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1 **TITLE**

2 **Single-Subject Design: Experimental Designs for Research and for Clinical Practice.**

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ABSTRACT

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28 **Background:** The individual variability among people presenting motor impairments often leads to
29 the difficulty to obtain an adequate sample size in the conduction of trials in physiotherapy.
30 Furthermore, in clinical practice, it is often difficult to recognize the relationship between the
31 administration of a treatment and its expected results. Psychological and educational sciences often
32 use single-subject design (SSD) studies to explore behaviours under experimental conditions. This
33 study design allows to test the relationship between an independent variable, the treatment, and a
34 dependent variable, the main outcome of interest. The purpose of this work is to present researchers
35 and clinicians the methodology of the SSD studies and their application in physiotherapy both in
36 research context and everyday practice.

37 **Results:** In SSD studies, repeated measurements of the outcome of interest occur across time
38 starting from a condition without treatment, the so called “A-phase”, and continuing during the
39 administration of the treatment, the so called “B-phase”. A-phase measurements serve as a standard
40 of performance that can be compared to B-phase measurements in terms of change in the mean
41 level, change in trend or change in variability of measure, depending on the nature of the assessed
42 outcome. Different types of SSD studies exist, those alternating introduction and removal of the
43 treatment called “treatment removal”, following the AB, ABA or ABAB schemes, those with the
44 introduction of one or more alternative treatments, named C, D and so on, called “alternating
45 treatments”, following the ABACAD scheme, those with a progression of different treatments
46 according to achieved levels of the outcome of interest called “changing criterion”, following the
47 ABCD scheme, and those where more subjects follow the scheme of alternating phases starting at
48 different time points, called “multiple baseline”.

49 **Conclusions:** SSD studies offer an option for the identification of an individual response to a
50 specific intervention when traditional between-group designs would not be appropriate both in
51 clinical and research contexts. SSD studies result in acceptable internal validity but in very low
52 external validity.

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KEY WORDS

55 Research Design - Rehabilitation - Translational Medical Research.