

# THE EMERGING EVIDENCE BASE FOR THERAPY FOR CHILDREN WITH LANGUAGE IMPAIRMENT, AND ITS IMPLICATIONS FOR LOGOPEDISTS

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This paper reflects on the current state of the evidence base relating to therapy interventions for language-impaired children. It accepts that logopedists should provide evidence for the effectiveness of their practices, and are eager to do so in order to enhance services for children. It reviews the ways that intervention effectiveness is measured, with some examples from personal research studies. It identifies two recent databases giving information relevant to logopedists: speechBITE™, and the 'What Works' data base that resulted from the Better Communication Research Programme in England. The paper notes that, while the number of relevant studies is increasing, and positive effects of therapy are shown, there are few interventions as yet that show convincing evidence of effectiveness. The problem is largely that appropriate research studies have not been conducted, and such studies are not easy to undertake given small therapy services, the variety of children on individual therapists' case loads, and a lack of research funding.

The paper concludes that a commitment to collect and evaluate evidence has been helpful to the development of logopedic professionals internationally, but that the current paucity of evidence on effective treatments may impact upon funders' willingness to pay for logopedic services, affecting all practitioners. The need for closer integration between higher education institutions and clinical services in order to trial therapy approaches, and the overwhelming need for research funding, are stressed. The importance of practising logopedists acting as researchers, collecting data and measuring outcomes, as exemplified by the case studies in this special edition of *Logopedie*, is also emphasised.

### ► Keywords

Children; language impairment; language intervention; clinical trials; evidence based medicine

### Introduction

Professionals providing intervention for language impaired children have to answer the reasonable questions that arise from service users and service funders: 'Does what you are doing work? Do language impaired children benefit from therapy, and if so, by how much?'. These questions are also asked by logopedists about their own practice, as they aim to develop and improve the services they provide. Such questions lead to others about costs and efficiency, which are not addressed here. This paper aims to identify key issues in researching therapy. It briefly outlines the clinical model used for collecting and evaluating evidence of intervention effectiveness, with examples, then reports on two new and key sources that summarise how far the evidence-base has developed for children with language impairments: the SpeechBITE™ website, and the 'What Works' (2013) data base, developed following a recent research programme in England (the *Better Communication Research Programme*: BCRP: c.f. Law et al. 2012). This programme amongst other important findings updated systematic reviews on intervention, and listed the evi-

dence for efficacy of widely-used language interventions on a searchable data-base.

### Developing evidence

Procedures for evaluating evidence for interventions, including therapy interventions, derive from medical models. The aim is to develop interventions that are effective for specified types of children and that will 'work' when used by suitably qualified practitioners. Interventions must therefore be shown to be replicable and reliable, so that their procedures can be understood and used by many therapists, and if necessary can be explained to and used by others, such as parents, teachers and support staff.

The framework used internationally for identifying levels of evidence, the quality of studies and the implementation cycle will briefly be reviewed, then current evidence for language impairment interventions will be related to this framework.

### Levels of evidence

Interventions are ranked by the levels of evidence inherent in their study designs. The Centre for Evidence Based Medicine (2009) presents a refined hierarchy, but the six broad levels presented in Evidence Based Nursing Practice (no date) will be used in this discussion.

A series of randomised control trials (RCTs) identified by a comprehensive review of the literature (systematic review) comprises Level One 'best evidence'. RCTs randomly allocate sufficiently large numbers of children to the intervention being trialled, and compare their progress with another intervention (the 'counterfactual' or control condition), often the current therapy programme on offer. Randomisation eliminates unintended child selection factors, and so results can reasonably be expected to transfer to similar clients and contexts. If an intervention has received at least one full-scale RCT (Level Two evidence) it is possible to be fairly sure that results are not influenced by unintended or undetected factors in the selection of children. An RCT also shows how much progress children would (probably) have made without the intervention, or if they had continued with their existing therapy (the counterfactual comparison), through measuring the progress of children in the control condition. RCTs require a sufficiently large number of children to show change; having children and their parents agree to inclusion in the trials (informed consent); randomising the children; delivering the planned amount of therapy (the prescribed 'dosage'), and sticking closely to the pre-planned intervention (treatment fidelity). A full-scale RCT for language-impaired school-aged children is described in detail in Boyle et al. (2007), and summarised in Boyle et al. (2009).

If an RCT shows evidence of effectiveness with these procedures in place, and if several such trials subsequently show very similar effects, it is possible to both assess the benefits attained by the intervention (effect sizes), and to be confident that the intervention will work when the therapy is replicated in comparable contexts.

