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Delivering Effective Non-Invasive ventilation in amyotrophic lateral sclerosis using intensive remote support (DENIM): Protocol for an embedded process evaluation in a hybrid type 3 implementation-effectiveness trial

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Abstract

Background: Non-invasive ventilation (NIV) is the only intervention that significantly improves survival and quality of life in motor neuron disease, extending life by 8-13 months. However, at least half of patients are unable to reach the recommended ≥4 hours daily NIV use, and current NHS services provide insufficient follow-up for intensive optimisation. Delivering Effective Non-Invasive ventilation in Motor neuron disease using intensive remote support (DENIM) is a stepped-wedge cluster randomised trial. This protocol describes a process evaluation embedded within DENIM aiming to understand how and why the implementation strategy works (or does not work) across different contexts.

Method: The process evaluation employs a convergent mixed-methods multiple-case study design across twelve NHS ventilation services. We developed a programme theory informed by Normalization Process Theory (NPT), the Consolidated Framework for Implementation Research and Expert Recommendations for Implementing Change, which states how the DENIM implementation strategy is expected to achieve normalisation of evidence-based NIV practice. Data collection across twelve sites include: ethnographic observations of patient-staff interactions; semi-structured interviews with staff (n=24-48) and patients/carers (n=24) exploring implementation experiences; the NoMAD questionnaire measuring normalisation perceptions from healthcare professionals within the services and NIV adherence data from participants' ventilators. Barriers and facilitators to research participation for underserved populations including ethnic minorities, those with low digital literacy, and women over 80 with bulbar onset disease will also be identified. Qualitative data will be analysed using NPT-informed thematic analysis. Integration occurs at three levels (design, methods, interpretation) with joint display tables presenting quantitative and qualitative findings alongside meta-inferences.

Discussion: This process evaluation will generate explanatory insights into how implementation strategies can address the evidence-to-practice gap in complex, technology-supported care for progressive diseases, with implications for health equity and wider NHS digital transformation.

Trial registration ISRCTN10105285. 16/04/2025

Contribution to the literature

- Non-invasive ventilation is the only intervention that significantly improves survival and quality of life in motor neuron disease, however less than half of patients are gaining this benefit. The DENIM implementation strategy comprises several components, including remote monitoring. Digitally supported care is timely and aligns with national and international agendas to modernise health care delivery and the DENIM implementation strategy may provide a blueprint for future innovations.
- The noteworthy study design demonstrates how to systematically integrate multiple implementation theories within a hybrid trial to yield findings that will help to promote the uptake of research into routine care for people with motor neuron disease, and more broadly, for people with progressive diseases.
- Elements of the study design may have wider applicability and provide important insights to future research seeking to assess and explore how digitally enabled care interventions can be implemented equitably into everyday practice.

Keywords: motor neuron disease, telehealth, non-invasive ventilation, process evaluation, normalisation process theory, implementation.

Background

Amyotrophic lateral sclerosis, referred to in the UK as Motor Neuron Disease (MND) is a terminal disease. The lifetime risk of developing MND is around 1 in 350 for men

and 1 in 472 for women[1], with respiratory failure being the major cause of death within 2-4 years[2]. Non-invasive ventilation (NIV) is the only intervention that significantly improves both survival and quality of life, extending life by 8-13 months[3–6]. However, at least half of patients with MND fail to achieve adequate therapy which is typically defined as four or more hours daily of effective NIV use, in order to correct for hypoventilation and deliver symptomatic and survival benefits[6–9]. Studies show approximately half of patients do not reach ≥4hr/day use, with one UK service reporting 34% not using NIV at all[10]. Even among those achieving adequate hours, half have inadequate correction of nocturnal hypoventilation which doubles mortality risk at twelve months[11].

There are multiple barriers to achieving ≥4 hours daily effective NIV use[12–14]. These include physical barriers (e.g. bulbar dysfunction, mask discomfort); psychological barriers (e.g. cognitive difficulties, anxiety); social barriers (e.g. isolation, carer burden); service barriers (e.g. limited time, fragmented care, inability to travel to hospital); and, equipment barriers (e.g. mask leakage, incorrect settings). Current UK ventilation services typically provide limited follow-up (two to four weeks then three-monthly), insufficient for the intensive optimisation required[15, 16].

The DENIM trial (Delivering Effective NIV in MND) is a stepped-wedge cluster randomised controlled trial examining whether an implementation strategy, targeting healthcare professionals, enables them to deliver intensively supported effective NIV at ≥4 hours daily thereby improving adherence and clinical outcomes in MND (ISRCTN10105285). This process evaluation is embedded within the DENIM trial to understand how and why the DENIM implementation strategy works (or does not work) across different contexts. We draw upon three complementary frameworks:

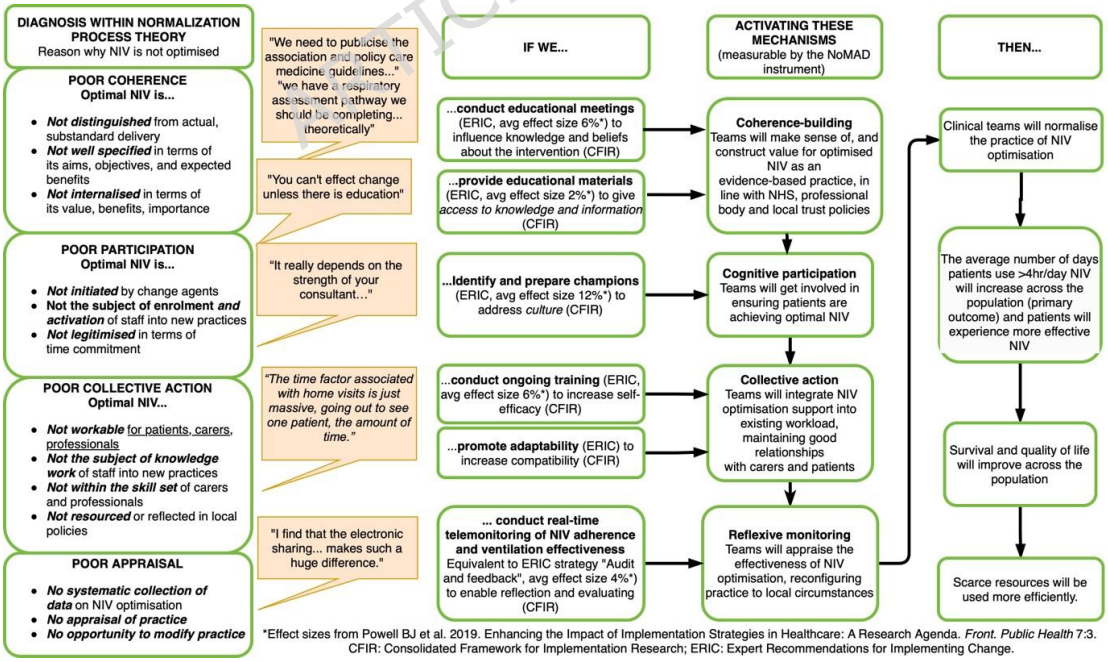
Normalization Process Theory (NPT) is a sociological theory explaining how new practices become embedded in routine healthcare. It identifies four mechanisms through which professionals work to implement change: making sense of the practice (coherence), engaging with it (cognitive participation), enacting it (collective action), and appraising its effects (reflexive monitoring)[17]. The Consolidated Framework for Implementation Research (CFIR) provides a comprehensive taxonomy of factors influencing implementation across five domains: innovation characteristics, individuals involved, inner setting, outer setting, and implementation process. These help identify contextual determinants that may act as barriers or facilitators[18]. Expert Recommendations for Implementing Change (ERIC) is a compilation of 73 implementation strategies providing a common language for describing the active components of implementation efforts[19].

Using these frameworks and our empirical research, we developed a programme theory - a detailed articulation of how the DENIM implementation strategy is expected to work (Table 1) and a logic model (Figure 1). A programme theory makes explicit the causal assumptions linking implementation activities to intended outcomes, allowing these assumptions to be tested[20]. Our programme theory proposes that current services fail to normalise ≥4 hours of daily effective NIV use due to deficits in coherence (professionals not seeing value in optimisation), participation (lacking confidence or resources), action (insufficient expertise and funding), and monitoring (inability to detect problems)[17]. DENIM addresses these through targeted implementation strategies matched to specific determinants[18, 19, 21] (Table 2).

Table 1: Programme theory for the DENIM implementation strategy

If we:

• activate local clinical leaders/champions, provide educational materials, meetings, outreach/ongoing training and local adaptation
Then we can help healthcare professionals caring for people with MND to:
• make sense of, and construct value for the timely optimisation of NIV use and ventilation, as an evidence-based practice, in line with NHS, professional local policies;
• get involved in ensuring patients are achieving optimal NIV
• take action, integrating NIV optimisation support into existing workload, maintaining good relationships with patients
• appraise the effectiveness of the NIV optimisation, reconfiguring it to local circumstances.
Then clinical teams will:
• normalise the practice of NIV optimisation
So that NIV is optimised:
• the average number of days patients use >4hr/day NIV will increase across the population (the primary outcome in the RCT) and patients will experience more effective NIV
So that patient-important and system-important outcomes are improved:
• Survival and quality of life will improve across the population
• Scarce resources will be used more efficiently.



*Effect sizes from Powell BJ et al. 2019. Enhancing the Impact of Implementation Strategies in Healthcare: A Research Agenda. *Front. Public Health* 7:3.
CFIR: Consolidated Framework for Implementation Research; ERIC: Expert Recommendations for Implementing Change.

Figure 1. DENIM programme theory articulated using Normalisation Process Theory, EIRC, CFIR and empirical data from pilot work and literature

[Insert Table 2 here]

Aims

- To understand how the DENIM implementation strategy influences the normalisation of evidence-based NIV practice across diverse clinical contexts.
- To identify the mechanisms through which implementation strategies address barriers and leverage facilitators to achieving ≥4 hours daily effective NIV use.
- To explore how contextual factors moderate the relationship between implementation processes and outcomes.

Objectives

- A mixed-methods case study analysis across twelve UK National Health Service (NHS) ventilation services, documenting variation in implementation processes and outcomes.
- Ethnographic observations of up to 24 patient-healthcare professional interactions capturing implementation enactment in practice.
- Semi-structured interviews with healthcare professionals (n=24-48) and patients/carers (n=24) exploring experiences of the DENIM implementation strategy.
- NoMAD[22] questionnaire data from approximately 50 healthcare professionals measuring normalisation prior to switching in the intervention, during (six months after switching to the intervention arm) and at the end of the study.

- Reflexive thematic analysis mapping qualitative data to NPT constructs and CFIR domains.
- Triangulated analysis linking implementation processes to primary implementation outcomes (NIV usage) and secondary effectiveness outcomes (quality of life, survival).
- ACCESS sub-study: Purposive sampling and analysis of barriers and facilitators to participation in complex intervention trials for underserved populations including global majority populations, those with low digital literacy, and women over 80 with bulbar onset disease

Methods

Design of the trial in which the process evaluation is nested

The DENIM trial is a multicentre, type three hybrid implementation-effectiveness[23], open-label, stepped-wedge cluster-randomised controlled superiority trial, with health economic analysis. It includes a nested process evaluation alongside a clinical trial and long-term cost effectiveness modelling. Twelve UK NHS ventilation services will be selected which reflect variation in service configuration based on a previous questionnaire of UK practice[14]. All twelve will open recruitment for a roll-in period of six months, during which all patients will receive usual care. Following this, every three months, two ventilation services will receive training and transition to delivering the implementation strategy, continuing until all ventilation services have begun using the strategy. Ventilation services are allocated to implementation sequence using constrained random allocation stratified by service size, telemonitoring use, and location of initiation. The trial will recruit up to 252 participants over 24 months,

with the primary outcome being the number of days patients use NIV for more than four hours per day during weeks nine to twelve following initiation. Using the TIDieR framework (Table 3) we report the clinical standard of care for NIV in MND and the DENIM implementation strategy (the experimental condition).

[Insert table 3 here]

Site assessment forms completed during the control phase will document the details of usual care for each ventilation service. These capture caseload, current standard of care, proportion of patients using telemonitoring, and proportion initiated as inpatients. These factors will inform the stratified randomisation and will be examined as potential moderators of implementation success.

