patient and nurse-level participant outcomes (except the WHO Clinical Progression Scale) as intention to treat using linear mixed-effects models with normally distributed random-effects using the KR degrees of freedom approximation (Kenward & Roger, 1997) to account for the small number of clusters. For patient-level outcomes, we adjusted for ethnicity by using the cluster-level percentage of patients reporting non-White British ethnicity, operationalized as White British vs non-White British, centred by the cluster-level mean, and including NHS Hospital Trusts (clusters) as random effects. As a sensitivity analysis, we fitted the same model, adjusting instead for cluster-level ethnicity using 2011 census data ethnicity. We present estimated between-group differences alongside 95% Confidence Intervals (CIs) and p-values. We estimated NHS Trust-level outcomes as log rates with estimated patient-days as the denominator and analysed using linear regression with the log rates as the dependent variable and including adjustment for ethnicity at the cluster level by using the same cluster-level mean as for patient outcomes. We exponentiated the results to generate geometric mean ratios which are presented alongside 95% CIs and *p*-values. As a *post hoc* sensitivity analysis of the NHS trust-level outcomes, we fitted Poisson mixed effects regression models and again present results as rate ratios alongside 95% CIs and *p*-values, to facilitate inclusion of clusters with no events in the model.

Pre-specified Bayesian regression models were used to re-analyse the primary outcomes and facilitate probabilistic interpretations of the results, rather than typical hypothesis testing. Specifically, we used Bayesian generalized linear mixed effects models to model each of the primary outcomes against allocated group, with adjustment for ethnicity (by cluster-level mean of patient participant ethnicity) and including each site as a random effect. We specified weakly informative prior distributions for all parameters. Specifically, normal prior distributions were specified for intercept terms, centred at the mean value of the relevant outcome with standard deviations scaled to 2.5 multiplied by the standard deviation of the relevant outcome. Remaining model coefficients were assigned normal prior distributions with means of zero and standard deviations equal to 2.5 multiplied by the standard deviation of the relevant outcome, divided by the standard deviation of the associated independent variable. For the within-cluster standard deviation parameter, an exponential prior distribution was specified with rate parameter equal to the reciprocal of the standard deviation of the relevant outcome. These specifications are in line with the default recommendations used within the rstanarm R package (Goodrich et al., 2018). We report posterior probabilities of treatment effects greater than 0, and greater than 0.2 (the pre-specified target difference).

We assessed effect moderation for duration of trial participation and calendar time by analysing between-group differences in patient participant outcomes over time, including both time from the beginning to the end of each cluster's data collection period, and also calendar time encompassing the overall study schedule. We used a mixed effects model with intervention status at participant level and time measured as week/month from cluster data collection start/trial commencement at cluster level, as well as a cross-level interaction between allocated group and week from implementation at cluster level.

We undertook pre-specified subgroup analyses of the primary patient-level outcomes only by inclusion of an interaction term between allocated group and ethnicity (White British versus Other). We present the coefficient of this interaction term alongside a 95% CI and *p*-value.

We calculated health-related quality of life (HRQoL) index scores as quality-adjusted life years (QALYs) from responses to the

EQ-5D-5L (EuroQol Research Foundation, 2019). In the absence of a baseline patient-completed EQ-5D-5L on admission to hospital, a survey of research site nurses provided an estimate of baseline patient EQ-5D-5L responses which we converted to HRQoL index scores. We mapped patient participant responses to EQ-5D-3L utility values using the van Hout et al. crosswalk and multiplied by duration in each health state to generate QALYs (Van Hout et al., 2012). We used resource use costs and HRQoL data to estimate the incremental cost-effectiveness ratios (ICERs), adjusting for baseline variables as above. We quantified parameter uncertainty using non-parametric bootstrapping techniques and presented incremental cost-effectiveness ratios (ICERs). We applied the NICE threshold of £20,000 per QALY.

4.9.1 | Treatment of missing data

Because data were collected from patients and nurses at one time point, we determined that missingness was likely to be at item level within scales and at scale level. Where >50% of items in a scale were completed (including 'not applicable' or 'do not know' responses), we generated a scale score by either taking the average of remaining items (all QPP subscales, RACQ, MMD-HP) or by rescaling sum scores to the full range (Barthel Index), an appropriate strategy when factor loadings are homogeneous and reliability for scales is good (Graham, 2012). Observations from single-item or two-item scales (WHO Clinical Progression Scale, PHQ-2, GAD-2) were dropped from the analysis.

4.10 | Ethical considerations

We obtained national ethical approval for the original study and amendments from the UK NHS Health Research Authority North East-Newcastle & North Tyneside 2 Research Ethics Committee (IRAS ID 288479; REC reference: 20/NE/0253).

4.11 | Patient and public involvement

We developed our guideline in partnership with a patient advisory group (seven patients with experience of hospitalization with COVID-19). A patient representative (FD) was involved in trial decisions as a member of the core management team. Both she and the wider patient advisory group were involved in the writing of the guideline, the interpretation of trial findings and its implications. The involvement of patients was supported by a patient involvement facilitator (EC).