RCTs are however expensive to conduct, and often require collaboration across many therapy services, and need to be staffed to deliver a sufficiently large amount of intervention. For these reasons, many therapy studies use less expensive designs that do not use randomisation. These allow less certainty that their results would transfer to other therapists and to other children. Level Three evidence is offered by studies that report on a complete group (cohort) of children, all of whom get the intervention being evaluated, and that use reliable measures of language outcomes. Cohort studies provide no counterfactual evidence to say how much change would have occurred without therapy or with a different intervention. If however a cohort is well matched to a previous cohort of children whose outcomes are known, some comparisons can be made. An example of a cohort study with 'historical control' of this kind is McCartney et al. (2011).

Level Four evidence is from studies that are not experimental, but where similar results are found by several research centres. Individual case studies contribute to this evidence level, and case study series, where information on a number of clients is collected. Case studies provide examples of promising interventions and their outcomes, but offer no counterfactual evidence. However, a series of case studies with good outcomes offers grounds for further developing and evaluating an intervention. Individual logopedists make significant contributions here, as evidenced in the papers in this special edition.

Level Five evidence comprises consensus views from respected practitioners or committees of experts about what comprises good therapy, and Level Six the views of practitioners as to 'what is currently done'. Levels Five and Six of course do not evidence efficacy, but collect views from logopedists who presumably believe their practices are helpful, and are keen to share them with others. Professional position statements often include professional consensus views in their guidance on best practice (e.g. *Communicating Quality 3*: Royal College of Speech and Language Therapists (RCSLT) 2006).

In order to move evidence into practice, however, even an intervention with one or more RCTs demonstrating efficacy should be tried out in 'real life' conditions. Interventions that work in trials do not always prove effective in real-life situations. There can be many reasons for this – logopedists may not be able to apply the procedures, or for some reason children may not comply with them, or a family may not be able to attend throughout a lengthy intervention period. To establish real-world effectiveness, an implementation trial is needed that determines the continued good outcomes of the intervention under real-life conditions (Medical Research Council 2008 p.8). No control is needed for an implementation trial, as it is the real-world use of the therapy, not its efficacy, which is being checked. Beyond this, there are studies of efficiency, i.e. the costs related to the benefits of the intervention, which are not discussed here. The level of evidence and whether or not it has received a real-life implementation study determine the scientific community's perception of an intervention, and of course influences a therapy funder's views of what interventions may be supported and paid for.

### Evaluating interventions for language impairment

Practitioners need to assess the level of evidence for the interventions they want to use, and at times to access

the studies that provide this. Evaluating studies reporting on logopedic interventions has recently become simpler for professionals with the publication of the open-access speechBITE™ (no date) database. This catalogues 'Best Interventions and Treatment Efficacy' (BITE). The database lists systematic reviews (which are not rated) and rates clinical trials across the range of speech and language interventions for children and adults. It may be searched by clinical group, mode of intervention and target speech or language area. Trials are evaluated (by logopedists in Australia) using a reliable scoring system, Pedro-P – an amended version of the Physiotherapy Evidence Database Rating (Pedro) scale (Murray et al. 2013).

Randomised and non-randomised trials are rated, noting the presence or absence of key features of scientific quality, and giving a total score. The eleven features of high-quality trials are that:

1. Participant eligibility criteria are specified;
2. Participants are randomly allocated to interventions. For cross-over studies, where participants all receive intervention(s) but at different times, participants are randomly allocated to the order in which treatments were received;
3. Allocation is concealed from participants, i.e. they enter the study without knowing to which intervention they will be allocated, and the researchers do not influence the allocation;
4. The intervention groups are similar at baseline (first measures) regarding the most important prognostic indicators;
5. There is 'blinding' of participants so that they do not know which arm of the trial they are in. This is not usually achieved in logopedic interventions, when children and their parents are aware of the therapy procedures undertaken, and so know which intervention they are receiving;
6. There is 'blinding' of logopedists who administer therapy as to which arm of the trial a participant is undertaking. As for five above, this cannot usually happen in language therapy;
7. There is 'blinding' of assessors who measure at least one key intervention outcome, so that assessors do not know what intervention arm the children they assess have undertaken. This is an important feature in clinical research, as those who undertake therapy and then assess their clients may unconsciously influence the measurement of outcomes;
8. Measures of at least one key intervention outcome are obtained from more than 85% of the participants initially allocated to each group, so that participants lost to the trial do not overly affect the outcomes of the trial;

9. All participants for whom intervention outcome measures are available will have received the treatment or control condition as allocated. This should be available for at least one key outcome measure and preferably more;

10. Between-intervention group statistical comparisons are reported for at least one key outcome;

11. The study provides both point measures (measures of the intervention effect) and measures of variability (e.g. standard deviations, confidence intervals) for at least one key outcome.

