Plan Overview

A Data Management Plan created using DMPonline

Title: Acceptability, fidelity, and feasibility of the PROTECT behaviour change intervention to improve responsiveness to clinically deteriorating patients in acute hospital wards: a pre-pilot and randomised pilot study

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Template: DCC Template

Project abstract:

Background

Clinical deterioration - the worsening of a patient's condition that increases the risk of morbidity or mortality - remains a major source of preventable harm in hospitals. Despite widespread implementation of the National Early Warning Score 2 (NEWS2) to support recognition and escalation, patients continue to deteriorate without timely or appropriate care. Changes in routinely monitored vital signs, such as respiratory and heart rate, often precede serious adverse events, offering opportunities for early intervention. However, patients and families can detect subtle changes in illness before these are physiologically evident.

The recent introduction of *Martha's Rule* mandates that patient and family concerns are systematically captured and acted upon, reinforcing the importance of integrating these insights into care. Yet, interventions supporting frontline staff to operationalise these principles remain underdeveloped.

Through previous NIHR-funded research, I developed the PROTECT (**P**romoting **R**ecognition **O**f deteriora**T**ion and **E**s**C**ala**T**ion of care) intervention - a theory-informed behaviour change programme underpinned by the Theoretical Domains Framework and Behaviour Change Techniques. PROTECT provides structured support to embed key behaviours, including effective use of NEWS2 and engagement with patient and family perspectives. Preliminary work found PROTECT acceptable to users, but it has not yet been tested in clinical settings.

Aims

This research comprises two work packages: 1.) a pre-pilot to explore the acceptability, fidelity, and feasibility of implementing PROTECT; 2.) a randomised pilot study to test the feasibility of using trial methods to evaluate its impact on acute hospital wards.

Methods

The pre-pilot will assess the acceptability of PROTECT to clinical staff and the fidelity and feasibility of implementation on two wards using theory-informed questionnaires, semi-structured interviews, and non-participant observations. Quantitative data will be analysed descriptively and qualitative data analysed using Framework Method, before integration and refinement of PROTECT and the implementation materials.

A scaled-down cluster randomised controlled pilot will then compare NEWS2 + PROTECT versus NEWS2 alone. Eight wards (across four hospitals) will be randomised 1:1. Any inpatient on a participating ward with a first high NEWS2 score ≥7 ('a trigger') will be included. The full trial primary outcome will be hospital-free days in the 30 days after a trigger. During the pilot, feasibility outcomes - including recruitment, outcome data completeness, intervention acceptability, and fidelity - will inform further refinement of PROTECT and development of

materials for a full trial, including an implementation package, fidelity checklist, and economic evaluation strategy.

Knowledge mobilisation

Knowledge mobilisation will be embedded throughout, guided by NIHR frameworks and underpinned by the Knowledge-to-Action Framework. Patients, clinicians, researchers, and policymakers will co-produce dissemination activities and interpret findings, ensuring outputs inform national practice and policy, including implementation of *Martha's Rule*.

Research inclusion

Research inclusion is embedded across all stages, ensuring diverse representation of patients and staff. Recruitment, materials, and dissemination will reflect NIHR inclusion principles, promoting equitable participation and meaningful involvement from underrepresented groups.

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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?

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?

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?

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.

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