5 | RESULTS

Between 7th December 2020 and 19th August 2021, we randomized 15 clusters (nine intervention, six control); one intervention site dropped out post-randomization prior to data collection, leaving eight in this trial arm. Research staff screened 2567 potential patient participants (1837 intervention, 730 control) of which 583 (290 intervention, 293 control) met inclusion criteria and consented to participate. Details of those not meeting inclusion criteria are in the CONSORT Diagram (Figure 1), most often due to unwillingness to participate, refusal to consent once the study had been explained, and patients who lacked capacity. We recruited 422 nurse participants (186 intervention, 236 control) (CONSORT Diagram, Figure 1). We ended recruitment when our resources were exhausted, having almost reached our revised recruitment target ($n=590$ patient participants).

5.1 | Characteristics of the sample

For patient participants, characteristics were balanced across allocated groups (Table 1) with a slightly higher proportion aged over 80 years ($n=26$, 9% vs. $n=11$, 3.8%), and those with 'other' pre-existing medical conditions affecting vulnerability to COVID-19 ($n=69$, 24% vs. $n=47$, 16%) in the intervention group. Overall, the most common age group, 275 (47.3%), was aged 50–69, 123 (20.1%) were not white British, and 246 (42.3%) were women. For nurse participants (Table 2), most were aged 50 or under ($n=337$, 80.6%), the majority were women ($n=322$, 77%) with a slightly higher proportion of women in the control group ($n=190$, 80.5% vs. $n=132$, 72.5%). Of those giving details ($n=381$, 91.1%), 219 (57.5%) were registered nurses, the remainder either students or nursing assistants and associates. Of 381 nurse participants giving ethnicity data, 154 (40.4%) were not white British.

5.2 | Fidelity

Nurses reported high delivery rates of the intervention. Their modal rates of use were 'all of the time' or 'most of the time' for 21 of the 26 intervention strategies, 'only very occasionally' for one strategy and 'never' for four strategies. The five least used strategies were IT-mediated communication and mental health care of patients' significant others (supplementary document 6).

5.3 | Patient participant outcomes

For the four scales of the QPP, data were available for 570 (98.1%) or 571 (98.3%) of patient participants. For the RACQ-14 scale, the figure was 572 (98.5%). We found little evidence of between-group differences on either measure (Table 3). Our Bayesian analyses estimated posterior probabilities of treatment effects exceeding 0 of at most 62% for the QPP scales and of exceeding 0.2 of no more than 2%. For the RAC-Q, the probability of a treatment effect exceeding 0 was 75%.

We achieved similar levels of data completeness (>98%) for all secondary measures as we did for the primary outcomes. We found