Roles within each ventilation team vary in ways likely to influence implementation. NIV initiation is typically delivered by respiratory physiotherapists and nurses, with involvement from neurologists, respiratory physicians, palliative care specialists, psychologists, speech and language therapists, and dietitians within the wider multidisciplinary team. The NoMAD questionnaire will capture healthcare professionals' roles within the team and their experience of the implementation strategy (see Quantitative methods), enabling analysis of whether normalisation differs by professional group or level of involvement[22]. Healthcare professional interviews will sample across roles to explore how professional background shapes engagement with the implementation strategy (see Qualitative methods: Sampling).

Relationships between healthcare professionals, patients and carers are central to NIV optimisation. Prior research identified that successful NIV involves careful attention to relationships: healthcare professionals working as a multidisciplinary team, effective communication between healthcare professional and patients and

carers, and alignment between clinical goals and patients' own priorities[14]. Ethnographic observations will examine verbal and non-verbal interactions between participants, including how decisions are negotiated and how barriers are addressed in practice (see Qualitative methods: Data collection).

Interactions between individuals and between teams shape how the implementation strategy is enacted in practice. Within ventilation teams, interactions occur during multidisciplinary team meetings where patient progress is reviewed, and decisions are made about NIV adjustment. Observations of these meetings will examine how the implementation strategy influences team behaviour and decision-making. Between sites, interactions occur through the DENIM research network led by experts and local champions enabling sharing of approaches and mutual support. Informal conversations following observations will explore how healthcare professionals experience these interactions and how they influence local implementation (see Qualitative methods: Data collection).

The CFIR provides a structure for examining contextual factors at the inner setting, including organisational culture, available resources, and healthcare professional self-efficacy, and at the outer setting, including NHS policies and professional guidelines. NPT and the CFIR[21, 24] will guide exploration of how ventilation teams shape the adaptation and integration of the implementation strategy. NPT attends to the relational and interactional dimensions of context: strategic intentions concern how actors formulate plans; adaptive execution concerns how actors find workarounds; negotiating capacity concerns how actors integrate new practices with existing ways of working; and reframing organisational logics concerns how existing social structures shape what is possible[24]. Interview topic guides framed around

these constructs will elicit accounts of how roles, relationships and interactions enable or constrain implementation (see Qualitative methods: Data collection).

Process Evaluation Design

The process evaluation employs a convergent mixed methods multiple-case study design. This approach combines quantitative measurement of normalisation and adherence patterns with qualitative exploration of implementation processes and contextual factors, enabling an understanding of what is implemented, how context shapes implementation, and how mechanisms produce outcomes[25, 26].

The design is convergent, with qualitative and quantitative data collection occurring concurrently throughout the trial. Priority is given to the qualitative component for understanding implementation processes, while the quantitative component establishes patterns against which qualitative findings can be interpreted. All twelve NHS ventilation services serve as cases, with data collection during both control and implementation phases enabling within and between ventilation team comparison. Each case comprises four embedded units of analysis: ethnographic observations, semi-structured interviews, the NoMAD healthcare professional questionnaire, and NIV-use data from participants' ventilators.

Fidelity will be assessed through quantitative telemonitoring data identifying healthcare professional engagement, audit of ten percent of workbooks (per ventilation service) for application of the components of the DENIM strategy, ethnographic observations of patient-professional interactions, and observations of multidisciplinary team meetings.

Qualitative methods

Methodological orientation

The qualitative component utilises a focused ethnography approach[27], drawing on NPT as the interpretive framework. Focused ethnography is suited to examining specific aspects of healthcare practice within defined settings and timeframes, rather than prolonged immersion characteristic of traditional ethnography. NPT provides conceptual tools for understanding how new practices become embedded in routine healthcare through the mechanisms of coherence-building, cognitive participation, collective action, and reflexive monitoring.

Sampling

Patient participants will be recruited using purposive sampling based on predefined diversity criteria including ethnicity, gender, age, disease severity, NIV use at four weeks, and digital health literacy levels. One to two patients per ventilation service will be recruited (up to 24 total) alongside family members. Healthcare professionals (average n=2 per ventilation service, total 24-48 across two timepoints) will be recruited to participate in interviews, with sampling to achieve variation in roles and years of experience working with people with MND. Recruitment will be formally monitored monthly to ensure participants with a range of characteristics are being recruited, with three-monthly reports presented to the trial management group.

Approach

Following recruitment into the trial, a subset of participants and their relatives or friends will be contacted to explore willingness to participate in an observation and/or interview. Non-trial participation rates and reasons will be documented and a subset

of patients who declined will be invited to participate in an interview to explore the barriers to trial participation (see ACCESS sub-study below).

Setting

Focused ethnographic observations will be conducted where NIV care is delivered, including clinic settings and/or home visits. Researchers will spend approximately two to three hours with each participant, including, where appropriate, time in waiting rooms or their homes before, during and appointments. Observations of multidisciplinary team meetings will also be conducted. Family members may be present during observations and/or interviews where this reflects usual practice or participant preference. Interviews may be conducted face-to-face, by telephone, or by video according to participant preference.

Participant characteristics

Sociodemographic characteristics of patient participants will be collected including ethnicity, gender, age, disease severity, and digital health literacy. For healthcare professional participants, demographic information including NHS Trust ventilation service, job title, and experience of working with patients with MND will be collected from questionnaires.

Data collection

Focused ethnographic observations will be guided by an observation framework, focusing on how healthcare professionals align or diverge from components of the DENIM implementation strategy. Observation field notes will be made during and after observations, capturing verbal and non-verbal behaviours, communication between participants, decision-making, barriers and facilitators, and identified care

needs, particularly reflecting on how the person with MND was involved in conversations. The researcher will be a non-participant observer attending in person. Post observation informal conversations will be held to explore participants' emotional responses to the appointment and clarify alignment with expectations.

Semi-structured interview topic guides will be developed, framed around CFIR domains and NPT constructs and with input from patient and public involvement representatives. Examples from observations will be used to stimulate discussion.

Healthcare professional interviews will be conducted at two timepoints per ventilation service, scheduled in accordance with observations. Patient participant and carer interviews will be conducted once, though patients can participate in multiple observations.

