

Mengoni, S., Gates, B., & Durand, M.-A. (2015). An intervention for people with learning disabilities and epilepsy. *Learning Disability Practice*, 18(2), 28-31. doi: 10.7748/ldp.18.2.28.e1620

Accepted for publication in Learning Disability Practice on 9<sup>th</sup> January 2015

This is the post-print version of the article, i.e. author's version accepted for publication. The version of record can be found on RCN Publishing Learning Disability Practice website

<http://journals.rcni.com/doi/10.7748/ldp.18.2.28.e1620>

Post-print

Title: A wordless intervention for epilepsy in learning disabilities (WIELD): Reflections and insights on recruitment challenges and facilitators of an on-going study

Running head: Epilepsy and Learning Disabilities

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**Keywords:**

Epilepsy; Learning Disabilities; Public Involvement; Patient Involvement; Randomised Controlled Trial

**Acknowledgements**

The authors would like to acknowledge the wider study team, and particularly Mary Ellen Khoo, the WIELD Research Nurse. The study team are grateful for the continued support and valuable contributions of the Public Involvement in Research Group at the University of Hertfordshire, The Making Better Services Group, Inclusion East, the East of England Research Design Service, The Norwich Clinical Trials Unit, Books Beyond Words, and Professor Tim Gale at Hertfordshire Partnership University NHS Foundation Trust. This paper presents independent research funded by the National Institute for Health Research (NIHR) under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number PB-PG-0213-30042). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

## **Abstract**

Epilepsy is relatively common in people with learning disabilities, and can be complex and refractory to treatment, with negative effects on quality of life and service costs. This article introduces the WIELD study, a randomised controlled feasibility trial of a Wordless Intervention for Epilepsy in Learning Disabilities, which is currently underway. This article briefly outlines the design of the study, and discusses reflections on recruitment progress and the benefits from public and patient involvement (PPI). Recruitment has been affected by logistical issues such as difficulties in identifying potential patients and contacting carers. However PPI has benefited the study design and management, and has helped to maximise recruitment.

## **Introduction**

Epilepsy is 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, Morgan et al., 2003, World Health Organisation, 2012). Epilepsy can be more severe and complex in this group, with frequent and poorly controlled seizures that are often refractory to treatments (Kerr, 2007, Hannah and Brodie, 1998, Brodie and Dichter, 1996). It is also often accompanied by health, mental health, sensorimotor and communication issues (Bowley and Kerr, 2000, McGrother et al., 2006). Consequently, epilepsy can be difficult to manage for people with learning disabilities and their carers, and can severely affect relationships, work, quality of life, mortality and service costs (Pennington et al., 2012, van Blarikom et al., 2006).

According to current guidelines, 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 does not appear to be 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). Interventions designed to improve the health and quality of life for people with learning disabilities and epilepsy can help health and social care services meet these principles of good care (van Blarikom et al., 2006, Clark et al., 2001).

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. Its aim is to help people with learning disabilities better understand and manage their epilepsy, and ultimately improve their quality of life.

Books Beyond Words have never been formally evaluated despite their popularity and the receipt of various awards. The WIELD (Wordless Intervention for Epilepsy in Learning Disabilities) study is a randomised controlled feasibility trial (feasibility RCT) of an intervention that is using the Books Beyond Words 'Getting on with Epilepsy' book. The aim of this ongoing study is to determine whether a full-scale trial can be undertaken in the future, and to provide evidence that will inform the eventual selection of a sample size, methods and data analysis techniques.

## **Study outline**

The WIELD study 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, from July to December 2014. Participants are being randomly allocated to an intervention or control arm. The structure and

timeline of the study can be seen in Figure 1, and is outlined in detail in the published study protocol (Durand et al., 2014).

[insert Figure 1 about here]

### ***Participants***

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 nonverbal communication. Their primary carer must also have sufficient levels of English to complete questionnaires. People with learning disabilities and epilepsy who have dementia or a vision impairment, or have used 'Getting on with Epilepsy' before are being excluded from this study.