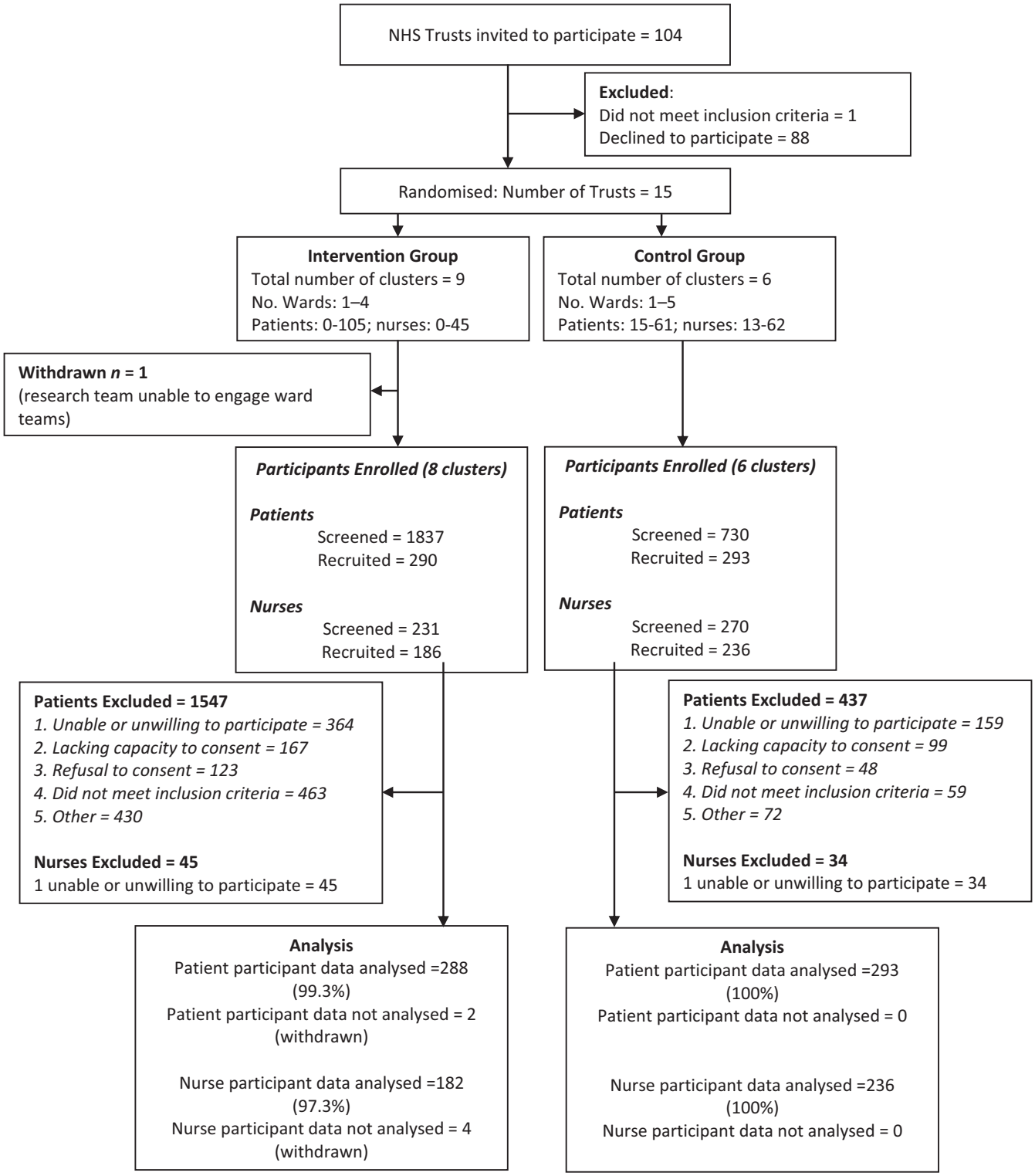

FIGURE 1 CONSORT diagram.

little evidence of differences between groups on functional ability, treatment outcomes, depression, or anxiety or patient safety indicators (Table 3).

We found between-group differences over time, starting from the beginning of each cluster's intervention/data collection period until its completion (Table 4) in favour of the intervention clusters in three of our five primary outcome scales: two of the QPP scales (QPP Medical-Technical Competence, QPP Identity-Orientation) and the RACQ, driven by outcomes in the control sites worsening over time. This effect was not seen in overall time related to the pandemic. Secondary outcomes show no similar relationships.

TABLE 1 Patient participant demographic characteristics.

Characteristic	Intervention ($n = 288$)	Control ($n = 293$)	All ($n = 581$)
Age (years), *n* (%)			
18–29	18 (6.3%)	13 (4.4%)	31 (5.3%)
30–49	58 (20.1%)	75 (25.6%)	133 (22.9%)
50–69	128 (44.4%)	147 (50.2%)	275 (47.3%)
70–79	55 (19.1%)	43 (14.7%)	98 (16.9%)
80+	26 (9.0%)	11 (3.8%)	37 (6.4%)
Missing	3 (1.0%)	4 (1.4%)	7 (1.2%)
Gender, *n* (%)			
Female	121 (42.0%)	125 (42.7%)	246 (42.3%)
Male	163 (56.6%)	164 (56.0%)	327 (56.3%)
Prefer not to say	1 (0.3%)	0 (0.0%)	1 (0.2%)
Missing	3 (1.0%)	4 (1.4%)	7 (1.2%)
Marital status, *n* (%)			
Single, never married or civil partnered	61 (21.2%)	76 (25.9%)	137 (23.6%)
Married including separated	157 (54.5%)	148 (50.5%)	305 (52.5%)
Civil partnered, including separated	8 (2.8%)	6 (2.0%)	14 (2.4%)
Divorced, including legally dissolved civil partners	26 (9.0%)	39 (13.3%)	65 (11.2%)
Widowed, including surviving civil partners	33 (11.5%)	20 (6.8%)	53 (9.1%)
Missing	3 (1.0%)	4 (1.4%)	7 (1.2%)
Level of education, *n* (%)[a]			
No qualifications	73 (25.3%)	57 (19.5%)	130 (22.4%)
Level 1	18 (6.3%)	30 (10.2%)	48 (8.3%)
Level 2	31 (10.8%)	39 (13.3%)	70 (12.0%)
Apprenticeship	15 (5.2%)	24 (8.2%)	39 (6.7%)
Level 3	46 (16.0%)	43 (14.7%)	89 (15.3%)
Level 4 or above	61 (21.2%)	70 (23.9%)	131 (22.5%)
Other	38 (13.2%)	25 (8.5%)	63 (10.8%)
Ethnicity *n* (%)			
Asian/Asian British	13 (4.5%)	21 (7.2%)	34 (5.9%)
Black/African/Caribbean/Black British	15 (5.2%)	10 (3.4%)	25 (4.3%)
Mixed/multiple ethnic group	1 (0.3%)	6 (2.0%)	7 (1.2%)
White British	226 (78.5%)	232 (79.2%)	458 (78.8%)
White other	23 (8.0%)	13 (4.4%)	36 (6.2%)
Other	6 (2.1%)	7 (2.4%)	13 (2.2%)
Missing	4 (1.4%)	4 (1.4%)	8 (1.4%)
Medical conditions *n* (%)			
Asthma	61 (21.2%)	63 (21.5%)	124 (21.3%)
Diabetes Type 1	4 (1.4%)	6 (2.0%)	10 (1.7%)
Diabetes Type 2	68 (23.6%)	62 (21.2%)	130 (22.4%)
Heart failure	15 (5.2%)	9 (3.1%)	24 (4.1%)
Heart disease	36 (12.5%)	35 (11.9%)	71 (12.2%)
Hypertension	78 (27.1%)	69 (23.5%)	147 (25.3%)
Cerebrovascular or cardiovascular disease	24 (8.3%)	10 (3.4%)	34 (5.9%)
Respiratory	35 (12.2%)	31 (10.6%)	66 (11.4%)
Renal disease	21 (7.3%)	15 (5.1%)	36 (6.2%)

