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2

EVIDENCE-BASED TREATMENT

Caroline M. van Heugten

Introduction

In our current health-care systems it becomes more and more important to show that our interventions are effective and, often just as important, cost-effective. Clinicians are required to use evidence-based treatment protocols and researchers are encouraged to study the clinical- and cost-effectiveness of treatment. Policy makers and management need to make decisions about which forms of care to offer in a society where health-care costs are growing and budgets are shrinking. A distinction can be made between effectiveness (does the treatment work, how does it work, for whom does it work), efficacy (does it help) and efficiency (cost-benefit ratio). From a patient perspective, efficacy is the most relevant.

In this chapter a basic scheme for planning and evaluating neuropsychological treatment as proposed by Wilson, Herbert and Shiel (2003) is presented. In this approach 11 steps are outlined, from specifying the behaviour to be changed to planning for generalisation of treatment results.

In addition, different forms of treatment evidence in general are discussed from single case studies to group designs and ultimately the randomised controlled trial (RCT). Special attention is be given to the single case experimental design (SCED), which offers a valuable alternative when it is not possible to conduct large-scale group studies. Quality standards for reporting the results of RCTs and SCEDs are discussed. Finally, an overview of the basics of economic evaluation studies is presented. Application of general information on evidence-based medicine (EBM) to neuropsychological rehabilitation in particular is done for every topic and illustrated with examples.

Planning and evaluating treatment

One of the key elements of good clinical practice is to make our clinical actions explicit. This is not only important for the clinician, but also for the other members of the treatment team. Moreover, it is of great importance to the patients and their caregivers. Evaluating individual treatments provides information on the efficacy. Finally, it is a way of showing management and policy makers whether your treatment is effective. Making your clinical actions explicit will improve communication among the different parties involved and will help multidisciplinary and interdisciplinary treatment because goals are shared and the frame of reference is known to all. One of the ways to do this is by planning and evaluating the treatment of the individual patient in a treatment plan. Wilson et al. (2003) proposed an 11-step basic plan for treatment, as outlined in Table 2.1.

Table 2.1 Setting up a treatment plan

Step	Action	Example
1	Specify the behaviour to be changed	Poor concentration
2	Decide whether or not an operational definition is needed	Unable to stick to a task for more than 3 minutes
3	State the goals or aims of treatment	To stick to a task for 3 minutes, 2 times a day, for 5 consecutive days; for instance, tooth brushing
4	Measure the problem (take a baseline)	Develop a rating scale for nurses to rate attentional behaviour during tooth brushing
5	Consider motivators or reinforcers	Use specific and positive feedback and praise Avoid multitasking
6	Plan the treatment	Who, when, where, how often, which strategies, etc.
7	Begin treatment	Inform patient, caregivers and treatment team when the treatment begins
8	Monitor treatment progress	Regular measurement of the problem, for instance use the rating scale (step 4) every day and evaluate weekly
9	Evaluate treatment	Regular evaluations are discussed within the team and compared to monitor progress
10	Change if necessary	Goals in step 3 may have been too ambitious, change goals to a more realistic aim Or goals are met and new goals need to be set
11	Plan for generalisation	How can concentration be improved during other tasks besides tooth brushing?

Evidence-based medicine

Evidence-based medicine (EBM) is 'an approach to caring for patients that involves the explicit and judicious use of the clinical research literature combined with an understanding of pathophysiology, clinical experience, and patient preferences to aid in clinical decision making' (EBM Working Group, 1992). Although EBM was designed in the field of medicine, the principles and practice can easily be applied to neuropsychological rehabilitation. EBM is designed to make treatment decisions less biased to preferences or expertise of professionals. Additionally, the application of EBM processes helps to ensure that the most effective form of care is offered on the basis of arguments and responsibility, as supported by scientific evidence. The term was originally used for an educational method of the McMaster Medical School in Canada in which physicians were taught to improve their decisions for individual patients.

Applying EBM in clinical practice is done via a five-step method (Schouten, Offringa and Assendelft, 2014):

1   Translate the clinical problem into an answerable question.
2   Search efficiently for the best evidence.
3   Assess the evidence in terms of methodological quality and applicability in your own clinical situation.
4   Make a decision on the basis of the evidence.
5   Evaluate the quality of this process on a regular basis.