### ***Intervention***

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

### ***Outcome measures***

As can be seen from the study flowchart, data is gathered at baseline, and 4, 12 and 20 weeks post randomisation through questionnaires, a seizure diary and semi-structured interviews. Table 1 shows the outcomes that will be measured throughout the study, which include recruitment rates, quality of life, seizure control and severity, and acceptability of the intervention.

[insert Table 1 about here]

### ***Progress, insights and next steps***

At the time of writing, recruitment is ongoing. Eighty-six eligible people with learning disabilities and epilepsy have been identified, and so far 19 have consented to participate, and are at varying stages of the study.

### ***Reflections on recruitment challenges***

Recruitment is progressing more slowly than was originally anticipated. There are a number of reasons for this:

- 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.

Where the research nurse has contacted the carer and they have declined to participate on behalf of the person with learning disabilities and epilepsy, reasons typically provided included that:

- The carer thought that the patient would be unlikely to benefit from, or enjoy, the intervention;
- The carer did not want to, or felt unable to, complete the questionnaires.

A potential explanation for some of the recruitment difficulties may be that some of the carers are paid carers with competing priorities and duties. To address some of the issues outlined above and to maximise recruitment, the recruitment period is being extended until April 2015.

### ***A multi-disciplinary team with public and patient involvement (PPI)***

The WIELD study team includes consultant psychiatrists, academic researchers and a research nurse, who all sit on the trial steering group. The WIELD reference group includes people with learning disabilities, carers and members of the public. This PPI group reports to the trial steering group and is represented by a member of the public who is a member of both groups. There is also support from epilepsy nurses, and a clinical studies officer for the recruitment of patients to the study. The insights and perspectives brought by this multi-disciplinary team, with such a strong PPI component, has proven essential in maximising recruitment as well as overcoming some of the challenges encountered so far.

PPI has been central to the design and management of this research project, for example, through lay review of the funding application, the review of study materials, and ongoing discussions about the study's progress. This has benefited the study, and led to a number of changes such as alterations to easy-read materials and interview guides, as well as widening the originally suggested inclusion criteria, which now includes people with learning disabilities and epilepsy who have meaningful non-verbal communication. The PPI group will remain involved throughout the study, and their input will be particularly valuable when disseminating the study findings.

### **Conclusions**

There is an ever growing need for interventions that empower and inform people with learning disabilities and epilepsy and their carers with the aim of improving quality of life and reducing epilepsy-related health issues. This feasibility study aims to inform the design of a definitive trial, which would assess the impact of the Books Beyond Words 'Getting on with Epilepsy' as an intervention.

Although recruitment is slower than originally anticipated, progress is being made, and many carers and people with learning disabilities and epilepsy are enthusiastic about their involvement in the study to date. The definitive trial should allow a longer time period for recruitment to account for some of the difficulties encountered in the feasibility study. The input of members of the public, carers and people with learning disabilities in planning and managing the study has led to improvements in recruitment procedures and materials. This has undoubtedly resulted in a more successful study design and a clearer translation to the everyday experiences of people with learning disabilities and their carers.

Should the present study confirm feasibility, a full-scale RCT will address the impact of the Books Beyond Words 'Getting on with Epilepsy' intervention for people with learning disabilities and epilepsy on quality of life, and will estimate cost-effectiveness. The results of this would be likely to inform our understanding of effective healthcare management and evidence-based interventions that aim to improve the standard of care and quality of life for people with learning disabilities who live with epilepsy.