TABLE 1 (Continued)

Characteristic	Intervention ($n=288$)	Control ($n=293$)	All ($n=581$)
Non-blood cancer	20 (6.9%)	13 (4.4%)	33 (5.7%)
Blood cancer	10 (3.5%)	12 (4.1%)	22 (3.8%)
Liver disease	6 (2.1%)	6 (2.0%)	12 (2.1%)
Neurological	14 (4.9%)	5 (1.7%)	19 (3.3%)
Transplant	2 (0.7%)	4 (1.4%)	6 (1.0%)
Disorders of the spleen	1 (0.3%)	2 (0.7%)	3 (1.0%)
Rheumatoid/lupus/ psoriasis	30 (10.4%)	34 (11.6%)	64 (11.0%)
Immunosuppression by disease or treatment	17 (5.9%)	14 (4.8%)	31 (5.3%)
Other conditions affecting vulnerability to COVID	69 (24.0%)	47 (16.0%)	116 (20.0%)
Blood-related conditions	7 (2.4%)	3 (1.0%)	10 (1.7%)
Pregnant	1 (0.3%)	3 (1.0%)	4 (0.7%)
If yes, >28 weeks pregnant	0 (0.0%)	1 (33.3%)	1 (25.0%)

[a]Level of education: Level 1: 1–4 UK General Certificates of Secondary Education (GCSE); Level 2: 5 or more GCSEs; Level 3: 2 or more advanced levels, or Higher National Certificates, Higher National Diplomas, Scottish Vocational Qualifications or equivalent; Level 4 or above: first or higher university degree, professional qualifications or equivalent higher education qualifications; other qualifications include other vocational/work-related qualifications and non-UK/foreign qualifications (England, Wales and Northern Ireland only).

Although the study was not powered to assess treatment by subgroup interactions, nor was multiplicity accounted for, we found a significant interaction between ethnicity (white British vs. other) and allocated group in favour of the 'other' ethnicity subgroup on one of the four QPP scales—Physical-Technical Conditions (interaction term 0.4, 95% CI −0.1 to 0.7, $p=.019$), providing evidence of a larger intervention treatment effect in this subgroup relative to the white British subgroup. We found no similar effect on any other outcome.

5.4 | Nurse participant outcome

Data for the measure of moral distress were available for 376 (90%) of nurse participants (intervention $n=159$, 87.4%; control $n=217$, 91.9%). We found little evidence of differences between the groups (Table 3).

5.5 | Economic outcomes

We estimate 214 nurses and 192 healthcare assistants completed one 2-hour training session for the evidence-based nursing guideline giving a total cost of staff time of £23,142. For patient participants, there was little difference in use of healthcare resources and associated costs between allocated groups (mean difference (£) -969.8, 95% CI -3194.9 to 1255.2, $p=.393$) (Table 5). A baseline participant EQ-5D-5L value of 0.518 was assigned to each participant based on 23 nurse-completed questionnaires in December 2021. Mean discharge EQ-5D-5L scores from patient-completed questionnaires were higher in the usual care arm. However, multiple regression analysis indicated no significant difference between groups (mean difference −0.02, 95% CI -0.08 to 0.03, $p=.419$). The intervention had lower costs, but also lower QALY gain over the trial period. Neither the mean differences in costs nor QALYs was statistically significant. The results were robust to the sensitivity analyses. Bootstrapped estimates show a 1.2% probability of the evidence-based nursing guideline being cost-effective.

5.6 | Adverse events

Twenty-two SAEs were reported for 10 patient participants by five sites: 17 from control sites and five from intervention sites. Of the 10 patient participants with a SAE, nine were reports of a death. All SAEs were assessed as unrelated to the intervention.

6 | DISCUSSION

We found no evidence of between-group difference in the experience of care reported by patients hospitalized with COVID-19 cared for by nurses using a fundamental nursing care guideline in addition to usual care, compared to those receiving usual care only, nor did we find evidence of differences in patient safety, functional ability, treatment outcomes, and mental health. We found no evidence of differences in moral distress for nurses using the guideline compared to those in usual care sites. The point estimates for the mean differences in the primary outcomes were very close to zero, with confidence intervals tending to rule out our pre-specified clinically meaningful effects. We found evidence of a group-by-time interaction in favour of the intervention arm of the trial in three of our five primary outcome scales (QPP Medical-Technical Competence, QPP Identity-Orientation, and the RACQ). We also found evidence that people with an ethnicity other than white British reported better experience of care from the intervention on one QPP scale

TABLE 2 Nurse participant demographic characteristics.

