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EPILEPSY IN PEOPLE WITH LEARNING DISABILITIES

Evaluating a novel intervention

This article reports on an on-going novel feasibility randomised controlled trial [RCT] that is being undertaken to inform the design of a definitive RCT, which will assess the impact of *Getting on with Epilepsy*, from the ‘Books Beyond Words’ series, as an intervention for people with learning disabilities who have epilepsy. The intervention itself is novel in a number of ways. For example, this is the first time that these acclaimed books have been evaluated in a controlled context. Also the intervention itself is readily available, relatively inexpensive and could, if proven to have impact, provide a cost effective intervention to address known health issues in a population where health inequity and inequality is problematic.

Learning disability is a term used in the UK to describe people with a significantly reduced ability to understand new or complex information (impaired intelligence) and a reduced ability to cope independently (impaired social functioning), and which generally is said to have occurred before 18 years of age. There is general agreement that 3-4/1000 of the general population will have severe learning disabilities, and that 25-30/1000 of the general population will have mild learning disabilities. It is well documented that there is a known disparity between the health of people with learning disabilities and that of the general population (Parliamentary and Health Service Ombudsman and Social Services Ombudsman, 2009). This means that interventions aimed at reducing such disparity are important to the healthcare needs of this group of people. It is also important to recognise that such disparities in health and health outcomes are avoidable (van Schrojenstein Lantman-de Valk *et al*., 2000), and can be improved through appropriate interventions (Ouellette-Kuntz, 2005).

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Epilepsy as a health issue for people with learning disabilities

Epilepsy is a neurological disorder characterised by at least two unprovoked seizures due to abnormal electrical activity in the brain. It causes disturbances of consciousness, and changes in behaviour and emotion, motor function, and sensation. It is estimated to affect between 362,000 and 415,000 people in England (NICE, 2012), and in the UK prevalence is likely to be 5-10 cases per 1000 population (NICE, 2012). Importantly, and relevant to this study, it is known to be the most common neurological disorder in people with learning disabilities, with a reported prevalence of 16 to 44 % compared to 0.4 to 1 % in the general population (Bowley and Kerr, 2000; McGrother *et al.*, 2006; World Health Organisation, 2012). In people with learning disabilities, epilepsy is often more severe and complex in this group, with frequent, and poorly controlled seizures that are often refractory to treatments (Kerr, 2007 for example). Also it can often be accompanied by co-morbid issues (Bowley and Kerr, 2000; McGrother *et al.*, 2006). Subsequently, managing epilepsy can be difficult for people with learning disabilities and their carers, with poorly controlled epilepsy affecting relationships, work, quality of life, mortality and leading to higher health costs (Pennington *et al.*, 2012).

Current health guidelines state that people with learning disabilities and epilepsy should be offered the same standard of care, services and investigations as is the general population, and they should be empowered to improve the management of their condition through the provision of appropriate information and education (Learning Disabilities Observatory *et al.*, 2012; Improving Health and Lives, 2014; National Institute for Health and Care Excellence, 2012). However, this is not the case, and people with learning disabilities and epilepsy tend to experience poor access to specialist services, and poorer outcomes (All Party Parliamentary Group on Epilepsy, 2007). Therefore, interventions, such as this, that are designed to improve the health and quality of life of people with learning disabilities and epilepsy are important in order to achieve equitable health care and reduce disparities (Clark *et al.*, 2001).

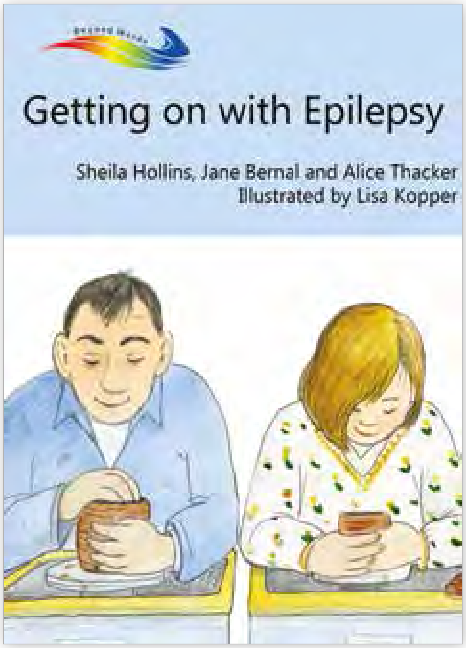


FIGURE 1 'Beyond Words' *Getting on with Epliepsy* a book especially designed for people with learning disabilities and other people who understand pictures better than words

