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An annotated bibliography on single subject research design

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Selected citations of texts and journal literature were reviewed and annotated. The strategy of single subject research design is set out and reviewed within the annotated template.
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KEY WORDS: research, design, chiropractic, manipulation.

Des citations de textes et de revues choisies ont été analysées et commentées. La stratégie de méthode de recherche auprès d'un seul sujet est fondée et analysée selon un modèle pré-établi.
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MOTS-CLÉS: recherche, méthode, chiropratique, manipulation.

Introduction

Single subject research designs represent one of several strategies that can be used in practice-based research. These prospective observation designs focus on a single subject and have the advantage of being adaptable to the needs of the individual patient and the clinical approach of the practitioner. There are various approaches ranging in experimental rigor from randomized single case study designs ($N = 1$) and single case experimental designs to diary or calendar methods. These designs are appropriate for the development of research hypotheses, and the testing of those hypotheses in individual patients.

This annotated bibliography contains citations from book and journal articles which focus on a selection of design methods, implementation of methods, analysis of results, and several examples of single subject designs used in chiropractic, physical therapy, and health related professions literature.

Methods Citations

1 Albridge D. Single-case research designs. Complementary Medical Research 1988; 3(1):37–46.

This article discusses single-case research designs as a feasible and appropriate method for clinicians to incorporate research into their practice. Three designs are introduced and described including comments on their strengths and weaknesses.

2 Center DB, Leach RA. The multiple baseline across subjects design: proposed use in research. J Manipulative Physiol Ther 1984; 7(4):231–236.

This paper centers on the multiple baseline across subjects design. The authors propose that it has the most promise for field based chiropractic research. The discussion clearly outlines consideration for applying this approach to research and an example of such a study is plainly described.

3 Gemmel HA, Jacobson BH. Appropriateness of the replicated AB design in chiropractic field research. Chiropr J Aust 1991; 21(2):42–46.

This article proposes replicated AB research design to be the best method for single-subject research in the chiropractic practice. The author describes the design and points out how the usual threats to validity in single-subjects research are ruled out in the replicated AB design. Also mentioned is the use of visual analysis of graphed data using four suggested criteria: change in mean, level and trend; and latency of change.

4 Gonnella C. Single-subject experimental paradigm as a clinical decision tool. Phys Ther 1989; 69:601–609.

This article presents a good overview of single-subject design. The alternating-treatment design is emphasized as a tool for clinical decision making. Also provided are brief examples of design options.

5 Guyatt G. A clinician's guide for conducting randomized trials in individual patients. Can Med Assoc J 1988; 139:497–503.

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Offers guidelines for conducting an N-of-1 randomized controlled trial. The guidelines are set in a question format and in an easy to follow table.

6 Johannessen T, Fosstvedt D. Combined single-subject trials. Scand J Health Care 1991; 9:23–27.

This article supports replication of an N-of-1 randomized controlled trial to increase the generalization of the information gained. Also provides discussions on pre-requisites, statistical issues and validity assessments.

7 Johannessen T, Petersen H. The controlled single-subject trial. Scan J Prim Health Care 1991; 9:17–21.

Written from the standpoint of drug trials, this article discusses the advantage of single-subject over group designs and factors that influence the appropriateness of controlled single-subject trials. Heavy emphasis is placed on the control aspect in this design.

8 Keating JC. Toward an experimental chiropractic: time-series designs. J Manipulative Physiol Ther 1985; 8(4):229–238.

This article emphasizes the responsibility of the chiropractic profession to develop an experimental data-base. Time-series designs are discussed as viable experimental strategies. The methods of time-series designs (TSDs) and variations of them are explained with an emphasis on chiropractic application. The discussions and examples provided made this article essential for the understanding of TSDs and their place in chiropractic.

9 Meeker WC. Research in the chiropractic office. California Chiropractic Association 1995; January:17–19.

Meeker nicely summarizes the concepts concerning single subject time-series designs. Not only is the reader introduced to the design, but is also guided step-by-step through the process of conducting a study and how to write it. This article is an excellent starting point for learning about single subject design.