Characteristic	Intervention ($n = 182$)	Control ($n = 236$)	All ($n = 418$)
Age (years), *n* (%)			
<25	33 (18.1%)	49 (20.8%)	82 (19.6%)
26–30	33 (18.1%)	44 (18.6%)	77 (18.4%)
31–40	50 (27.5%)	55 (23.3%)	105 (25.1%)
41–50	28 (15.4%)	45 (19.1%)	73 (17.5%)
51–60	15 (8.2%)	19 (8.1%)	34 (8.1%)
61–66	3 (1.6%)	6 (2.5%)	9 (2.2%)
Prefer not to say	1 (0.5%)	0 (0.0%)	1 (0.2%)
Missing	19 (10.4%)	18 (7.6%)	37 (8.9%)
Gender *n* (%)			
Male	29 (15.9%)	27 (11.4%)	56 (13.4%)
Female	132 (72.5%)	190 (80.5%)	322 (77%)
Other	1 (0.5%)	0 (0.8%)	1 (0.7%)
Prefer not to say	0 (0.0%)	1 (0.4%)	1 (0.2%)
Missing	20 (11.0%)	18 (7.6%)	38 (9.1%)
Occupation *n* (%)			
Student nurse	11 (6.0%)	27 (11.4%)	38 (9.1%)
Care or nursing assistant	38 (20.9%)	70 (29.7%)	108 (25.8%)
Nursing associate	8 (4.4%)	8 (3.4%)	16 (3.8%)
Staff nurse	65 (35.7%)	81 (34.3%)	146 (34.9%)
Charge nurse	24 (13.2%)	24 (10.2%)	48 (11.5%)
Specialist/advanced practice nurse	6 (3.3%)	6 (2.5%)	12 (2.9%)
Management	7 (3.8%)	2 (0.8%)	9 (2.2%)
Research nurse	4 (2.2%)	0 (0.0%)	4 (1.0%)
Missing	19 (10.4%)	18 (7.6%)	37 (8.9%)
Number of years post-qualification: *n*, mean (SD) [range]; median [IQR]	96, 12.1 (10.6) [0,40]	109, 10.5 (9.2) [0,40]	205, 10.8 (9.9) [0,40]
	9 [3.5, 16]	9 [4, 16]	9 [4, 16]
Employment *n* (%)			
Full time	147 (80.8%)	184 (78.0%)	331 (79.2%)
Part time	14 (7.7%)	34 (14.4%)	48 (11.5%)
Missing	21 (11.5%)	18 (7.6%)	39 (9.3%)
Education Level *n* (%)[a]			
No qualifications	4 (2.2%)	6 (2.5%)	10 (2.4%)
Level 1	6 (3.3%)	13 (5.5%)	19 (4.5%)
Level 2	6 (3.3%)	15 (6.4%)	21 (5.0%)
Apprenticeship	4 (2.2%)	6 (2.5%)	10 (2.4%)
Level 3	22 (12.1%)	39 (16.5%)	61 (14.6%)
Level 4 or above	108 (59.3%)	115 (48.7%)	223 (53.3%)
Other	13 (7.1%)	24 (10.2%)	37 (8.9%)
Missing	19 (10.4%)	18 (7.6%)	37 (8.9%)
Ethnicity *n* (%)			
Asian/Asian British	31 (17.0%)	43 (18.2%)	74 (17.7%)
Black/African/Caribbean/ Black British	13 (7.1%)	20 (8.5%)	33 (7.9%)
Mixed/multiple ethnic groups	3 (1.6%)	9 (3.8%)	12 (8.9%)
White British	101 (55.5%)	126 (53.4%)	227 (54.3%)

TABLE 2 (Continued)

Characteristic	Intervention ($n = 182$)	Control ($n = 236$)	All ($n = 418$)
White other	10 (5.5%)	13 (5.5%)	23 (5.5%)
Other	5 (2.7%)	7 (3.0%)	12 (2.9%)
Missing	19 (10.4%)	18 (7.6%)	37 (8.9%)

[a]Level of education: Level 1: 1–4 UK General Certificates of Secondary Education (GCSE); Level 2: 5 or more GCSEs; Level 3: 2 or more advanced levels, or Higher National Certificates, Higher National Diplomas, Scottish Vocational Qualifications or equivalent; Level 4 or above: first or higher university degree, professional qualifications or equivalent higher education qualifications; other qualifications include other vocational/work-related qualifications and non-UK/foreign qualifications (England, Wales and Northern Ireland only).

TABLE 3 Primary and secondary participant and safety outcomes.