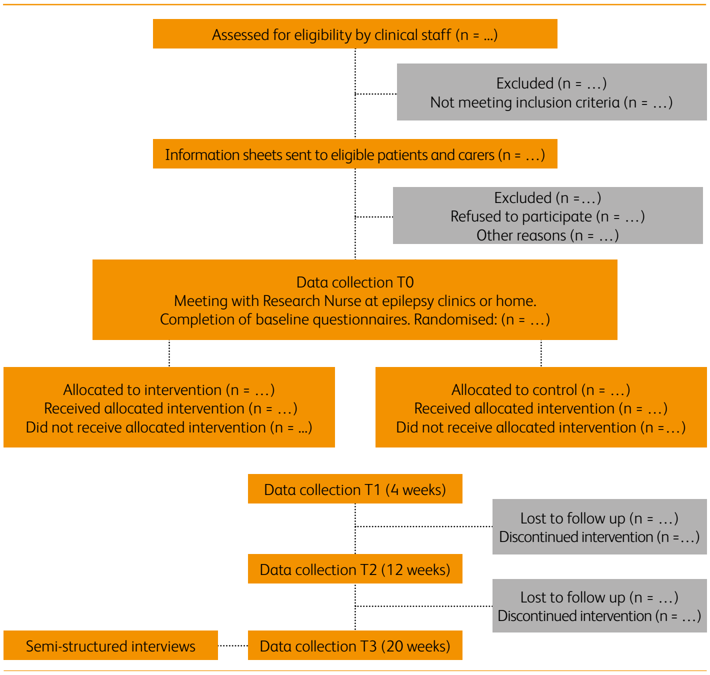


FIGURE 2 Study flowchart

Books Beyond Words

'Beyond Words' produce books, e-books and other resources for people with learning disabilities and other people who understand pictures better than words. *Getting on with Epilepsy* is a book that uses images to tell the story of a young man with learning disabilities and epilepsy (see Figure 1). Its aim is to help people with learning disabilities better understand and manage their epilepsy, reduce the risk of seizure-related injuries and ultimately improve their quality of life.

