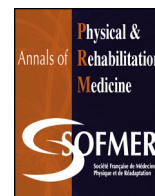




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Update article

## Single-case experimental designs (SCEDs) to assess intervention effectiveness in rehabilitation: A practical guide

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### ABSTRACT

Single-Case experimental designs (SCED) are experimental designs aiming at testing the effect of an intervention using a small number of patients (typically one to three), using repeated measurements, sequential ( $\pm$  randomized) introduction of an intervention and method-specific data analysis, including visual analysis and specific statistics. The aim of this paper is to familiarise professionals working in different fields of rehabilitation with SCEDs and provide practical advice on how to design and implement a SCED in clinical rehabilitation practice. Research questions suitable for SCEDs and the different types of SCEDs (e.g., alternating treatment designs, introduction/withdrawal designs and multiple baseline designs) are reviewed. Practical steps in preparing a SCED design are outlined. Examples from different rehabilitation domains are provided throughout the paper. Challenging issues such as the choice of the repeated measure, assessment of generalisation, randomization, procedural fidelity, replication and generalizability of findings are discussed. Simple rules and resources for data analysis are presented. The utility of SCEDs in physical and rehabilitation medicine (PRM) are discussed.

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## 1. Introduction

### 1.1. What are SCEDs?

The term Single-Case Experimental Designs (SCEDs) refers to a set of experimental methods that can be used to test the efficacy of an intervention using a small number of patients (typically one to three), and involve repeated measurements, sequential ( $\pm$  randomized) introduction of an intervention, specific data analysis and statistics. SCEDs are not case reports but studies carefully designed prior to the start of an intervention and are therefore truly “experimental” designs.

Different names have been given to SCEDs (see column 1 of Table 1), and many different types of SCEDs have been used in the literature (see column 2 of Table 1), which will be described later in this paper. Regardless of the terminology, the design framework is essentially the same: [1] studying prospectively and intensively a

single person or small group of persons over time, [2] measuring repeatedly and frequently the outcome in all phases of the study, and [3] sequentially applying and/or withdrawing the intervention [1]. What distinguishes SCEDs from group designs is that individual behavior is repeatedly measured both in the absence and presence of a specified intervention. These repeated measures allow patients and participants to serve as their own controls by reflecting each individual's performance at baseline (i.e. before the intervention is introduced), then with intervention. Individuals are studied during multiple discrete phases—at minimum two phases, generally baseline (by convention designated with the letter, A) and treatment or intervention phase (designated with the letter, B) [2].

SCEDs have been used for 50 years, especially in the field of education and psychology. In the medical setting, the term “N-of-1 trial” arose in the mid-1980s in response to limitations that were apparent in applying the findings of randomized controlled trials (RCTs) to the individual patient when making treatment decisions [3]. In psychology, SCEDs have a long history of use in the evaluation of behavior management interventions and in the context of learning disability, whilst in rehabilitation, most SCED papers examine cognitive interventions (especially in aphasiology,

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**Table 1**  
Different names give to SCEDs.

Different names given to SCEDs	Different types of SCEDs
Single case experimental designs (SCED)	Reversal/withdrawal = ABAB trial
Single subject experimental designs (SSED)	N-of-1 trial <sup>a</sup>
Single subject research design (SSRD)	Multiple baseline design: across participants, across settings, across behaviours
N-of-1 trial <sup>a</sup>	
Small N-designs	Mixed multiple baseline design
Multiple-case design	Alternating treatment design
Single-case design (SCD)	Changing criterion design
Single-systems designs	Changing intensity design [1]

<sup>a</sup> N-of-1 trial is the term usually used for SCED in medicine (research on drugs using single cases especially). Although the term “N-of-1 trial” is sometimes used for different types of SCEDs, Guyatt et al. [3] have proposed to limit the term N-of-1 trial to introduction/withdrawal designs, i.e. ABAB designs with multiple cross-overs, blinding of patient and therapist, and randomization.

neuropsychological rehabilitation and special education) with a number of tutorials and didactic papers presenting SCED use in cognitive rehabilitation and behavioral interventions [4–6]. Introductory papers on SCEDs and reviews have been published in motor areas as well, such as sports [7], adapted physical activity [8] and domains important to rehabilitation such as pain treatments [9]; technology-based health interventions [10]; music therapy [11]. Graham, Karmarkar and Ottenbacher wrote an excellent special communication presenting SCED use across numerous fields of rehabilitation [1].