	Intervention *n*, mean (SD)	Control *n*, mean (SD)	Between-group difference/rate ratio (95% CI)	*p*-value	ICC
Patient primary outcomes					
QPP medical-technical competence	282, 3.6 (0.5)	288, 3.6 (0.6)	−0.00 (−0.2 to 0.2)	.980	0.03
QPP physical-technical conditions	282, 3.4 (0.6)	288, 3.4 (0.7)	0.01 (−0.2 to 0.2)	.907	0.01
QPP identity-orientation	283, 3.5 (0.5)	288, 3.5 (0.6)	0.02 (−0.1 to 0.2)	.744	0.03
QPP sociocultural atmosphere	282, 3.4 (0.7)	288, 3.5 (0.7)	−0.05 (−0.3 to 0.2)	.610	0.04
RACQ-14	284, 87.8 (17.0)	288, 87.1 (17.4)	1.25 (−2.9 to 5.4)	.512	0.01
Patient secondary outcomes					
Barthel index	282, 84.3 (21.4)	288, 87.6 (18.9)	−2.69 (−7.7 to 2.3)	.256	0.01
PHQ-2	281, 2.2 (2.0)	285, 2.2 (2.1)	0.03 (−0.5 to 0.6)	.899	0.02
GAD-2	281, 1.9 (2.0)	285, 1.8 (2.2)	−0.02 (−0.7 to 0.6)	.944	0.03
WHO clinical progression scale	286, 4.8 (1.5)	291, 4.7 (1.5)	−0.08 (−0.9 to 0.7)	NA	0.18
Nurse outcome					
Measure of moral distress	159, 82.2 (74.6)	217, 77.4 (72.2)	5.8 (−31.8 to 43.5)	.735	
Patient safety data					
Falls	8, 0.46 (0.21)	6, 0.41 (0.22)	1.23, (0.64 to 2.36)	.493	
Pressure injuries	8, 0.05 (0.10)	6, 0.04 (0.07)	0.3[a] (0.01 to 11.34)	.410	
Medication errors	8, 0.28 (0.17)	6, 0.16 (0.13)	2.47 (0.88 to 6.98)	.081	
Sensitivity analysis—poisson mixed effects					
Falls	8, 0.46 (0.21)	6, 0.41 (0.22)	1.26 (0.75 to 2.12)	.388	
Pressure injuries	8, 0.05 (0.10)	6, 0.04 (0.07)	1.33 (0.12 to 14.52)	.816	
Medication errors	8, 0.28 (0.17)	6, 0.16 (0.13)	2.22 (1.06 to 4.66)	.035	

Abbreviations: GAD, general anxiety disorder; PHQ, patient health questionnaire; QPP, quality from the patient's perspective; RACQ, relational aspects of care questionnaire.

[a]Seven sites (3 intervention, 4 control) did not report any pressure sores and were therefore excluded from the analysis due to the inability of the pre-specified analysis method to handle zeros.

(Physical-Technical Conditions). We did not find evidence that using the nursing guideline is likely to be cost-effective, as the small incremental differences in QALYs drove the ICER value to far exceed the NICE recommended cost-effectiveness threshold of £20,000 per QALY gained.

6.1 | Strengths and limitations of the study

COVID-NURSE is the only randomized controlled trial of direct nursing care in any pandemic. It was funded but not prioritized for NHS research network resources and conducted under extremely difficult circumstances as the pandemic waxed and waned, affecting both site and participant recruitment. Nursing teams were hugely stretched and exhausted meaning that a trial of a behaviour change intervention was felt too challenging for many sites to participate in. There are several limitations to our study. Firstly, we were unable to recruit sufficient patient participants to meet our planned sample size calculation as admissions to hospital were reducing as our funding ceased. Secondly, given the nature of the intervention we could not blind nurses or data collectors to treatment allocation. However, we did use self-report outcome measures and analysed

TABLE 4 Primary and secondary patient participant outcomes over time.

	Baseline between-group difference (95% CI)	Change over time in control group (95% CI)	Difference in intervention and control time trends (95% CI)	*p*-value
Patient primary outcomes				
QPP medical-technical competence	−0.18 (−0.41 to 0.06)	−0.01 (−0.02 to −0.002)	0.01 (0.001 to 0.03)	.035
QPP physical-technical conditions	−0.12 (−0.36 to 0.12)	−0.01 (−0.02 to 0.004)	0.01 (−0.004 to 0.02)	.179
QPP identity-orientation	−0.18 (−0.38 to 0.03)	−0.01 (−0.02 to −0.004)	0.01 (0.003 to 0.03)	.014
QPP sociocultural atmosphere	−0.20 (−0.49 to 0.09)	−0.01 (−0.03 to −0.002)	0.01 (−0.003 to 0.03)	.116
RACQ-14	−5.13 (−11.15 to 0.88)	−0.39 (−0.64 to −0.12)	0.45 (0.11 to 0.78)	.010
Patient secondary outcomes				
Barthel index	−0.63 (−8.36 to 7.11)	−0.01 (−0.33 to 0.32)	−0.14 (−0.55 to 0.28)	.514
PHQ-2	−0.08 (−0.85 to 0.69)	−0.01 (−0.04 to 0.02)	0.01 (−0.03 to 0.05)	.702
GAD-2	−0.18 (−1.04 to 0.70)	−0.01 (−0.05 to 0.02)	0.01 (−0.03 to 0.06)	.619

Abbreviations: GAD, general anxiety disorder questionnaire; PHQ, patient health questionnaire; QPP, quality from the patient's perspective; RACQ, relational aspects of care questionnaire.

TABLE 5 Economic data.