Interviews will be audio-recorded and transcribed verbatim. Interviews will be approximately 30-60 minutes, dependent on participants preferred interview pace. Adjustments will accommodate communication needs including use of proxies, interpreters, communication devices, use of NIV during the interview and frequent breaks. Informal conversations will be offered to participants who may struggle with semi-structured interviews, conducted shortly following observations. Data from medical records including the DENIM intervention workbook regarding NIV-related care will supplement observational data.

Information power and transcript review

Analysis will be conducted concurrently with data collection to monitor data quality and inform subsequent data collection. Sampling will continue until sufficient depth is achieved across the diversity criteria and across ventilation services with varying

implementation outcomes. Transcript return for participant checking is not planned to minimise burden on participants.

Quantitative methods

NIV usage data from participants' ventilators will provide the primary implementation outcome. This is collected at timepoints throughout the twelve-week NIV initiation process. Further details regarding patient recruitment be found in the DENIM Trial protocol (ISRCTN10105285). The Normalisation Measure Development questionnaire (NoMAD), a validated measure based on NPT[22], will be used to assess healthcare professionals perceptions of normalisation. The NoMAD includes questions on role within the team and experience of the implementation strategy. Healthcare professionals will complete the NoMAD via an online platform immediately before, during (six months after switching to the intervention arm) and at the end of the study, with approximately 50 respondents expected across twelve ventilation services. A unique identifier will link questionnaires across timepoints. Site assessment forms will document contextual characteristics. Fidelity assessment will include audit of 10% of sets of medical records and workbooks per ventilation service, for application of the components of the DENIM strategy.

Qualitative analysis

Ethnographic field notes and interview transcripts will be analysed through inductive coding using reflexive thematic analysis[28, 29], subsequently deductively mapped to NPT constructs, using the NPT coding manual[24]. Codes and themes will be compared across ventilation services and participants to develop contextualised understanding. Healthcare professional interview data will initially be analysed

separately from patient and carer data; developed themes will then be compared and contrasted to produce definitive themes. Patient and public involvement (PPI) representatives will contribute to theme development in group discussion sessions.

Quantitative analysis

NoMAD data will be analysed descriptively and compared between timepoints and across sites. Differences in NIV adherence will be compared across ventilation services in relation to normalisation measures and site characteristics. Analysis will examine how implementation success depends on aspects of context including caseload and current standard of care.

Mixed methods integration

The embedding of intensive qualitative case studies within a broader quantitative questionnaire follows a nesting approach, whereby ethnographies and interviews provide depth within cases while the NoMAD questionnaire provides breadth across wider clinical teams. Our qualitative sampling will be informed by quantitative baseline data, including NIV use at four weeks and digital health literacy scores. Data integration will be conducted by the core research team with input from the wider team with methodological and clinical expertise. A comparing procedure[30] will be conducted, examining relationships between qualitative and quantitative findings without requiring data transformation. Cross-case framework analysis[31] will integrate findings in joint display tables[25]. Theoretical lens joint displays structured around NPT constructs will present quantitative and qualitative findings alongside integrated meta-inferences[30, 32]. Cross-case comparison displays will compare themes and scores across sites, building on hypothesised implementation

mechanisms from the programme theory (Figure 1). Quantitative data, particularly NoMAD results and adherence statistics, will test whether these predicted patterns of normalisation and outcome emerge across ventilation services (induction: checking predictions against empirical data to assess whether the theory holds). We will look for convergence and divergence among qualitative and quantitative findings.

Insights from this integration of data will be used to refine understanding of implementation processes. Where meta-inferences indicate specific strategies that could improve adherence, these will be shared with those monitoring data quality and across sites to support ongoing implementation.

ACCESS sub-study

There is substantial inequality in access to research and effective NIV within different MND populations. Patients who are male, younger, have limb onset or slowly progressive disease are more likely to participate in MND clinical trials[33]. These patients are also more likely to successfully use NIV (along with those who are married and of a high socioeconomic status)[34, 35]. Conversely those with significant barriers to NIV use (e.g. older patients, including bulbar onset disease, who are more commonly female, and those with cognitive impairment) face significantly poorer outcomes including low NIV use and poor survival.

To gain a better understanding of the barriers and enablers to effective recruitment, retention and engagement in research from under-served MND populations and how these could be addressed, semi-structured interviews will be conducted with DENIM participants, people who have declined to participate and healthcare professionals working in the service.

To recruit DENIM participants, a purposive sampling approach will be undertaken to sample those with worse health outcomes and/or who are less likely to take part in MND research specifically older patients, females, those with bulbar onset, low digital health literacy[36] and global majority populations or those whose first language is not English. Moreover, we will also interview 10-15 patients and/or carers who have declined to participate in DENIM, but consent to be contacted about the ACCESS sub-study to understand how best to make the study more accessible. To reduce the burden on DENIM participants and healthcare professionals, questions focusing on inclusivity in recruitment and engagement will be incorporated within the topic guides for the interviews and observations that form part of the process evaluation.

Methods for gaining informed consent and conducting the interviews are identical to the ones detailed above (see section: Qualitative methods).

Involvement of experts by experience

The DENIM trial has been designed in conjunction with members of the Sheffield Better Outcomes in MND Advisory Group (BOND) and consulted members of the Cicely Saunders Public Involvement Forum. These groups include people living with MND, family members, carers, and ex-carers and members of the charity the Motor Neuron Disease Association who are peer supporters and have extensive experience visiting people with MND in their homes.

A PPI advisory group of 6-10 people with lived experience of MND meets regularly to advise on the DENIM trial, including the process evaluation. The aim of involving the PPI advisory group members in the design of the process evaluation was to ensure the relevance of the activities and that these were conducted in ways that were inclusive and placed minimal burden on people with MND. The PPI advisory group

members have been involved in ways that reflect individual preferences (e.g., by email, group meetings, one-to-one) and have reviewed and advised on all patient-facing study documents, including the topic guides, participation information sheets, questionnaires and consent forms. They also advised on how to approach potential participants who are commencing NIV, a significant milestone in their disease. The PPI advisory group will be involved in the analysis and interpretation of the findings and will be offered the opportunity to attend a training session delivered by the research team to enable them to engage in data analysis.