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Figure 1. Study flowchart

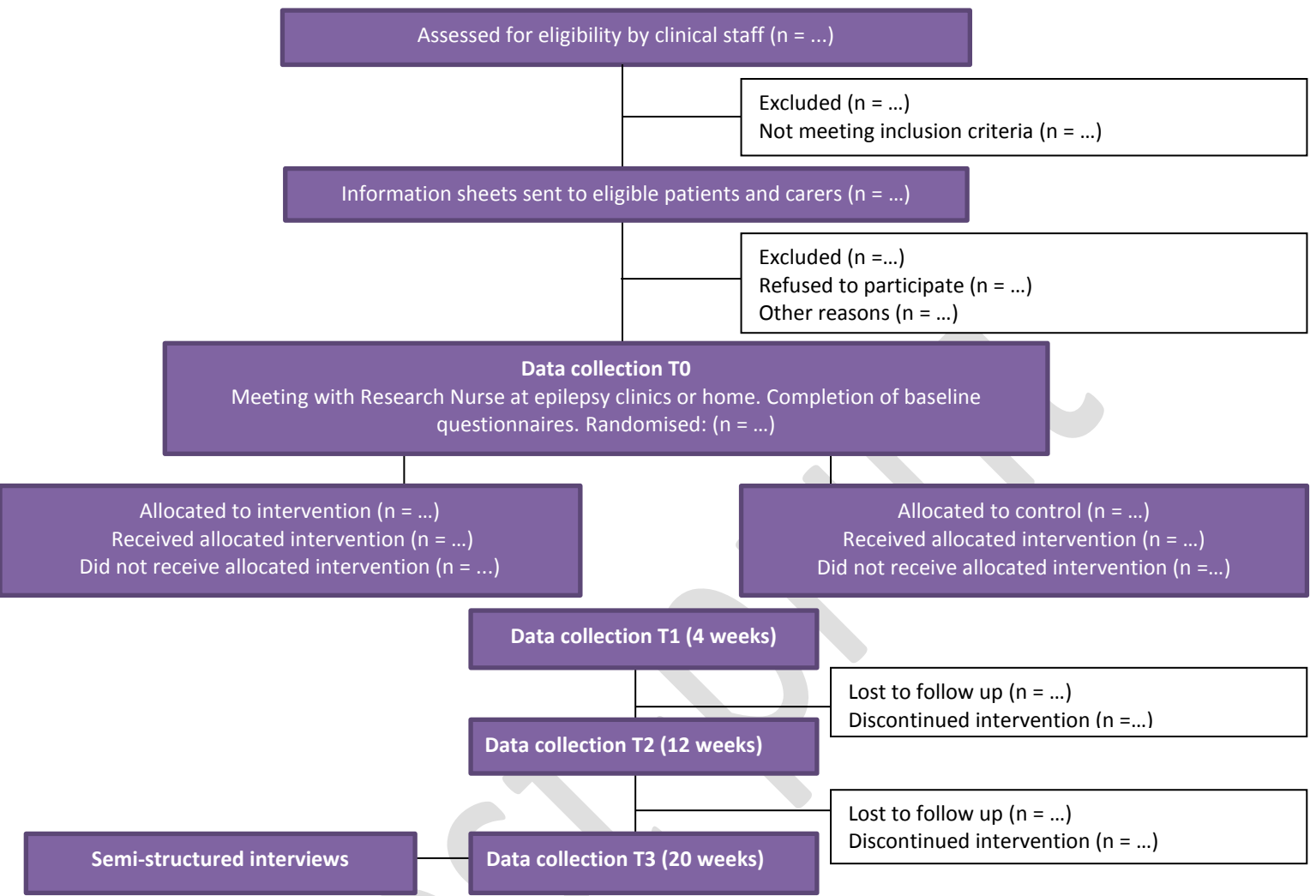




Table 1. Study outcome measures

	<b>T0 Baseline</b>	<b>T1 Week 4</b>	<b>T2 Week 12</b>	<b>T3 Week 20</b>
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 <ul style="list-style-type: none"> <li>Epilepsy and Learning Disabilities Quality of Life (ELDQOL) scale (Buck et al., 2007, Baker et al., 1994)</li> <li>Health-related quality of life using the EQ-5D-5L scale (Brooks, 1996)</li> </ul>	✓	✓	✓	✓
Seizure severity. <ul style="list-style-type: none"> <li>ELDQOL scale</li> </ul>	✓	✓	✓	✓
Resource use	✓			✓
Seizure diary				
Seizure control	✓	✓	✓	✓
Interviews				
Feasibility and acceptability				✓