	Intervention mean (SD)	Usual care mean (SD)	Incremental difference (95% CI)	ICER (95% CI)
Cost per participant (£)	11,492 (12,898)	12,080 (14,282)	−969.80 (−3194.90 to 1255.20)	
QALYs	0.019 (0.015)	0.020 (0.017)	−0.001 (−0.004 to 0.002)	
ICER (£/QALY)				998,200 (−8,821,135 to 11,042,612)

Abbreviations: ICER, incremental cost-effectiveness ratio; QALY, quality adjusted life year.

routinely collected patient safety data. Nonetheless, we cannot rule out measurement bias for nurse participants in particular, in terms of overly positive responses (a 'yea-saying' effect), or reluctance to participate due to nurse participants having to hand over paper copies of their outcome measures to research staff whom they knew from the same organization. Indeed, reluctance to do so was the reason that one site was unable to recruit any nurse participants to our trial. Thirdly, only a relatively small proportion of patients treated in randomized clusters contributed data. Ethically and practically, one cannot collect patient-reported primary and secondary outcome data from patient participants who decline to give consent. However, patient safety data were collected from routine hospital data representing a much larger population which confirmed the absence of evidence for any effect of the intervention. Finally, in common with other clinical research undertaken during the pandemic, we were forced to redesign our study, including to remove the three planned a priori review stages which we had intended to use as an integrated pilot feasibility strategy. Essentially, we were left without a pilot phase and unable to amend the intervention, as we had planned, to focus on implementing those guideline elements which were most acceptable and feasible.

Our main finding that there was no evidence for an effect of the intervention compared to usual care only may be because the intervention was not implemented adequately, effects could not be detected by our outcome scales, or that the control group also used similar strategies. Firstly, although nurses did report via fidelity questionnaires that they implemented the intervention, quarantine regulations denied us the opportunity to conduct detailed independent observations on the implementation of behavioural aspects of the intervention. We cannot, therefore, be entirely sure that implementation was consistent and comprehensive for all nurses in the study. Secondly, our outcome measures may not be sufficiently sensitive to changes in fundamental care as, despite being widely used, they may not have measured outcomes specifically related to target behaviours of our guideline. Our QPP scores in both groups were at least as high or higher than most other published studies (Larsson et al., 2005). It might be that with patient participants often immensely relieved to recover from a COVID-19 hospitalization, these measures have little sensitivity to detect differences between groups. Indeed, our patient and public involvement (PPI) group noted that 'individuals [nurses] were doing their best in terrible circumstances' and patients may have been reluctant to appear critical in such a situation. Finally, it is certainly a weakness of our study that we were unable to adequately assess usual care using the same fidelity questionnaire as for our intervention. To do so would have unblinded the control group nurses to the intervention components, and we did not want to risk this. Given our guideline was devised in consultation with over 1000 nurses caring for COVID-19 patients, it is likely that many of the procedures used in both groups were identical.

Our economic analysis was hampered by a lack of individual-level baseline EQ-5D pandemic-specific data. In asking sites to estimate EQ-5D-5L values we missed the nuances in HRQoL of participants when joining the study, and also any change in presentation at baseline over time. However, the resources utilized in the two arms of the trial are similar with no significant differences, which suggests similar populations in each group. The relatively short duration over which participants were followed is also a limitation. It would have been beneficial to have assessed the longer-term costs and HRQoL associated with long-COVID.

6.2 | Recommendations for further research

Outside of our primary analyses, the fact that we did find two significant results in other pre-specified analyses can generate further hypotheses. The group-by-time interactions, showing experience of care was lower at the end of the trial for the control group compared to intervention in three out of five co-primary outcomes, suggests a potential clinical trial effect whereby nurses in the control group adjusted their practice in response to the novel presence of research evaluators on their wards. As observed in other trials (Menezes et al., 2011), this effect waned over time, leading to differences between trial arms as the control group showed lower scores in these outcomes. It is possible that in response to data collection, control sites adopted similar if not identical strategies to those in the clinical guideline. This explanation is plausible since most clinical nurses are rarely exposed to clinical trials in nursing, and the appearance of researchers and the requirement to sign consent forms will have alerted them to the testing of fundamental care practices.

We also found weak evidence for an effect of the intervention on non-white British compared to white British participants, albeit in only one of our co-primary outcome scales. We might hypothesize that the usual experience of fundamental nursing care for non-white British patients is poorer than other patients and that the intervention raised the quality of care experienced to the same level. Further observational studies would be required to test this hypothesis.

Our experience of this trial leads us to make a number of research recommendations. Well-designed and conducted RCTs of core nursing interventions are few and far between. Although cluster randomized trials of behavioural interventions delivered by nurses are challenging to implement, compounded in our case by exceptional COVID-related recruitment, epidemiological, clinical and managerial factors, such trials are not impossible to conduct given careful planning and implementation. For example, had we had the time and capacity, we would have undertaken several pilot and feasibility phases to enhance the acceptability and feasibility of the intervention prior to full trial. Further, had it not been for quarantine restrictions and other pandemic pressures we would have used additional behaviour change strategies to enhance intervention implementation. Future trials of fundamental care, in both pandemic and non-pandemic situations should, therefore, be undertaken with careful piloting and feasibility stages and the use of behaviour change strategies to ensure optimal implementation. Any future trials should also pay particular attention to the experience of non-majority populations. For fundamental care in particular, researchers need to identify, select and possibly produce outcome measures which are more sensitive to change in patient experience.

6.3 | Implications for policy and practice

Given we were unable to detect evidence of between-group differences in our main outcomes we cannot recommend the wholescale implementation of our guideline into routine nursing practice. However, absence of evidence is not evidence of absence. We do have some indication that the guideline may have aided in sustaining good practice over time and had a more positive impact on non-white British patients' experience of care.

