Plan Overview

A Data Management Plan created using DMPonline

Title: Feasibility trial

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Template: DCC Template

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Project abstract:

Background

A change in the condition of a patient from one clinical state to a worse clinical state is termed clinical deterioration. Without recognition and intervention, clinical deterioration can result in increased patient morbidity and mortality. Patients who clinically deteriorate will often have changes in routinely monitored vital signs (e.g., heart rate, respiratory rate). The National Early Warning Score 2 (NEWS2) has been implemented in the United Kingdom to support recognition of clinical deterioration. From inputting vital signs, an aggregate score (range 0-20) is provided by NEWS2 which signals the patient's risk of ongoing deterioration with higher scores indicating greater risk. When the NEWS2 is ≥7 nursing staff are prompted to monitor more frequently and contact a doctor and/or critical care outreach practitioner (a clinician with critical illness management expertise) to assess the patient. Despite NEWS2, patients continue to clinically deteriorate without appropriate care resulting in avoidable patient deaths.

In previous research, we used a theory-based approach to develop a behaviour change intervention to support nursing staff to enact appropriate behaviours when a patient has a high NEWS2 (≥7). The intervention (called OPTIMISE-NEWS) includes 12 Behaviour Change Techniques and a training package that will be delivered to registered nurses, nursing associates, and healthcare assistants.

Aim

The aim of this study is to 1.) conduct a feasibility trial to establish essential parameters for designing a full trial to assess the outcomes of introducing OPTIMISE-NEWS on acute hospital wards; 2.) explore the acceptability of the OPTIMISE-NEWS intervention to clinical staff and the fidelity and feasibility of implementation.

Methods

A scaled down and simpler version of a pragmatic stepped wedge cluster randomised controlled trial will be conducted to test the feasibility of using this trial design to compare patient outcomes when nursing staff working on acute hospital wards are receiving the behaviour change intervention (alongside NEWS2) with NEWS2 alone (usual care).

Clustering will be at hospital level, and we will recruit three hospitals, representing diverse populations, and six wards. Any inpatient on a participating ward within a cluster who has a trigger event (defined as first NEWS2 7) at any time during the feasibility trial will be included. The primary outcome for the full trial will be reduction in patient NEWS2 24 hours after a trigger event. During the feasibility trial, primary and secondary outcomes (all

routinely collected data) will be obtained to test the feasibility of accurately and reliably extracting these data from patients’ health records.

We will assess the acceptability of OPTIMISE-NEWS to staff and the fidelity and feasibility of implementation using theory-informed questionnaires, semi-structured interviews, and focused observations. Quantitative data will be analysed descriptively but with no hypothesis testing and qualitative data will be analysed using Framework Method before integration.

Anticipated impact

Findings will inform decisions about progression to a full trial and the development of materials including a definitive intervention manual, implementation package, a fidelity checklist, and an economic evaluation strategy. Demonstrating ‘proof of concept’ will enable us to apply for funding to conduct a full randomised trial.

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Copyright information:

Feasibility trial

Data Collection

What data will you collect or create?

- Data from clinical staff
- Routinely collected patient outcome data
- Reflections from researchers involved in implementing the intervention

How will the data be collected or created?

Collection of staff data

Using the seven constructs of the Theoretical Framework of Acceptability (TFA): *affective attitude, burden, ethicality, intervention coherence, opportunity costs or gains, perceived effectiveness, and self-efficacy effectiveness* [74, 75] questionnaires will be developed using published methods from the TFA literature [76]. TFA-informed questionnaires will be issued after transition to the intervention condition, and again after closeout [77]. Paper copies of questionnaires will be left in the staff room of participating wards alongside a locked box where completed questionnaires can be deposited. Questionnaires will also be distributed electronically by ward managers using a group email list.

An interview topic guide will be developed to include one question (minimum) for each TFA construct [74, 75] but with adequate flexibility to permit individualised questions to be asked. Having flexibility in the topic guide will provide researchers with opportunities to explore other factors that influenced implementation and could affect ongoing engagement with the intervention. The interview topic guide will be piloted with staff not involved in the study. A minimum of two weeks after clusters transition to the intervention condition, we will begin attending to conduct audio-recorded semi-structured interviews and/or to observe intervention components being implemented in workshops and on participating wards. The focus of these observations will be on the fidelity of implementation [78, 79]; that is, the extent that intervention components are delivered as expected [25, 80]. Observational data will be captured using voice and journal notes [66].