Ethical considerations

The DENIM trial has received NHS Research Ethics Committee approval (Leeds East 25/YH/0019; IRAS ref334849). Written, audio-recorded or witnessed informed consent will be obtained from process evaluation participants. Healthcare professionals and carers will be informed about observations through posters and letters and may opt out. Participants may decline questions, end interviews, or withdraw data without reasons.

Discussion

This process evaluation will address a gap between evidence and routine practice in the delivery of NIV for people living with motor neuron disease. NIV is a well-established, guideline-recommended intervention with proven survival and quality-of-life benefits, but its real-world effectiveness is limited by substantial variation in implementation, optimisation, and sustained use. This study will generate explanatory insights that extend beyond the primary effectiveness outcomes of the DENIM trial, examining how – if at all – an implementation strategy improves

intensive, goal-based NIV optimisation across diverse UK NHS ventilation service contexts.

A key strength of our design is the explicit articulation and empirical testing of a programme theory informed by Normalization Process Theory, the Consolidated Framework for Implementation Research, and ERIC implementation strategies. By embedding a convergent mixed-methods process evaluation within a hybrid type three trial, the study is well positioned to improve understanding of not only whether the implementation strategy works, but how and under what conditions.

The timing of the DENIM study is salient in the context of current NHS policy. Having only recently opened to participant recruitment, the study has already been cited in a Department of Health and Social Care press release as an exemplar of the government's strategic shift towards digitally enabled care delivered closer to home[37]. This policy emphasis on remote monitoring, self-reporting, and reduced reliance on face-to-face appointments reflects a broader transformation agenda within the NHS. While effectiveness remains to be demonstrated, the publicity underscores the relevance of the study and highlights the importance of rigorous evaluation to inform future scale-up decisions. The process evaluation is well positioned to generate timely evidence on how complex interventions including remote monitoring technologies can be integrated into routine care for people with progressive neurological conditions. By examining implementation across a range of NHS ventilation services with varied resources, delivery models, and prior experience of telemonitoring, the study will also provide insights into the practical conditions required for national policy ambitions to be realised in everyday clinical practice.

The study explicitly attends to questions of equity and access both to research and complex interventions, recognising that complex and digital health innovations may risk exacerbating existing inequalities[38–41]. By purposively sampling underserved groups and examining how the implementation strategy is adapted in practice, the process evaluation will generate insights into how complex care models, including digital monitoring, can be delivered inclusively and responsively.

Although the multi-site design enhances transferability, findings may not be directly generalisable to other health systems. National policy and service configurations related to digital care are evolving rapidly, which may influence implementation during the study.

Findings from this process evaluation will be essential for interpreting the outcomes of the DENIM trial and for informing decisions about wider implementation. By identifying which components of the implementation strategy are core, which are adaptable, and which are context-dependent, the study will provide actionable knowledge for clinicians, service leaders, and policymakers considering the expansion of remote monitoring approaches. Although focused on MND, the insights generated are likely to be relevant to other long-term conditions requiring complex, technology-supported care.

Abbreviations

CFIR- Consolidated Framework for Implementation Research
CSS-MND- Clinical Saliva Scale for Motor Nerone Disease
DENIM - Delivering Effective Non-Invasive ventilation trial
ERIC- Expert Recommendations for Implementing Change
MiND-B- Motor Neurone Disease Behaviour Scale
MND- Motor neurone disease
NHS - National Health Service

NIV- Non-invasive ventilation
NOMAD - Normalisation Measure Development questionnaire
NPT- Normalisation Process Theory
PPI- Patient and Public Involvement
S3-NIV – Simple Non invasive Ventilation questionnaire
TIDieR- The Template for Intervention Description and Replication
UK – United Kingdom

Declarations

Human Ethics and consent to participate

The DENIM trial has received HRA and NHS Research Ethics Committee approval (Leeds East 25/YH/0019; IRAS ref334849) and will be conducted in line with the Declaration of Helsinki. Written, audio-recorded or witnessed informed consent will be obtained from process evaluation participants. Healthcare professionals and carers will be informed about observations through posters and letters and may opt out. Participants may decline questions, end interviews, or withdraw data without reasons.

Consent for publication: not applicable.

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Use of artificial intelligence

Claude was used to prepare the research proposals and this manuscript for publication. It was used to: improve the clarity, structure and formatting of the writing and check that the paper meets the required reporting standards. Claude was also used to check the consistency and coverage between the logic model, the programme theory and the TIDieR statement.

Authors contributions: EHo, AG, DH and CM designed the process evaluation with operational input from TC, CG and NH and the wider DENIM trial co-author team (MB, EHe, HH, MC, GK, CM, EM, BM, SB, DN, RP, CMcD, EF). CG, DH, EHo, AG and GR drafted the manuscript. SD reviewed the ACCESS sub study description. All authors read and approved the final manuscript.

Data Availability: The dataset(s) supporting the conclusions of this research will be made available in the White Rose repository, at the conclusion of the trial.

Competing interests: The authors have no competing interests to declare.

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Table 2. **Implementation strategy components mapped to NPT and CFIR-ERIC**

Implementation Strategy Component	**Simplified place in Normalisation Process Theory**[17, 21]	**CFIR-ERIC Mapping**
Staff education and training: Remote training for NIV-initiating staff (recorded webinars, self-directed online learning, online resources). Content covers evidence-based NIV optimisation; telemonitoring and oximetry interpretation with ventilator adjustment; MND-specific challenges (bulbar	Staff education maps to **Differentiation and Internalisation (Coherence-building)**: "Identify the value and benefits of implementation for staff" and "Create and disseminate materials for staff that illustrate the positive outcomes of implementation." The general strategy is "Clearly	Staff education and training addresses a deficit in **knowledge and beliefs (CFIR)** through **conducting educational meetings (ERIC)** and **distributing educational materials (ERIC).**

dysfunction, cognitive impairment); goal setting and coaching; Acceptance and Commitment principles; advanced care planning; staff wellbeing; cultural competence; and health-literacy awareness. Other MDT members receive a shorter overview webinar.	identify the value of the intervention to staff." Training maps to **Skill-set workability (Collective Action)**: "Assess and develop the required skills among staff" and "Provide targeted training and redistribute tasks according to skill sets." The general strategy is "Ensure staff have the skills required for effective implementation."	
Implementation blueprint: Formal document defining the rationale and aims of goal-based intensive NIV optimisation, scope of change, milestones, allowable local or individual adaptations,	Implementation blueprint maps to **Strategic Intention and Individual specification (Coherence-building)**: "Develop a comprehensive plan for staff and service users that outlines the implementation's objectives" and "Provide clear, role-	Implementation blueprint addresses a deficit in **access to knowledge and information (CFIR)** through **developing a formal implementation blueprint (ERIC)**.