The amount of evidence in medicine (nowadays) is overwhelming and it needs to be gathered and translated into evidence-based guidelines for use in clinical practice (i.e. evidence-based practice).
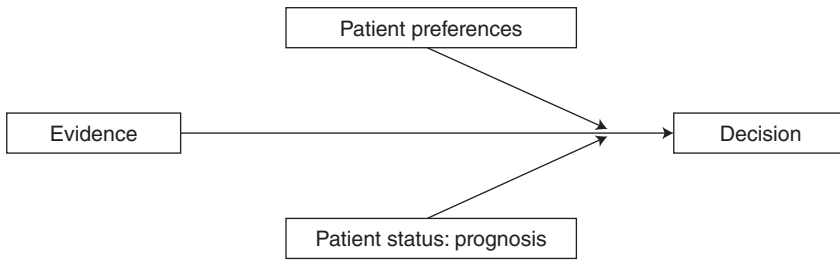
Figure 2.1   Process of clinical decision-making.

This way, clinicians can use the best and most up-to-date evidence for decisions about individual patients. In the definition of EBM the clinician is supposed to use the evidence 'carefully, explicitly and judiciously'. In addition to the best evidence, the clinician will use the preferences of the patient and the information available about the prognosis of the patient to guide the decision, as shown in Figure 2.1.

Some common pitfalls in EBM are the use of habits, rules and rituals of professionals (why is the evidence better than what I have done over the last 20 years?) and the often hierarchical structure in a medical setting. For example, the head of the department may lead decisions about treatment rather than the evidence. In addition, patients have become more informed and empowered over the years, which makes the role of the patients' preferences more influential in decision making. One of the developments along this line is shared or collaborative decision making, a process in which clinicians and patients communicate together about the best available evidence to guide the treatment decision. In the field of neuropsychological rehabilitation we use, for example, client-centred rehabilitation approaches in which collaborative goal setting among the treatment team, the individual with brain injury and their family is used (see too Chapter 45 in this volume, 'Summary and guidelines for best practice').

Best evidence on the basis of group studies

The RCT offers the best design to study the effectiveness of treatment. The reporting of RCTs can be improved by using well-accepted checklists, such as the Consolidated Standards of Reporting Trials (CONSORT) statement that was developed with the intention of facilitating the clear and transparent reporting of trials (CONSORT Statement, 2010). A recent review showed that journal endorsement of CONSORT may indeed benefit the completeness of trial reports (Turner et al., 2012). Originally, the CONSORT statement was developed for use in pharmacological trials. In non-pharmacological treatment studies – such as those evaluating neuropsychological rehabilitation – it is not always possible to offer a sham intervention, and blinding of patients and professionals is also difficult. As a result, these RCTs could potentially be rated as having lower quality and therefore an alternative checklist for the report of non-pharmacological studies was developed. Specifically, the checklist to evaluate a report of a non-pharmacological trial (CLEAR-NPT) (Boutron et al., 2005) is a more suitable tool to critically appraise RCTs in the field of neuropsychological rehabilitation.

Every year the number of peer-reviewed papers in the medical field is growing and it has become impossible for clinicians to gather the evidence themselves. Bjork, Roos and Lauri (2009) estimated that in 2006, 1.346 million articles were published in 23,750 journals. The average annual growth of the indexes in the Web of Sciences is estimated to be 2.5 per cent. One of the most efficient ways to translate this enormous amount of evidence into clinical practice is to use evidence-based guidelines. These are often published by professional societies (such as the Royal College of Physicians) or governmental organisations (such as the American Heart Association) or teams of researchers and

clinicians working together to formulate recommendations for clinical practice (such as the INCOG group). An example in the field of brain injury rehabilitation in adults are the sign guidelines from the Scottish Intercollegiate Guidelines Network (SIGN) (2013).

In the field of neuropsychological rehabilitation the INCOG recommendations for the management of cognition following traumatic brain injury can be used. An international group of researchers and clinicians (known as INCOG) convened to develop clinical practice guidelines for cognitive rehabilitation following traumatic brain injury. The INCOG group formulated recommendations on five topics: post-traumatic amnesia and delirium (Ponsford et al., 2014a), attention and information processing speed (Ponsford et al., 2014b), executive function and self-awareness (Tate et al., 2014), cognitive communication (Togher et al., 2014) and memory (Velikonja et al., 2014).

The group led by Keith Cicerone formulated recommendations for cognitive rehabilitation after stroke and traumatic brain injury on the basis of a series of systematic reviews evaluating the effectiveness of cognitive rehabilitation (Cicerone et al., 2000, 2005, 2011). The results of these reviews have been translated into the cognitive rehabilitation manual published by the American Congress of Physical Medicine (Haskins, 2012).