Collection of patient outcome data

The proposed primary outcome for the full trial will be reduction in patient NEWS2 24 hours after a trigger event (defined as first NEWS2 of 7). In observational studies related to the rapid response system, a composite primary outcome of unplanned ICU admission, cardiac arrest, and death has been used for statistical modelling [28, 40, 81–86]. However, due to a low event rate and the associated difficulty in achieving statistical power, the feasibility of using this as a primary outcome for studies with interventional designs has been questioned [87, 88]. Consequently, I have opted to use reduction in NEWS2 which is a reliable proxy for clinical improvement in a patient's condition. This decision was informed by the literature [38–45] and by conversations with statisticians, methodologists, clinicians, health economists, and by members of my patient and carer advisory group.

Routine patient data will be collected at 24 hours (T1), 48 hours (T2), and 72 hours (T3) after a trigger event (T0) and again at study closeout (T4). During the feasibility trial, data will be collected at these different time points to test the feasibility and reliability of extracting a range of outcome measures from different EHRs during the full trial. Collecting these data will also enable me to calculate the standard deviation for the primary outcome which will be used for the full trial sample size calculation [89]. Proposed secondary outcomes for the full trial (all available through patients' electronic records) will be:

- Patient's NEWS2 (T0, T1, T2, T3)
- Time between trigger event and ward doctor review (T1, T2, T3)
- Time between trigger event and CCOT review (T1, T2, T3)
- Number of new Do Not Attempt Resuscitation/Treatment Escalation Plan decisions (T1)
- Number of planned admissions to a level 2 (high dependency) or level 3 (intensive care) area (T1, T2, T3)
- Number of unplanned admissions to a level 2 or level 3 area (T1, T2, T3)
- Acute Physiology and Chronic Health Evaluation II score within 24 hours of admission to a level 3 area (T1, T2, T3)
- Death (T3)
- Time between trigger event and discharge from a level 2 or level 3 area (T1, T2, T3, T4)
- Time between trigger event and hospital discharge (T1, T2, T3, T4).

Collection of researcher's reflections from supporting implementation

Researcher's reflections from supporting implementation activities in a coaching role (section 3.5) will be captured through voice and/or journal notes. The person who supports implementation within a cluster (me or a research fellow) will not participate in data collection in the same cluster to minimise confusion from participants and researcher bias.

Documentation and Metadata

What documentation and metadata will accompany the data?

I will be collaborating with the Queen Mary University of London (QMUL) Pragmatic Clinical Trials Unit. They will be building a database for me to record the data. They will also support quality assurance as part of their package of support.

Ethics and Legal Compliance

How will you manage any ethical issues?

In ACAF year 1, I will seek NHS research ethics, Confidentiality Advisory Group (CAG), and Health Research Authority approvals. Cluster-level recruitment will be formalised, and subsequently eligible wards will be recruited from within each hospital as follows: managers from eligible wards will be emailed to provide brief information about the study, and invited to contact me if they are interested. Following an expression of interest, I will attend the ward with a representative from the hospital CCOT to meet with the ward manager and provide further information. Ward managers will be invited to email me and opt-in if they would like staff from their ward to participate.

Any inpatient on a participating ward within a cluster who has a trigger event (defined as a first NEWS2 7) at any time point during the feasibility trial will be included in the study. It is plausible that any patient on an acute ward could deteriorate at any time, therefore screening and identifying individual patients who will later develop elevated NEWS2 (and become eligible for involvement) would be difficult. Equally, pre-emptively consenting all patients on the ward in case they deteriorate (when only a proportion will) would be impractical, onerous, and could increase patient anxiety. For these reasons, approval will be sought from the CAG to access routinely collected data for a sample of patients on participating wards with a first NEWS2 7 without consent. These decisions were informed by discussions with patient advisors. Throughout data collection, posters will be displayed on participating wards notifying patients and visitors that research is taking place and describing how they can access further information.

Staff who agree to complete a questionnaire and/or participate in an audio-recorded interview will be asked to prospectively sign a consent form.

The purpose of the observations will be to explore how components of OPTIMISE-NEWS are implemented. Due to the unpredictable clinical context in which some intervention components will be implemented and the group-level mode of delivery, it may not be practical to consent all staff members individually and prospectively for participation in an observation. Consequently, an opt-out procedure will be used [7].

How will you manage copyright and Intellectual Property Rights (IPR) issues?

Not applicable

Storage and Backup

How will the data be stored and backed up during the research?

I will be collaborating with the Queen Mary University of London (QMUL) Pragmatic Clinical Trials Unit. They will be building a database for me to record the data. They will also support quality assurance as part of their package of support.

How will you manage access and security?

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Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

N/A

What is the long-term preservation plan for the dataset?

The data will be retained for 10 years.

Data Sharing

How will you share the data?

Data Transfer Agreements will be put in place where appropriate.

Are any restrictions on data sharing required?

Not applicable

Responsibilities and Resources

Who will be responsible for data management?

Dr Duncan Smith
Colleagues at the QMUL PCTU

What resources will you require to deliver your plan?

Collaboration with the clinical trials unit