and metrics for monitoring progress and success.	specific guidelines and expectations for staff." The general strategy is "Define and communicate individual roles and responsibilities related to the intervention."	
Patient and carer resources: Low-burden, accessible materials adapted from existing resources (e.g. MyBreathing website, paper resources, local site resources).	Patient and carer resources maps to **Individual specification (Coherence-building):** "Provide targeted information tailored to service user needs and circumstances" and **Internalisation (Coherence-building):** "Ensure that service users understand how implementation could improve their care or quality of life."	Patient and carer resources addresses a deficit in **access to knowledge and information (CFIR)** through **distributing educational materials (ERIC)**.
Effective preparation: Pre-initiation support to enable patient and carer readiness. Psychological	Effective preparation maps to **Internalisation (Coherence-building)**: "Ensure that service users	Effective preparation addresses a deficit in **recipient need (CFIR)** through

preparation includes education, emotional processing, and shared decision making. Physical preparation addresses modifiable barriers (e.g. secretion management). Social planning supports integration into daily life.	understand how implementation could improve their care or quality of life" and **Enrolment (Cognitive Participation):** "Make it easy for service users to get involved, providing clear information and support as needed." The general strategy is "Eliminate obstacles to participation in the implementation process."	**preparing patients/consumers to be active participants (ERIC)**.
Leadership and change agents: NHS clinician co-applicants and telemonitoring experts act as initial leaders. Site consultation and training identify early adopters and local change agents who sustain implementation through	Leadership and change agents map to **Initiation (Cognitive Participation):** "Identify key staff who will drive and champion for the implementation" and "Assign leadership roles to key staff and provide them with the necessary resources." The general strategy is "Select and support key individuals	Leadership and change agents address a deficit in **culture (CFIR)** through **identifying and prepare champions (ERIC).**

peer networks and MDT engagement.	who will drive the intervention forward."	
Community of practice and peer support: Ongoing skills reinforcement via a community of practice, incorporating workshops, drop-in sessions, peer support, and distributed leadership.	Community of practice and peer support maps to **Enrolment and Activation (Cognitive Participation):** "Make staff participation accessible and attractive" and "Ensure that staff leaders continuously engage with and support colleagues." The general strategy is "Eliminate obstacles to participation in the implementation process."	Community of practice and peer support address a deficit in **culture (CFIR)** and **relational connections (CFIR) through creating a learning collaborative (ERIC)** and **promoting network weaving (ERIC)**.
Intervention Workbook – initiation: Structured assessment prompts using brief validated tools (respiratory symptoms, saliva scale, cognitive screening) to identify NIV barriers. Guides discussion of facilitators (target	Intervention Workbook (initiation) maps to **Interactional workability (Collective Action):** "Adjust workflows for staff as necessary to integrate the implementation seamlessly." The general strategy is "Ensure that the intervention	Intervention Workbook (initiation) addresses deficits in **self-efficacy (CFIR)** and **compatibility (CFIR)** through **developing and implementing tools**

symptoms, goals, advanced care planning) and supports tailoring of NIV schedules to patient priorities.	does what it is supposed to do with minimal disruption of other activities."	**for quality monitoring (ERIC).**
Value-based consultation at initiation (Day 0): Structured consultation aligning patient-defined values with clinician recommendations and objectives, establishing explicit NIV goals at treatment initiation.	Goal-based consultation at initiation maps **to Interactional workability (Collective Action):** "Identify how the implementation affects staff work routines" and "Understand and address how the implementation affects the daily lives and routines of service users." The general strategy is "Ensure that the intervention does what it is supposed to do with minimal disruption of other activities."	Goal-based consultation at initiation addresses a deficit in **compatibility (CFIR)** through **involving patients/consumers and family members (ERIC)**.
Supported initiation: Intensive early support to help patients persist	Supported initiation maps to **Skill-set workability (Collective Action):**	Supported initiation addresses a deficit in **self-efficacy (CFIR)**

through initial discomfort until symptomatic benefit is achieved. Psychological strategies reinforce agreed goals and perceived benefits. Physical strategies include mask selection and ventilator prescription changes, supported by early review.	"Assess and develop the required skills among staff" and "Provide service users with the knowledge and skills they need to participate effectively in the implementation." The general strategy is "Ensure staff have the skills required for effective implementation."	through **conducting ongoing training (ERIC)** and **providing ongoing consultation (ERIC)**.
Local adaptation and refinement: Permitted flexibility in review schedules and use of telemonitoring and oximetry, guided by evidence and refined through continuous consultation with sites, experts, local champions, and Patient and Public Involvement (PPI) contributors. Ongoing	Local adaptation and refinement maps to **Contextual Integration (Collective Action):** "Align organizational resources and policies to support the implementation" and "Involve management in resource allocation and support." The general strategy is "Demonstrate organizational commitment	Local adaptation and refinement addresses a deficit in **compatibility (CFIR)** and **available resources (CFIR)** through **promoting adaptability (ERIC)**.