10 Sandvik L. Single-case studies from a statistician's point of view. Scand J Gastroenterol Suppl 1988; 147:38–39.

This article offers a "to the point" description of a single-case study. The author points out the statistical short comings of this design but concludes that single-case studies may be a valuable tool in medical practice.

11 Barlow DH, Hersen M. Single case experimental design strategies for studying behavior changes. 2nd ed. New York: Pergamon Press, 1984.

This monograph discusses various designs for single-case studies and is meant to be a source of guidelines for their use in applied settings. Many examples of graphs and tables which simplify results are included. This book is indexed by subject and by author and has an extensive list of references.

12 Barlow BH, Hayes SC, Nelson RO. The scientist practitioner: research and accountability in clinical and educational settings. New York: Pergamon Press, 1984.

The authors have organized their monograph into three sections. The first, concerned with the introduction of the scientist-practitioner, provides a historical perspective and discusses the role of the model in today's practice. The second section concentrates on measures while section three focuses on strategies and designs. Issues, ethics and clinical replications are also discussed. Author and subject indexes are provided.

13 Kazdin AE. Single-case research designs: methods for clinical and applied setting. New York: Oxford University Press, 1982.

This monograph emphasizes methodology. Single-subject research design options are presented to exemplify the wide range of uses in research. Also presented are the limitations and problems of this type of design. Included are two appendixes concerning visual and statistical analysis and two indexes by author and by subject.

14 Keating JC, et al. Intrasubject experimental designs in osteopathic medicine: applications in clinical practice. J Am Osteopath Assoc 1985; 85(3):192–203.

Although this article was written for the osteopathic practitioner, its relevance to the chiropractor is significant. The authors clearly describe single-subject research designs and their place in research. An explanation of the statistical short-comings as well as the ethical considerations involved with single-subject designs are presented. Haldeman's five rival hypotheses that compete with the experimental hypothesis are presented with a discussion on how to minimize their competition with rigorous research methods.

15 Keating JC, Coyle BA. Time-series experimentation. In: Toward a philosophy of the science of chiropractic: a primer for clinicians. Stockton: Stockton Foundation for Chiropractic Research, 1992: 231–250.

The authors use a conventional style to explain time-series research designs in a simplified manner. The A/B/A/B and multiple-baseline designs are described and hypothetical examples are provided. The chapter concludes with a brief discussion on the importance of an investigative attitude in promoting time-series clinical research.

16 Kratochwill TR, Levin JR, eds. Single-case research design and analysis: new directions for psychology and education. New Jersey: Lawrence Erlbaum Associates, 1992.

This book was written for the "scholar of research methodology"; not necessarily for the clinician interested in incorporating N-of-1 studies within their practice. The language used throughout the text is entrenched with research terminology that may be unfamiliar to many.

The first chapter provides the standard overview of single-case research design and analysis. However, the author summarized much of the information and put it into tables which are understandable. One table compares low-inference strategies with high-inference strategies of 12 research characteristics. High-inference strategies increase validity.

17 Ottenbacher KJ. Evaluating clinical change: strategies for occupational and physical therapists. Maryland: Williams and Wilkins, 1986.

This monograph not only identifies the need of research for professional development but emphasizes, "the integration of empirical findings and methods into clinical practice." The author hopes to demonstrate how research and clinical practice can be combined. A general overview of research is offered as an introduction before an in depth discussion on single-subject research design ensues, including advanced designs, visual analysis and statistical analysis. The author kindly provides a glossary as well as an author and subject index.

Examples Citations

18 Aldridge D. Single-case research designs: an extended bibliography. Complementary Medicine Research 1991; 5(2):99–109.

A supplement to the first paper that provides examples of many studies that used the single case report format. Citations from the fields of psychology and neurology.

19 Beattie AJM. The effectiveness of spinal mobilization for low back pain: a single-case study. Physiotherapy Theory and Practice 1991; 7:57–62.

The author utilizes the ABAB single-case design to determine the effectiveness of Maitland spinal mobilization for low back pain. The method is clearly stated, allowing ease of replication. Although mobilization showed improvement, the author urges a follow-up study to determine long-term effects of mobilization.