Another way of gathering best evidence is by using information from the Cochrane Collaboration, which is a global independent network of researchers, professionals, patients, carers and people interested in gathering high-quality information to make health decisions. Results from systematic reviews are published in Cochrane Reviews, which can be accessed easily. For the field of neuropsychological rehabilitation, relevant reviews are available on many topics, for example: rehabilitation for memory deficits (Nair and Lincoln, 2007); attention deficits (Loetscher and Lincoln, 2013); executive dysfunction (Chung et al., 2013); spatial neglect (Bowen et al., 2013); perceptual disorders (Bowen et al., 2011); apraxia (West et al., 2008); aphasia (Brady et al., 2012); anxiety after stroke (Campbell Burton et al., 2011) and traumatic brain injury (Soo and Tate, 2007); and depression after stroke (Hackett et al., 2008) and after traumatic brain injury (Gertler, Tate and Cameron, 2015).

The evidence of intervention efficacy, which is summarised in meta-analyses and systematic reviews and translated into guidelines and recommendations for clinical practice, is mostly based on RCTs. However, implementing a treatment or replicating a study based on an RCT is not always possible because essential information in the reporting may be missing. First, it may not be possible to judge the reliability and validity of the trial findings, and second, information concerning the treatment itself may be missing. We recently reviewed 95 RCTs showing that there is a large body of evidence to support the efficacy of cognitive rehabilitation after brain injury, but we also concluded that most studies provided little information about the content of the actual treatment (van Heugten, Wolters-Gregorio and Wade, 2012). This makes it difficult to use the studies when making treatment decisions in daily clinical practice. In this paper, we suggested researchers and clinicians use a checklist when reporting rehabilitation interventions in future studies. Items in this checklist concern: (1) patient characteristics to help clinicians decide whether patients in the study are comparable to patients in their own setting; (2) treatment characteristics to help clinicians decide whether the treatment is applicable to their own setting; and (3) information on treatment goals, costs and benefits to enable clinicians to anticipate the outcomes.

Single case experimental design

SCED studies have a long tradition in education and psychology and are nowadays published in journals in the fields of special education, behavioural therapy, and neuropsychological rehabilitation (Evans et al., 2014). SCEDs have influenced clinical practice in some fields such as special education and intellectual disabilities, but in most medical settings RCTs, systematic reviews and meta-analyses

are valued as higher levels of evidence. SCEDs are classified under single case reports, despite the experimental basis and sometimes very high level of control for confounding factors.

The term SCED is used to describe studies in which one participant, or a series of participants, is studied in an experimental design in which the participant(s) act as their own control. Measurements are conducted repeatedly before the intervention (baseline phase), during the intervention (intervention phase) and possibly during a maintenance or treatment withdrawal phase. Confounding factors are controlled for in various ways. Many different designs are used, such as reversal designs (ABA or ABAB designs), multiple baseline designs and alternating or parallel treatment designs. Various names have been used to describe this type of study, including N-of-1 Trials (see Shadish and Sullivan, 2011). The power of the SCED relates to the number of measurements, rather than the number of participants as in group designs. The external validity of the SCED is increased when the design is replicated with more participants. SCEDs are different from case descriptions, case reports and pre-post designs where the design is mostly observational and outcomes are descriptive. A useful taxonomy of single case designs is given by Tate et al. (2013).

SCEDs are preferable when the patient population of interest shows high variability or cases are rare, which impedes the formation of homogeneous large-scale samples that are needed to conduct well-designed RCTs (Guyatt et al., 1990). For instance, this may be the case when studying people with brain injury with challenging behaviour such as aggression. The target behaviour may differ from patient to patient, which has consequences for the choice of a common outcome measure. An example of such specific target behaviour is a patient who frequently yelled, screamed and cursed, and threatened nurses during daily care (Winkens et al., 2014). Using a SCED this verbally aggressive behaviour was rated twice a day by a nurse immediately after activities of daily living (ADL) care, on a scale from 0 to 4: 0 = does not yell, scream or curse at all; 1 = yells, screams or curses once; 2 = yells, screams or curses several times; 3 = yells, screams or curses a lot, and threatens nurse once or several times; 4 = continuous yelling, screaming, cursing or threatening behaviour.

