

# Training nurses in a competency framework to support adults with epilepsy and intellectual disability: the EpAID cluster RCT

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**Declared competing interests of authors:** During the preparation of this report Howard Ring was the chairperson of the Health Technology Assessment Mental, Psychological and Occupational Health Panel and he was a member of the Psychological and Community Therapies Panel during the project. Cam Donaldson was a member of the Medical Research Council Methodology Research Panel.

Published February 2018

DOI: 10.3310/hta22100

## Scientific summary

### **The EpAID cluster RCT**

Health Technology Assessment 2018; Vol. 22: No. 10

DOI: 10.3310/hta22100

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# Scientific summary

## Background

In adults with an intellectual disability (ID) and epilepsy there are suggestions that the introduction of nurse-led care may lead to improvements in management. However, this has not been tested in a definitive clinical trial and results cannot be generalised from general population studies as epilepsy tends to be more severe and to be associated with additional clinical comorbidities in adults with ID. This trial investigated whether or not ID nurses, instructed in the use of a competency framework developed to optimise nurse management of epilepsy in people with an ID, can cost-effectively improve clinical and quality-of-life (QoL) outcomes in the management of epilepsy within this population compared with treatment as usual (TAU).

## Methods and study design

The Epilepsy And Intellectual Disability (EpAID) clinical trial was a two-arm cluster randomised controlled trial (RCT) of a competency framework designed to provide guidelines to inform the practice, training and development of nurses involved in the management of antiepileptic drug (AED) resistant epilepsy in adults with an ID, whatever their previous level of experience. Several competencies are addressed in the framework, including the clinical diagnosis and management of epilepsy, assessing and managing risk, the impact of epilepsy and multidisciplinary team working. The comparator condition was TAU. Clusters were randomly assigned to either a TAU control arm or the competency framework active arm. In both arms participants underwent 4 weeks of baseline data collection followed by a minimum of 24 weeks of intervention and 4 weeks of follow-up data collection. The primary outcome was a measure of seizure severity, including associated injuries and the level of distress manifested by the patient, as perceived by an informant. Secondary outcomes included an economic analysis, health-related QoL, carer strain, seizure frequency and side effects. Descriptive measures included demographic and clinical descriptors of participants and clinical services in which they were receiving their epilepsy management. A qualitative examination of clinical interactions and carers' views about participants' epilepsy management during the trial was also undertaken.

## Results

In total, 312 individuals were recruited into the study. Of the 17 research sites included in the trial, eight were randomised to the framework intervention and nine to TAU. A total of 128 participants were recruited in sites randomised to TAU and 184 were recruited in sites randomised to the competency framework. Of those entered into the trial, 41 (13%) either withdrew from the trial ( $n = 35$ ) or died ( $n = 6$ ) between the start of the baseline period and the end of the follow-up period.

The primary outcome measure employed to assess the effect of introducing the competency framework was the Epilepsy and Learning Disabilities Quality of Life seizure severity scale (ELDQoL-SSS) score. Using an intention-to-treat analysis controlling for baseline individual-level and cluster-level variables, there was no significant difference in ELDQoL-SSS score between the two arms of the trial [mean difference  $-0.326$ , 95% confidence interval (CI)  $-4.382$  to  $3.731$ ;  $p = 0.875$ ]. Likewise, in terms of the secondary outcomes, there were no significant differences between the arms in the Epilepsy and Learning Disabilities Quality of Life (ELDQoL) AED side effects scale score ( $0.194$ , 95% CI  $-2.981$  to  $3.369$ ;  $p = 0.905$ ), the ELDQoL behaviour scale score ( $0.661$ , 95% CI  $-1.295$  to  $2.617$ ;  $p = 0.508$ ), the ELDQoL mood scale score ( $0.854$ , 95% CI  $-2.167$  to  $3.874$ ;  $p = 0.580$ ), the Modified Carer Strain Index score ( $-0.569$ , 95% CI  $-3.766$  to  $2.629$ ;  $p = 0.727$ ) or the number of tonic-clonic seizures ( $-3.143$ , 95% CI  $-8.823$  to  $2.537$ ;  $p = 0.278$ ).

A planned subgroup analysis identified a significant interaction between treatment arm and level of ID for the ELDQoL-SSS score ( $p = 0.018$ ). However neither subgroup showed a significant intervention effect individually [treatment effect for those with mild to moderate ID ( $n = 95$ ): mean difference between intervention and TAU 3.931 (95% CI  $-0.554$  to  $7.307$ ;  $p = 0.092$ ); treatment effect for severe to profound ID ( $n = 185$ ): mean difference  $-1.968$  (95% CI  $-6.981$  to  $3.044$ ;  $p = 0.442$ )].

The economic analysis suggested that the competency framework intervention was cost-effective. The competency framework was associated with a reduction in monthly costs compared with TAU. However, the data also indicated that the framework intervention was associated with a reduction in QoL, although in all cases the effect associated with treatment was not significant at the 95% confidence level. Hospital costs were limited to the costs associated with epilepsy. Overall, the data indicate that the competency framework is likely to be cost-effective compared with usual care and that it is more likely to be cost-effective in patients with a severe or profound ID. Despite this, qualitative analysis of family carers' experiences of the nursing management received by participants during the intervention period revealed no clear evidence of any difference between the arms with respect to the family carers' perceptions of the ability of nurses to communicate effectively with health and social care professions. Family members' perceptions of the ability of nurses to manage the side effects of medications, appreciate the impact of comorbid physical health problems and work with multidisciplinary teams all depended on the professional or organisational status of the nurses, again regardless of which arm of the trial participants had been randomised to.

## Conclusions

The EpAID clinical trial is the first cluster RCT to test the possible benefits of a nurse-led intervention for epilepsy in adults with an ID. It demonstrated that differences in outcomes between the competency framework arm and the TAU arm were limited and associated with various degrees of uncertainty. For the population of adults with an ID and epilepsy as a whole, the framework conferred no clinical benefit compared with TAU. However, there was an indication that its use in those with a mild to moderate ID may be associated with a small amount of benefit in terms of reducing concerns over seizure severity. The economic analysis demonstrated that, in general, the competency framework intervention was cost-effective. It resulted in a small reduction in QoL but generated cost savings that would justify its introduction at currently accepted thresholds.

Nurses with experience in ID and epilepsy could be well placed to deliver or facilitate the epilepsy management recommended by the relevant National Institute for Health and Care Excellence clinical guidelines for adults with an ID. Future research will be able to explore the specific value of the competency framework for those with a mild to moderate ID and the potential for greater long-term benefits arising from application of the continuing professional development element of the framework.

## Trial registration

This trial is registered as ISRCTN96895428.

## Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.236

*Health Technology Assessment* is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the Clarivate Analytics Science Citation Index.

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## This report

The research reported in this issue of the journal was funded by the HTA programme as project number 10/104/16. The contractual start date was in August 2013. The draft report began editorial review in March 2017 and was accepted for publication in September 2017. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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