20 Campbell PH. Using a single-subject research design to evaluate the effectiveness of treatment. Am J Occup Ther 1988; 42(11):732–28.

This article offers a five step breakdown in the implementation of a single-subject study. Although the article is written in terms of occupational therapy, the issues discussed are of concern to any single-subject design. Example studies are presented.

21 Crawford JP, Noble WJ, Vernon H. Chiropractic management of spondylolisthesis with spondylosis of the pars interarticularis; an example of the single-case study experimental design. J Manipulative Physiol Ther 1988; 11(2):89–93.

Following a brief discussion of the clinical presentation of spondylolysis, the authors present an example single-subject study. The results were graphed in a typical N-of-1 format which concludes that chiropractic care may offer some relief for patients presenting with this condition.

22 Gemmell HA, Jacobson BH. Chiropractic management of enuresis; time series descriptive design. J Manipulative Physiol Ther 1989; 12(5):386–389.

Presented here is an example of a single-case time-series design. A case of a 14-year-old male with primary nocturnal enuresis was used to demonstrate the method of an A-B single-subject design.

23 Gemmell HA, Jacobson BH. Effectiveness of flaxseed oil on the symptomatic treatment of rheumatoid arthritis: a single-subject experimental design. Am J Chiro Med 1989; 2(4):151–154.

With the use of an AB-AB single-case experimental design, the authors of this article evaluate the effects of flaxseed oil as an ameliorative effect on the patient's symptoms.

24 Giesen JM, Center DB, Leach RA. An evaluation of chiropractic manipulation as treatment of hyperactivity in children. J Manipulative Physiol Ther 1989; 12(5):353–63.

The authors of this article provide yet another example of an N-of-1 study. The methods were well documented including difficulties encountered in the study. In so doing, future studies of chiropractic's effect on autonomic function will benefit by resolving these difficulties.

25 Kettle D. The effects of manipulative physiotherapy on chronic cervical dysfunction. Physiotherapy Theory and Practice 1991; 7:23–31.

The author examines the effectiveness of Maitland's concept of manipulation in treating chronic cervical dysfunction by employing an AB single-case design. Although the AB/AB design is more rigorous, it is not clinically feasible when the condition resolves during the first treatment phase.

26 Lowden TA, Keating JC, Meeker WC. A multivariate time-series descriptive case study of chiropractic care in the treatment of cervical pain. J Manipulative Physiol Ther 1986; 9(4):267–277.

This article presents an example of a study performed on a patient who complained chiefly of cervical pain and stiffness but also experienced dull left sacroiliac joint pain, loss of grip strength of her right hand, left arch pain and constipation.

27 Meyer JJ, et al. Effectiveness of chiropractic management for patellofemoral pain syndrome's symptomatic control phase: a single-subject experiment. J Manipulative Physiol Ther 1990; 13(9):539–549.

Provided here is an example of a multiple-interrupted, time-series design on a patient with bilateral patellofemoral pain syndrome. After a brief discussion on patellofemoral pain syndrome, a detailed description of the case and treatment protocol were provided. The graphed results of the pain diary were also provided, demonstrating the effectiveness of the conservative care. Recommendations for future research were provided by the authors.

General Citations

28 Aufdemkampe G. Some comments on single-case studies. Physiotherapy Theory and Practice 1991; 7:63–71.

This article presents information relevant to physiotherapy concerning single-case studies. The author stresses the importance of objective and reliable outcome measures in such studies and provides a brief discussion on visual and statistical analysis of data from single-case studies.

29 Bithell C. Single subject experimental design: a case for concern? Physiotherapy 1994; 80(2):85–87.

Bithell raises design issues that threaten the validity and reliability of an N-of-1 study. One of the issues discussed was how the use of frequent measures (a fundamental aspect of an N-of-1 study) may increase the effects of error. The article's conclusion states that single subject design is inappropriate for demonstrating the general effectiveness of a treatment.

30 Guyatt GH, Keller JL. The N-of-1 randomized controlled trail: clinical usefulness. Ann Intern Med 1990; 112(4):293–299.