Further, once we had broken the allocation blind and discussed the intervention guideline with nurse leaders from the control group sites, they overwhelmingly endorsed the strategies contained within it. Whilst some specific strategies were tailored to pandemic nursing, for example approaches designed to overcome pandemic-specific communication barriers, nurse leaders noted that the thematic elements of the guideline – communication, organization, values, interventions, mental health and emotional well-being – were also applicable in non-COVID-19 clinical situations. Our PPI group noted that fundamental care is a universal human need, independent of contexts, pandemic or otherwise, and that the guideline was designed to reinforce what is essentially core nursing practice.

Consequently, although our treatment over time results are tentative rather than conclusive, we suggest that clinical service managers and leaders might review the guideline and select elements that they believe may assist in maintaining the quality of nursing practice in multiple different contexts. Notwithstanding the above comment, given that the COVID-NURSE guideline is the only nurse-developed, patient-influenced clinical guideline for fundamental nursing care in a pandemic, we also suggest that policy-makers review those aspects of the guideline specifically relevant to pandemics and incorporate them into their pandemic preparedness training. COVID-19 and other pandemics have not gone away. Rather than being caught out by the (re-) emergence of another global pandemic, nurses now have at least some evidence on which to prepare for the next event.

7 | CONCLUSION

In this cluster randomized controlled trial of a fundamental nursing care guideline developed from the Fundamentals of Care framework (Kitson, 2010) compared to usual care alone for patients admitted to hospital with COVID-19, we found no evidence of between-group differences in patients' experience of care, patient safety, quality of care, functional ability depression, anxiety and nurses' moral distress. Although the guideline may have aided in sustaining good

practice over time and had a more positive impact on non-white British patients' experience of care, we cannot recommend the wholesale adoption of the guideline in routine pandemic clinical situations or beyond. Despite much evidence that fundamental nursing care has an impact on patient satisfaction, safety, clinical effectiveness, care quality, and treatment outcomes, including mortality and overall service use, additional intervention development and careful feasibility and piloting work is necessary before embarking on further clinical trials to evaluate the use of the Fundamentals of Care framework as the basis for maintaining and enhancing routine nursing care practice.

AUTHOR CONTRIBUTIONS

Conceptualization and funding acquisition: David A. Richards, G. J. Melendez-Torres, Claire Hulme, Emma Cockcroft, Joanne Cooper, Siobhan Creanor, Susanne Cruickshank, Faye Doris, Heather Iles-Smith, Pip Logan, Anne Marie Rafferty, Anne Marie Russell, Maggie Shepherd, Sally J. Singh, Holly V. R. Sugg, Jo Thompson Coon, Susannah Tooze, Stephen Wootton. Data curation: Fiona C. Warren, Phoebe Dawe, Rosie Owens, Lidia Romanczuk, Bethany Whale, Jakub Onysk. Formal analysis: G. J. Melendez-Torres, Ben Jones, Claire Hulme. Project administration: Jess Bollen, Abby O'Connell, Merryn Kent, Heather Cook, Lynne Quinn. Writing – original draft: David A. Richards. Review and editing: all authors. Patient and public involvement: Faye Doris, Emma Cockcroft. David A. Richards, G. J. Melendez-Torres, Ben Jones and Claire Hulme have directly accessed and verified the underlying data.

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The funder had no role in the writing of this article or the decision to submit it. DAR, the corresponding author, has full access to all data (including statistical reports and tables) in the study, takes responsibility for the integrity of the data and the accuracy of the data analysis and had final responsibility for the decision to submit for publication. All authors were not precluded from accessing data in the study, and accept responsibility to submit for publication.

CONFLICT OF INTEREST STATEMENT

All authors report no conflict of interests.

PEER REVIEW

The peer review history for this article is available at https://www.webofscience.com/api/gateway/wos/peer-review/10.1111/jan.15959.

OPEN RESEARCH BADGES

This article has earned Open Data, Open Materials and Preregistered Research Design badges. Data, materials and the preregistered design and analysis plan are available at https://ore.exeter.ac.uk/repository.

DATA AVAILABILITY STATEMENT

Deidentified individual participant data and a data dictionary will be made available following publication of these results in the University of Exeter's Open Research Exeter repository (https://ore.exeter.ac.uk/repository) to researchers undertaking secondary analyses, with a signed data access agreement after approval of a proposal.

ETHICAL APPROVALS

All data utilized in the submitted manuscript have been lawfully acquired. National ethical approval for the original study and amendments were obtained from the UK NHS Health Research Authority North East-Newcastle & North Tyneside 2 Research Ethics Committee (IRAS ID 288479; REC reference: 20/NE/0253).

STATISTICAL ANALYSES

There are four statisticians on the author team: Ben Jones, G. J. Melendez-Torres, Siobhan Creanor and Fiona C. Warren. Another statistician was a member of the independent Trial Steering Committee who approved our trial statistical analysis plan. We affirm that the methods used in the data analyses are suitably applied to our data within our study design and context, and the statistical findings have been implemented and interpreted correctly. We agree to take responsibility for ensuring that the choice of statistical approach is appropriate and has been conducted and interpreted correctly.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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