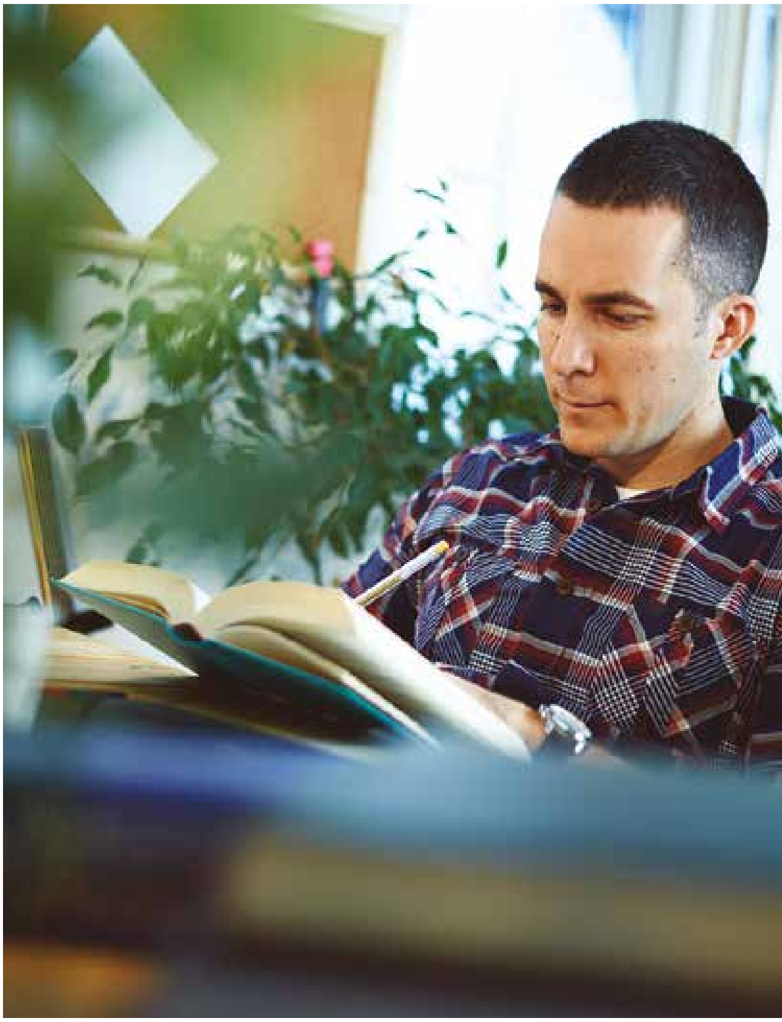
Despite the popularity and commendations of 'Books Beyond Words', they have never been formally evaluated and subjected to rigorous scrutiny. The WIELD (Wordless Intervention for Epilepsy in Learning Disabilities) study is a randomised controlled feasibility trial of the *Getting on with Epilepsy* book as an intervention to improve epilepsy self-management in people with mild to severe learning disabilities. The aim of this on-going study is to determine whether a full-scale trial can be undertaken in the future, and if so to provide evidence to inform the eventual selection of sample size, recruitment procedures, data collection and analysis techniques.

WIELD feasibility trial

The WIELD study, funded by the National Institute for Health Research, is currently being conducted at a single centre (Hertfordshire Partnership University NHS Foundation Trust) over a 20-month period. The target sample size is 40, and recruitment was initially planned to take place over a six-month period. Participants have been randomly allocated to an intervention or control arm. The structure and timeline of the study can be seen in Figure 2, and is outlined in detail in the published study protocol (Durand *et al*., 2014).

Eligible participants for this study comprise adults who have learning disabilities and epilepsy, who have had at least one seizure in the last 12 months, and who have meaningful verbal or non-verbal communication to read or follow the 'Books Beyond Words' story. Their primary carer must also have a sufficient level of English to complete questionnaires. People with learning disabilities and epilepsy who have dementia or a visual impairment, or have used *Getting on with Epilepsy* before have been excluded from this study.

The intervention involved a session with a research nurse along with the provision of the book which the participant keeps. In the intervention group, the research nurse uses the book with the participant, with their carer present. Participants who were randomly allocated to the control condition continued to receive their usual care only, and are to be given a copy of *Getting on with Epilepsy* when the study concludes.



	T0 **Baseline**	**T1** **Baseline**	**T2** **Week 12**	**T3** **Week 20**
Screening and recruitment log				
Rates of recruitment	✓	✓	✓	✓
Discontinuation rates	✓	✓	✓	✓
Questionnaire				
Demographic data	✓			
Patterns of use of the Books Beyond Words booklet	✓	✓	✓	✓
Use of other epilepsy-related information	✓			✓
Quality of life • Epilepsy and Learning Disabilities Quality of Life (ELDQOL) scale (Buck *et al*., 2007, Baker et al., 1994) • Health-related quality of life using the EQ-5D-5L scale (Brooks, 1996)	✓	✓	✓	✓
Seizure severity • ELDQOL scale	✓	✓	✓	✓
Resource use	✓			✓
Seizure diary				
Seizure control	✓	✓	✓	✓
Interviews				
Feasibility and acceptability				✓

TABLE 1 Study outcome measures

There is ever growing demands for health interventions that empower, and inform people to promote self-management and improve health outcomes

As can be seen from the study flowchart data is gathered at baseline [T0], and 4 [T1], 12 [T2] and 20 [T3] weeks post randomisation through questionnaires, a seizure diary and semi-structured interviews. Table 1 shows the outcomes of interest that will be measured throughout the study, which include; quality of life (primary outcome measure), recruitment rates, discontinuation rates, seizure control and severity, resource use and acceptability of the intervention.