Adding the points which studies meet gives a total score, and this with consideration of which of the eleven features were present or absent allows practitioners to make a rapid assessment of a trial's quality, and helps in considering, evaluating and selecting therapies. The speechBITE™ database is expanding, and should continue to support the adoption of evidence-based practice.

Another key source for professionals about evidence for interventions published in English is the searchable What Works (2013) database. This is collated from a review of interventions for speech, language and autistic spectrum disorders undertaken in England as part of the *Better Communication Research Programme* (Law et al. 2012). The What Works (2013) database identifies widely-used interventions, and rates them using a simplified three-point scale according to the level of evidence for their efficacy. Interventions are categorised as 'Strong' if at least one positive systematic review has been undertaken, with any subsequent trials. A 'Moderate' level includes a single RCT or a set of quasi-experimental studies, whereas an 'Indicative' level means that an intervention has good face validity but limited research evidence, such as only case studies or 'before and after' studies (Law et al. 2012, p. 12). By providing the level of evidence for interventions, the database gives the level of confidence with which they can be used.

However, levels of evidence are not high. Thirty-eight interventions for language impairment are listed, including those for non-specific language disorders and for pragmatic communication but excluding those for speech disorders and stuttering. Of the thirty-eight, only two had strong evidence of efficacy, including one that had strong evidence against effecting change (FastForWord®). Of the remainder, half had moderate evidence (including one, Earobics, that did not show language change in children although it showed changes in phonological awareness), and the other half indicative levels only.

This is rather a worrying finding for the logopedist profession. The high profile of the Better Communication Research Programme in England, and the accessibility of the data base, means that the limited research evidence base for language interventions is showing rather publicly. This will no doubt affect the decisions of therapy funders and commissioning bodies, perhaps especially in countries such as the UK where logopedists are part of national health services, and in others where health insurance funds interventions.

### Discussion

Accepting the need for a sound evidence base and adopting the unifying scientific framework for evaluating interventions has been helpful to the development of the logopedic profession internationally, and gives a sound footing for evaluating therapy interventions. But the current paucity of evidence for effectiveness may impact upon funders' willingness to pay for services, and undermine the confidence that practitioners and their clients place in the treatments offered.

However, the fact that many interventions for language impaired children have not as yet shown efficacy does not mean that they are not efficacious – rather that they have not as yet been subjected to the rigorous trialling that would demonstrate their effects. This is due to factors such as small therapy services serving different types of client groups, variation amongst children on the case-loads of individual therapists, making comparisons difficult and common interventions unlikely, and the variety of settings in which logopedists operate. There is also a lack of overall research policy in the field, and difficulties in transferring findings across language boundaries.

However, a major factor is the lack of resources for clinical research. Logopedic research is often competing for funds within larger medical or educational research programmes, and establishing the impact of language therapy may not be deemed sufficiently important to fund in contest with interventions considered to be more crucial. Research is expensive, and logopedic research may seldom reach priority status from funders.

In the UK, as a step towards strengthening clinical research, the Royal College of Speech and Language Therapists is encouraging higher educational institutions who teach SLT students to form research 'hubs' with logopedists in their regions. This is a good idea, as universities have research expertise, and operating at a regional level could augment the numbers of relevant therapists and

children eligible to enter trials, and provide an overarching framework. But moving funding responsibilities to universities is also problematic – they also have to seek research resources, as co-ordinating practice-based research in a systematic way can be very time-consuming. Nonetheless, such collaboration could fairly cheaply increase the number of repeat case studies and cohort studies available, with documented intervention procedures and validated (ideally standardised) outcome measures, where therapists implement agreed interventions faithfully. With careful recording of the children who join each study and what happens to them, appropriate ethical approval, assessment of outcomes by those who do not deliver the therapy, and confidential uses of modern technology to facilitate cross-site communications, the evidence base could be considerably enhanced.

### Conclusions

The commitment to collect and evaluate evidence has been helpful to the development of the logopedic profession internationally, but the current lack of evidence on effective treatments is not satisfactory, and may impact upon funders' willingness to pay for services. There is a need for all logopedists to become engaged in research, publishing case studies and the outcomes of intervention, including outcomes showing limited or no progress. Closer integration between higher education institutions and clinical services would offer further opportunity to trial therapy approaches systematically. However, large-scale randomised controlled trials are needed to move interventions upwards towards the 'strong evidence' category. Randomised trials require at least some (and often a lot!) of specific research funding. Logopedists now need to argue for appropriate research trial funding at all possible opportunities, and to engage alongside their professional bodies with policy makers in explaining how important this is.

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