A recent resurgence of interest in SCEDs has been noted by Smith [12] and by Tate et al. [2], and is reflected in a number of journal special issues on SCEDs, including in rehabilitation journals (*Aphasiology* Volume 29, 2015, Issue 5; *Neuropsychological Rehabilitation* 2014, 42; Evidence-Based Communication Assessment and Intervention (Volume 2, Issue 3) in 2008, Remedial and Special Education (Volume 34, Issue 1) in 2013). Evans et al. [13] identified three possible reasons for this recent resurgence:

- the Oxford Centre for Evidence-Based Medicine ([www.cebm.net](http://www.cebm.net)) now rank the randomised N-of-1 trial as Level 1 evidence for treatment decision purposes in individual patients, alongside systematic reviews of RCTs;
- the development of quality assessment tools and reporting guidelines, aimed at improving the methodological quality, and consistency in reporting, of SCEDs;
- the development of methods of analysis suitable for SCED data.

SCEDs enable high quality research with small numbers of patients, in the clinical setting, in populations that are small, too heterogeneous, or too atypical to constitute a group in RCTs. They allow an intervention to be tailored to the unique needs of a patient, and to assess its effectiveness through a rigorous methodology. Because one to three subjects are sufficient to draw reliable conclusions, SCEDs are less influenced by recruitment problems. They have, therefore, a lower risk of type 2 error, often caused in group studies by insufficient number of included subjects [14] -in SCEDs power comes from the number of repeated measures and not from the number of patients. Studying less subjects but more intensely and comprehensively allows insight into intervention mediating effects and better knowledge of the studied subjects [15]. Furthermore, SCEDs can detect an intervention effect within the (often large) variability of a subject's performance (due to pain, fatigue etc.). RCTs on the other hand, measure a patient's performance a limited number of times (most often: pre, post and at follow-up) and have a risk of obtaining a score that is not representative of the individual (e.g. if the patient was particularly in pain/tired on the day of the evaluation).

Compiling a list of advantages in using SCEDs is beyond the aim of this paper; readers can refer to excellent papers [1,6,16–18] that comprehensively outline the numerous positive aspects of SCED methodology.

### 1.2. Aim of the paper

The aim of this paper is to familiarise professionals working in all fields of rehabilitation with SCED methodology and provide practical advice on how to design and implement a SCED in clinical rehabilitation practice. It does not aim to be an exhaustive tutorial on SCEDs, but rather to be a practical guide for clinicians who are beginners in SCEDs wishing to use this methodology in their daily practice.

## 2. When to use SCED methodology

SCED methodology aims to test the effectiveness of an intervention or to compare the relative effectiveness of two or more interventions. “In general, small-N designs (i.e. SCEDs) are practical complements to larger N trials. They can be useful in the early developmental phase of research as well as in refining the application of research findings to individual patients.” (p s115) [1].

Situations that particularly lend themselves to SCEDs are:

- evaluating the efficacy of a current intervention for one particular patient in daily clinical practice to provide the best treatment based on evidence rather than clinical impressions;
- conducting research in a clinical rehabilitation setting (outside a research team) with a single or few patients;
- piloting a novel intervention, or application/modification of a known intervention to an atypical case or other condition/type of patients that the intervention was originally designed for;
- investigating which part of an intervention package is effective;
- working with rare conditions or unusual target of intervention, for which there would never be enough patients for a group study;
- impossibility to obtain a homogenous sample of patients for a group study;
- time limitation (e.g. a study needing to be completed within 8 months, e.g. for a master degree research...) or limited funding not allowing recruitment of a group.

Having decided that a SCEDs is, in principle, appropriate and preferable to a group design, the next questions is whether a SCED is feasible? The main reasons that may prevent use of a SCED is the difficulty in choosing a valid and reliable outcome measure that can be measured repeatedly.

## 3. Repeated outcome measures in SCEDs

One of the most challenging aspect of SCED methodology is finding an adequate outcome measure to assess intervention effectiveness. Contrary to group trials and clinical practice where norm-references, standardized tests of known clinimetrics are

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