support facilitates normalisation and dissemination of emerging best practice.	and support for interventions."	
Telemonitoring: Secure cloud-based systems provided by NIV manufacturers, accessed via modems on NIV devices. Enables real-time monitoring of adherence (hours and patterns of use) and ventilation effectiveness (tidal volume, leak, airway obstruction indicators, ventilator asynchrony), with capacity for remote ventilator adjustment, reducing travel burden and patient stress.	Telemonitoring maps to **Systematisation (Reflexive Monitoring):** "Establish a system for monitoring the implementation's effects" and "Implement and maintain a data collection and analysis system." The general strategy is "Deploy systems to track progress and outcomes of the intervention."	Telemonitoring addresses a deficit in **reflecting and evaluating (CFIR)** through **auditing and providing feedback (ERIC)**.
Intensive monitoring and optimisation schedule: Structured	Intensive monitoring and optimisation schedule maps to **Systematisation**	Intensive monitoring and optimisation schedule addresses a

reviews with patient/carer at 2, 5, 10 days, and 2, 3, 4, 8, and 12 weeks post-initiation, plus ad hoc contact. Time allocation: ~1 hour at initiation; ~30 minutes per follow-up. Focused on achieving ≥4 hours/day of effective NIV through frequent review of telemonitoring and oximetry data, patient-reported barriers and goals, and gradual, responsive up-titration of ventilator settings.	**(Reflexive Monitoring):** "Establish a system for monitoring the implementation's effects" and Communal appraisal (Reflexive Monitoring): "Conduct regular review meetings and surveys for communal feedback." The general strategy is "Create opportunities to continually improve the implementation process."	deficit in **reflecting and evaluating (CFIR)** through **auditing and providing feedback (ERIC)** and **purposely reexamining the implementation (ERIC)**.
Intervention Workbook – follow-up: Standardised prompts for each review, including telemonitoring checklist (usage, leak, tidal volume, AHI, triggered breaths, NIV goals, oximetry status),	Intervention Workbook (follow-up) maps to **Systematisation (Reflexive Monitoring):** "Train staff to use monitoring tools effectively" and Reconfiguration (Reflexive Monitoring): "Allow staff to	Intervention Workbook (follow-up) addresses a deficit in **reflecting and evaluating (CFIR)** through **developing and implementing**

review of prior barriers and aims, and documentation of adjustments and advice.	suggest and trial modifications." The general strategy is "Revise implementation process based on staff feedback."	**tools for quality monitoring (ERIC)**.
Home overnight oximetry: Mailed to patients once NIV use exceeds four hours per night, providing objective confirmation of ventilation effectiveness to guide optimisation.	Home overnight oximetry maps to **Systematisation (Reflexive Monitoring)**: "Establish a system for monitoring the implementation's effects" and "Implement and maintain a data collection and analysis system." The general strategy is "Deploy systems to track progress and outcomes of the intervention."	Home overnight oximetry addresses deficits in **reflecting and evaluating (CFIR)** through **auditing and providing feedback (ERIC)**.
Ongoing monitoring: Longitudinal optimisation as disease progresses, addressing emerging physical and psychological barriers, revisiting goals,	Ongoing monitoring maps to **Reconfiguration (Reflexive Monitoring)**: "Be responsive to feedback from service users, and be prepared to make changes	Ongoing monitoring addresses a deficit in **compatibility (CFIR)** through **providing ongoing**

and proactively preventing crises and unplanned admissions.	based on their experiences and suggestions"	**consultation (ERIC)**.

Table 3. TIDieR framework standard of care for NIV in MND and the DENIM implementation strategy (experimental condition).]

Clinical standard of care	
Brief name:	Non-invasive ventilation for respiratory insufficiency in motor neuron disease
Why (rationale):	Non-invasive ventilation (NIV) is the only intervention that significantly improves both life expectancy and quality of life in MND[2]. It improves breathlessness, sleep disturbance and fatigue and improves survival in early trials[3] and in-world observations[4–6]. NIV is part of standard care and there is good evidence that NIV is an effective treatment for people with MND. Effective NIV requires good adherence (at least four hours per day) and effective ventilation by delivering adequate tidal volumes, in synchrony with the patient's own breathing to reverse hypercapnoea and hypoxia and improve symptoms[7, 11, 42]. Low adherence and inadequate correction of hypoxia are associated with worse survival[43, 44].

What (materials):	The patient-facing equipment comprises a non-invasive ventilator device and associated consumables including a mask interface, headgear, tubing circuit and humidity chamber. Ventilators are capable of delivering positive pressure ventilation with adjustable settings including inspiratory positive airway pressure (IPAP), expiratory positive airway pressure (EPAP), rise time, inspiratory time and trigger sensitivity.
What (procedures):	The initial consultation involves patient and carer familiarisation with NIV equipment, acclimatisation and minimal optimisation. Standard optimisation varies across NHS services and depending on patient need but typically involves a follow-up telephone review without telemonitoring data at 2 weeks, face to face review at 12 weeks with or without blood gas measurements and with or without NIV data downloads, plus ad hoc consultations triggered by the patient or healthcare professional (based on UK wide survey of practice and NHS Trust consultations)[14]. Post-initiation optimisation typically requires periodic face-to-face visits to download NIV data from the machine then adjust ventilator settings. A limited number of NHS services have some access to telemonitoring of NIV data although this is not used intensively, some use overnight oximetry as a measurement of NIV effectiveness.
Who provided:	Healthcare professionals, typically physiotherapists or nurses. Guidelines recommend that healthcare professionals are adequately trained [45], although between specialist appointments most care at home is delivered by healthcare professionals who are not MND specialists.

How (mode of delivery):	NIV is delivered to individual patients. The initial consultation is face-to-face. Follow-up contact may be by telephone or face-to-face.
Where:	NIV initiation occurs in hospitals, outpatient clinics or homes, depending on service capabilities and patient needs. Long-term use occurs in the patient's own home (domiciliary NIV). Initiation and optimisation of NIV for patients with MND is guided by local and national guidelines which may include telephone, video or face-to-face contact in respiratory units or more limited availability at home.
When and how much:	The goal is to achieve ≥4hr/day effective ventilation to reverse or prevent nocturnal hypoventilation, improve symptoms and maximise patient survival and quality of life in a way that is in line with the patient's values. NIV is intended for long-term nightly use. The typical follow-up schedule in standard care comprises a telephone review at two weeks and face-to-face review at 12 weeks, with three-monthly reviews thereafter but varies across services and patients with no standardised approach. *Tailoring:* Local variation in NHS Trust practice is allowed. Initiation location (home, outpatient or hospital) depends on service capabilities and patient needs. Ventilator settings are adjusted according to individual patient response and tolerability.