Over the last few years, SCEDs have gained popularity. Evans et al. (2014) argued that this renewed interest is due to the following changes: SCEDs are now ranked as level 1 evidence by the Oxford Centre for EBM; tools for assessing the quality of SCEDs and guidelines for reporting the results of SCEDs are now available, such as the Risk of Bias in N-of-1 Trials (RoBiNT) scale (Tate et al., 2013); and the methods for analysing SCED data are improving and statistical analysis methods are becoming more available and accepted. The special issue on SCEDs in the journal *Neuropsychological Rehabilitation* (April 2014) is an example of the growing focus on SCEDs in the field of neuropsychological rehabilitation. (See too Chapter 43 'Avoiding bias in evaluating rehabilitation' this volume.)

Economic evaluation

Economic evaluation can be defined as the comparative analysis of alternative courses of action in terms of costs on the one hand (resource use) and consequences on the other hand (outcomes, effects) (Adamiak, 2006). The aim of economic evaluation studies is to describe, measure and value all relevant alternative costs and consequences (e.g. intervention X versus comparator Y) (Shemilt et al., 2011). Different types of economic evaluation exist, such as cost-benefit analysis, cost-effectiveness analysis and cost-utility analysis. In partial economic evaluations (e.g. cost-analyses and cost-description studies), less evidence on the description, measurement or valuation of health-care interventions and technologies is provided in comparison to full economic evaluations. To give a relevant example of the difference between partial and full economic evaluations, we recently published a full economic evaluation of an augmented cognitive behavioural therapy intervention in comparison to computerised cognitive training for post-stroke depressive symptoms (Van Eeden et al., 2015). In this study both costs and effects were taken into account from a societal perspective.

A few years ago we published a cost-analysis of a residential community reintegration programme for severe brain injury patients where only the costs of the programme but not the effects were taken into account (van Heugten et al., 2011).

Economic evaluation research can be used in different areas of health care, regardless of the type of intervention, population or disease. However, there are certain types of intervention which are of specific interest to the field of economic evaluation research due to their potential for being cost-effective for more than one population (e.g. self-management interventions). There is also a growing interest in chronic diseases because of their high social and financial burden. Acquired brain injury is universally acknowledged as a chronic disease because of the long-term consequences. Furthermore, the number of people living with the consequences of severe forms of brain injury is increasing as a result of improvements in acute medical care and population ageing. Therefore, the economic impact of these conditions, especially stroke and traumatic brain injury in young people, is becoming a topic of great interest for both researchers and health-care policy makers. This will probably lead to an increase in economic evaluation studies in the coming years. For more information on the cost-effectiveness of neuropsychological rehabilitation, see too Chapter 38, 'The cost-effectiveness of neuropsychological rehabilitation', this volume.

Evidence-based practice

As discussed in this chapter different forms of treatment evaluation are possible depending on the goal: does this treatment help my patient? Does this treatment work and for whom does it work? What are the costs and benefits of this treatment? Some requirements can be formulated for all forms of evaluation, regardless of the design. First, the level of functioning of the patient needs to be assessed at predetermined times, using the same instruments. Furthermore, measurements chosen to measure change in functioning should be aligned with the goals of treatment; for example, when the aim of treatment is return to work, it does not make sense to repeat a neuropsychological test. Finally, group studies typically report statistical significance on the basis of mean scores of the total group. In clinical practice mean scores are less relevant. Other forms of reporting results of studies on effectiveness should therefore also be considered. These forms may include the level of clinical relevance in addition to statistical significance by reporting, for instance, the percentage of patients that improved x points on the primary outcome measure. Other parameters can be reported in which individual improvements are taken into account, such as the Reliable Change Index (RCI). Finally, individualised outcome measures can be used on both a group and individual level. Goal Attainment Scaling is a valuable tool for this purpose and has been shown to be feasible in measuring outcome of rehabilitation after brain injury (Bouwens, van Heugten and Verhey, 2009). Client-centred outcome measures can also form a valuable source of information when considering outcome from a more individual point of view. The Canadian Occupational Performance Measure (COPM) can, for instance, be used to define problems in occupational performance on the basis of a semi-structured interview with the patient (Law et al., 1998). It can also assist in goal setting and measuring changes in performance over time from the patients' perspective. Jenkinson, Ownsworth and Shum (2007) showed the clinical utility of the COPM in community-based rehabilitation of brain injured individuals and recommend incorporating self-ratings in the context of other outcomes.

It is important that health-care professionals are able to justify their treatment decisions on the basis of available evidence and in consideration of patient preferences and their patients' status. Planning treatment explicitly and evaluating the outcome of treatment should therefore be a self-evident process, either by monitoring the individual patient or applying the best available evidence in a careful and judicious manner.

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