Progress, insights and next steps

Whereas recruitment is now complete initially recruitment progressed somewhat more slowly than was originally planned for, and there are a number of reasons for this that included:

- Difficulty in contacting carers
- Commencing recruitment over the peak summer holiday season
- Induction requirements for the research nurse
- Greater difficulty than anticipated in identifying eligible people, partly due to a reorganisation of the Trust (Mengoni *et al*., 2015)

To address these issues, the research team sought, and were granted, an extension of the recruitment period. As of May 2015, information sheets have been sent to n = 160 potential patients and carers, and of this; n= 43 were excluded as not eligible; n = 39 declined to participate; n= 14 were not followed up for a number of reasons; in the case of n = 12 the research nurse was unable to discuss the study with the carer, and finally n = 5 did not answer phone calls. The led to the research nurse meeting with n = 47 patients and their carers in their home. Of these a further n = 3 were excluded as not eligible; n= 3 declined to participate, and finally n = 1 was not followed-up. So at T0, n=21 were allocated to treatment, and n = 19 were allocated to the control arm of the study. All data will be gathered by September 2015. Where the research nurse contacted the carer and they declined to participate on behalf of the person with learning disabilities and epilepsy, reasons typically provided included that they thought that the patient would be unlikely to benefit from, or enjoy, the intervention, and carers reporting that the study involved 'a heavy load of paperwork', some of whom were paid carers with competing priorities and duties. This is an interesting finding, and will be further analysed when all data has been gathered, and as importantly this finding will impact on the construction of the research design for the full RCT.

Implications for the future

There is ever growing demands for health interventions that empower, and inform people to promote self-management and improve health outcomes. This is particularly so for people with learning disabilities with epilepsy who often struggle to manage their condition and access relevant services.

Whereas recruitment has been slower than was originally anticipated, the research team have now fully recruited to the study. And to counteract the recruitment issues it is the case that a definitive trial will allow a longer and more realistic time frame for recruitment, and this will address some of the difficulties encountered in this feasibility study. The research team have found that many carers and people with learning disabilities and epilepsy are enthusiastic about their involvement in this study.

Close collaboration between the higher education institutions involved, as well as a close working relationship with the host NHS Trust has positively impacted on the success of this feasibility trial. Also, crucially the input of members of the public, carers and people with learning disabilities in planning and managing the study has been invaluable, and has led to improvements in both recruitment

The results of a full-scale trial could contribute to a better understanding of effective healthcare management, and an evidence based intervention for people with learning disabilities, as well as exploring a potential way of improving the standard of care and quality of life for people with learning disabilities who live with epilepsy

procedures and materials used. This has undoubtedly resulted in a successful study design and a clearer translation to the everyday experiences of people with learning disabilities and their carers. This has been recognised nationally when in February 2015 the study received an award for outstanding carer involvement from the *National Institute for Health Research Clinical Research Network: Mental Health*.

Should the present study confirm feasibility of a definitive trial, then a national RCT is planned to establish the impact of the 'Books Beyond Words' *Getting on with Epilepsy* as a novel intervention for people with learning disabilities and epilepsy on their quality of life. This will also include a cost-effectiveness analysis. The research team successfully planned a dissemination event with the British Institute of Learning Disabilities that was run in May 2015, where some 60 delegates from across the UK and Ireland attended. As well as acting as a dissemination event it also provided the research team an opportunity to establish the potential for future collaborators for a national trial. Finally, the research team remain committed to the importance of involving carers and people with learning disabilities in on-going and future work. The results of a full-scale trial could contribute to a better understanding of effective healthcare management, and an evidence-based intervention for people with learning disabilities, as well as exploring a potential way of improving the standard of care and quality of life for people with learning disabilities who live with epilepsy. This might include for example: reduction in seizure frequency and severity; better compliance with prescribed medication; improved measures of quality of life; as well as potential reduction in associated health costs. This novel intervention is readily available, relatively inexpensive and could, if proven to have impact address a known health issue in a population where health inequity and inequality has long been problematic.

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