Implementation strategy (the experimental condition)	
Brief name:	DENIM - Delivering Effective Non-Invasive ventilation in Motor neuron disease using intensive remote support.
Why (rationale):	To embed and sustain the support required for effective NIV use, there must be both individual and service level change within healthcare teams. Normalization Process Theory (NPT), Consolidated Framework for Implementation Research (CFIR) and Expert Recommendations for Change (ERIC) have guided the theory and structure of a 12-week intense support intervention for MND healthcare teams. Optimal use of NIV is not currently normalised in services (implemented, embedded, spread and sustained). This is because there are barriers in; knowledge and beliefs (professionals may not value optimising adherence and ventilation or differentiate this from routine practice), culture (lack of confidence and resources to enact practice changes), self-efficacy (insufficient expertise to review patients, communicate efficiently and coach patients/carers to address biopsychosocial barriers), and goals and feedback (NIV data not routinely available to inform care). Funding constraints (time, equipment) further limit integration of optimised NIV into practice[14]. DENIM addresses these barriers through evidence-based implementation strategies: educational meetings (ERIC, average effect size 6%) and materials (ERIC, average effect size 2%), identifying and preparing local champions (ERIC, average effect size 12%), ongoing training with promotion of adaptability through context-specific strategies (ERIC, average effect size 6%), and real-time telemonitoring

	providing audit and feedback on NIV adherence and ventilation effectiveness (ERIC average effect size 4%)[46].
What (materials):	The DENIM implementation blueprint outlines the aims and justification for the implementation strategy, the scope of the changes proposed and the expected milestones, local/individual adaptations and ways to measure progress/success. The DENIM intervention workbooks guide healthcare professionals through each stage in the first 12 weeks of the initiation pathway including pre-initiation structured assessments, initiation visit including psychologically informed consultations to align patient and healthcare professional values and goals, and follow-up visits involving telemonitoring and patient reviews and ventilation optimisation. Training materials are shaped by literature and guidelines, subject experts, ongoing consultation with NHS Trusts and experts by experience. Needs-based training is delivered through webinars (recorded to allow replay and flexible learning) supported by self-directed learning and signposting to bespoke DENIM and existing online resources (e.g. www.niv4mnd.co.uk). Telemonitoring equipment comprises mobile internet enabled modems installed on NIV machines providing securely hosted existing commercial cloud-based telemonitoring systems. Sites will use their existing ventilators and are provided with telemonitoring equipment where required. Home overnight oximetry devices used once when the patient reaches ≥4hrs/day NIV use provide additional objective measures of NIV effectiveness. Patients and carers receive accessible resources adapted

	from existing resources already recommended to support NIV initiation (e.g. MyBreathing website www.mybreathing.mymnd.org.uk, DENIM bespoke paper resources and local materials). The initiation workbook prompts completion of a structured assessment using simple tools to identify potential barriers to NIV (e.g. S3-NIV[47], CSS-MND[48], MiND-B)[49].
What (procedures):	The implementation strategy has three core components: (a) a formal implementation blueprint of goal-based intensive NIV optimisation, (b) provision of the environment in which this can be delivered (sufficient time, information using telemonitoring and communication, and structured assessments to monitor and optimise NIV), and (c) healthcare professionals training to align their practice with these goals and routines. Healthcare professionals directly involved with initiating NIV receive online training plus ongoing peer support and additional training during the process. Other members of the MDT are offered a short webinar to align their practice with the aims of the project. Training topics include evidence-based NIV optimisation strategies and solutions, telemonitoring and oximetry data interpretation and NIV adjustment, the unique challenges of MND (e.g. cognitive and behavioural impairment), goal setting and coaching skills, psychological principles[50] (e.g. Acceptance and Commitment principles[51]), advanced care planning, healthcare professional wellbeing, cultural competencies and health literacy awareness. The workbook provides a structured assessment, promotion conversations about facilitators to NIV use (e.g. symptoms

	they wish to address, advanced care planning) and helps adapt the treatment schedule to the patient's goals. Following initiation, healthcare professionals review telemonitoring data remotely and perform a structured review of the patient/carer at 2, 5, 10 days, weeks 2, 3, 4, 8, 12 post initiation plus ad hoc (e.g. following patient contact). Healthcare professionals can remotely adjust NIV settings, change masks and communicate and provide support to patients/carers as needed. Patients undergo home overnight oximetry when usage exceeds four hours per day providing additional information about NIV effectiveness. Telemonitoring in MND provides information about NIV to healthcare professionals without needing any patient involvement.
Who provided:	Training is delivered by the research team with support from other healthcare professionals using telemonitoring and telemonitoring companies. It is sustained through the trial as a network/community of practice with additional options for workshops, drop-in meetings, peer support and leadership. NHS clinician co-applicants and experts in telemonitoring act as early leaders but consultation and training will enable identification of early adopters and change agents who, through the network of ongoing peer support, sustain momentum with the wider MDT. Clinical care following implementation strategy training is delivered by healthcare professionals already working within the ventilation service responsible for delivering NIV.
How (mode	Healthcare professionals training aims to be minimally disruptive: it is all remote, recorded to allow replay and flexible learning and supported by

of delivery):	self-directed learning and access to online resources. Patient/carer contact is driven by clinical need and options for digital communication are encouraged (e.g. TiM[52]/other patient apps where available, phone, video, text or email).
Where:	Training is delivered remotely. Patient reviews occur in the community, supported by telemonitoring accessed from service premises. The implementation is conducted at UK NHS ventilation services providing NIV for patients with MND.
When and how much:	Healthcare professionals review telemonitoring data and communicate with the patient/carer at 2, 5, 10 days, 2, 3, 4, 8, 12 weeks post initiation plus ad hoc consultations. The implementation strategy covers the first 12 weeks of NIV use. This additional time (one hour at initiation, 30 minutes per timepoint after this) has been accounted for in excess treatment costs.
Tailoring:	The intervention guide outlines the local and individual adaptations allowed during the study. Location adaptation includes limited variation in the patient review schedule and agreed use of telemonitoring and overnight oximetry if they are already part of usual care. Permitted variation is based on the current evidence and refined with consultations with ventilation teams, experts and local champions and PPI. Ongoing consultations allow further intervention refinement and support normalisation of NIV (for example, dissemination of new techniques through local champions). Healthcare professionals also vary their

	practice according to individual patient need and healthcare professional expertise (settings, roles, relationships and interactions).