Delivering Effective Non-Invasive ventilation in Motor Neuron Disease using intensive, remote optimisation

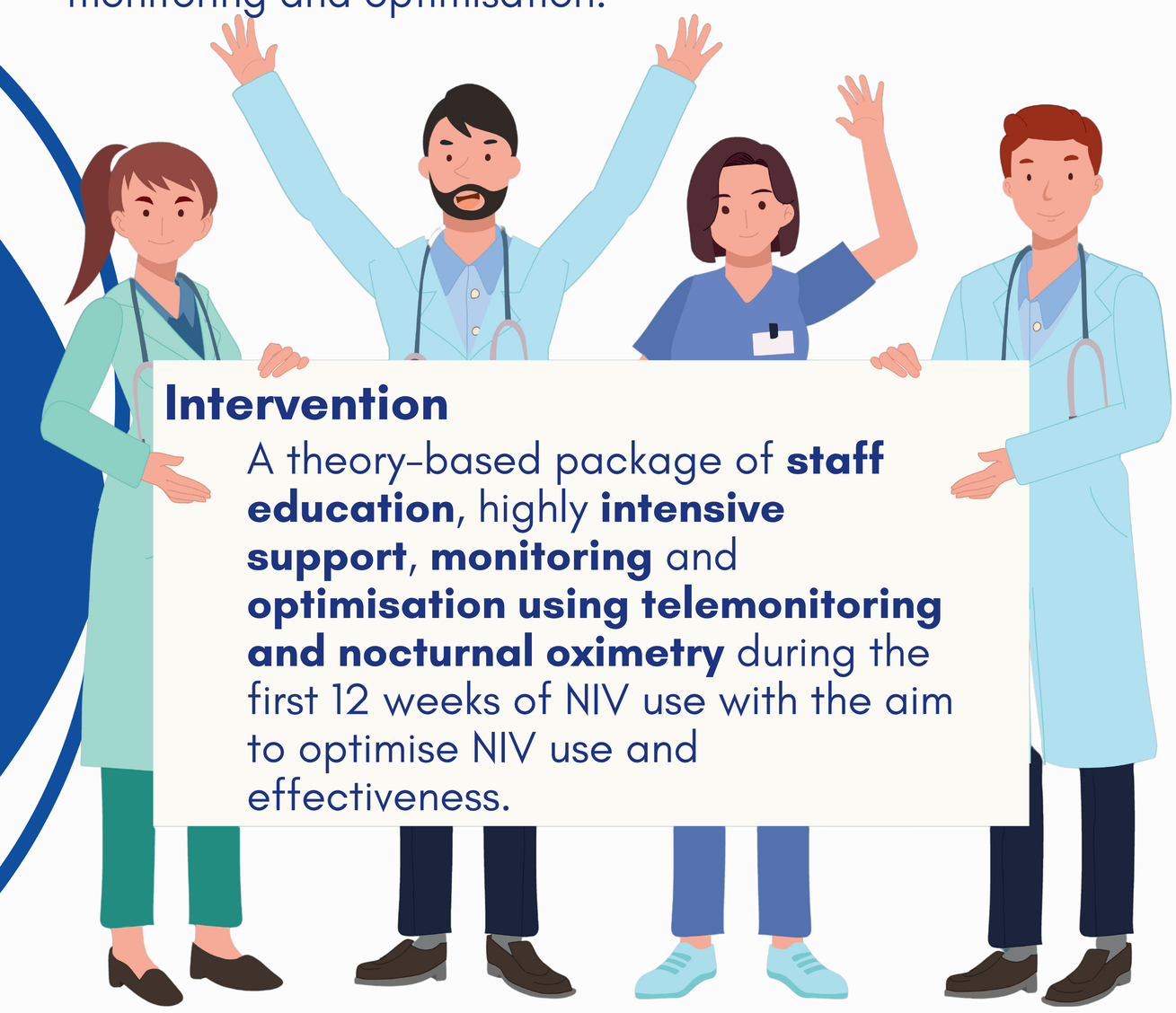
A protocol for a type III hybrid implementation-effectiveness cluster stepped wedge randomised controlled trial

Hobson E, Girling C, Bradburn M, Dawson S, Hill H, May C, Bianchi S, Cox M, Kaltsakas G, Massey C, Mayberry E, Messer B, Needham D, Playle R, Griffiths A, Hind D, McDermott C

DENIM

Background

More than half of patients commencing non-invasive ventilation (NIV) in motor neuron disease (MND) do not receive effective ventilation due to problems which could be identified and addressed early in the initiation process. Early low adherence and ineffective ventilation are associated with reduced survival. Optimal use of NIV requires effective patient preparation, initiation, ongoing support, monitoring and optimisation.

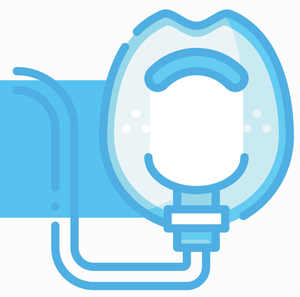


Intervention

A theory-based package of **staff education**, highly **intensive support**, **monitoring** and **optimisation using telemonitoring and nocturnal oximetry** during the first 12 weeks of NIV use with the aim to optimise NIV use and effectiveness.

Objectives

To evaluate the effectiveness of the DENIM implementation strategy, with a stepped-wedge cluster randomised controlled trial, to detect increase in adherence to NIV, effectiveness and cost effectiveness.



Methods

12 UK NHS home ventilation sites.

252 people with MND requiring NIV initiation and optimisation within 12 weeks.

Sites will commence the trial delivering usual care. Sites will then switch to implementing the intervention at random intervals.

Primary outcome: days of NIV usage over four hours per day at week 9-12.

Secondary outcomes: survival, NIV effectiveness, quality of life, respiratory symptoms, NIV comfort, health resource use.

Process evaluation: triangulation of NIV usage data with the perspectives of staff, patients (including those who declined to participate in the trial) and carers using interviews, ethnographic observations and questionnaires.

Hypothesis guided by a programme theory using Normalisation Process Theory, the Consolidated Framework for Implementation Research, and Expert Recommendations for Change, .

If we... conduct educational meetings, provide educational materials, identify and prepare champions, conduct ongoing training, promote adaptability and conduct real-time telemonitoring of NIV adherence and ventilation effectiveness

Activating these mechanisms... Coherence building, cognitive participation, collective action, reflexive monitoring

Then... clinical teams will normalise the practice of NIV optimisation, average no. days of >4hrs will increase, survival and quality of life will improve across the population, scarce resources will be used more efficiently

Anticipated impact



DENIM offers a blueprint for implementing a better standard of care for NIV initiation resulting in more patients experiencing longer survival and improved quality of life. It will deliver sustainable improvements in healthcare professionals' skills, experience and knowledge and will develop a national network of research-engaged and culturally sensitive staff, able to deliver further innovative interventions in MND and respiratory care.

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