In 1985, the authors of this article designed an N-of-1 service for clinician's involved with N-of-1 drug therapy efficiency studies. The purpose of the article is to discuss the feasibility and effectiveness of N-of-1 randomized controlled trials based on their three years experience with the service. They consider an N-of-1 trial to be clinically relevant if the results of the trial allowed high levels of physician confidence in a management plan. Also discussed were statistical criteria for assessing the results of an N-of-1 and the use of a 7-point scale questionnaire as an outcome measure. The authors, based on the results of 57 trials consider N-of-1 randomized controlled trials to be both feasible and useful.

31 Johannessen T, Lewis JA. Controlled trials in single subjects. Br Med J 1991; 303:173–174.

A debate is presented on the use of single subject trials for drug development. Johannessen concludes that such trials provide a valid means for new insight in poorly defined conditions and improve therapeutic decisions. Lewis discusses the limitation of such trials; mainly the lack of general inferences derived from the results of a N-of-1 trial.

32 Keller JL, Guyatt GH, et al. An N-of-1 service: applying the scientific method in clinical practice. Scand J Gastroenterol Suppl 1988; 147:22–29.

This article describes the format of an N-of-1 randomized clinical trial (RTC), presents some issues in methodology and plainly lists out terminology in N-of-1 RCT. The main purpose of the article is to introduce a N-of-1 service which will either run a trial on a referred patient or set up a trial for a clinician to run.

33 Marvel KN, Amodei N. Single-subject experimental designs: a practical research alternative for practicing physicians. Fam Pract Res J 1992; 12(2):109–121.

This article clearly demonstrates the benefit of single-subject research designs for the practicing doctor. Examples of three designs are presented, including advantages and disadvantages of each. The discussion on data analysis in terms of visual inspection and statistical tests provides an insight to the controversy of single-subject designs. The authors suggest guidelines for the application of these designs.

34 Ports MS. The search for more clinically meaningful research designs: single-patient randomized clinical trials. J Gen Intern Med 1986; 1:418–419.

This article cites clinical situations that would be good candidates for N-of-1 RCT. The author warns that clinicians planning single-subject studies should become familiar with such studies beforehand as to prevent repetition of common errors. The ability of an N-of-1 trial to ascertain treatment protocols for the general population is questioned since they only determine effective treatment for an individual patient.

35 Riddock J. Evaluation of practice. Physiotherapy 1991; 77(7):439–444.

The author discusses the short comings of group studies for the evaluation of a treatment protocol from the standpoint of rehabilitation. Group studies have mixed success in predicting the effects of a particular treatment on an individual. Single-case experimental studies are presented as an alternative with examples of alternating phase designs and multiple baseline designs.

36 Riddock J, Lennon S. Single subject experimental design: one way forward? Physiotherapy 1994; 80(4):215–218.

This article is a response to Bithell's paper on single subject design. The authors defend N-of-1 studies as a tool to evaluate practice, especially when done in series.

37 Robertson VJ, Lee VL. Some misconceptions about single designs in physiotherapy. Physiotherapy 1994; 80(1):762–766.

The authors argue the legitimacy of single subject designs as a means for the clinician to contribute to the documentation, evaluation and improvement of clinical practice. Single subject designs are described as the simplest form of replication-based research when a procedure is repeated on the same subject in the hopes to reproduce a past result. A discussion on baselines and various designs within the single subject design is provided.

38 Sterling YM, McNally JA. Single-subject research for nursing practice. Clin Nurse Spec 1992; 6(1):21–26.

An excellent paper written for clinical nurse specialists that compares well with chiropractic. This article provides the reader a good understanding of single-subject research design and their clinical implications. Non-experimental single-subject research is differentiated from single-subject experimental research. Conflicting requirements in research and in services are placed in tables allowing a clear understanding of this single-subject design issue.

39 Vernon H. The single case study experimental design in general chiropractic practice. J Can Chiro Assoc 1981; 25(1):15–17.

Acknowledging the challenge of a prospective control period in general practice, Vernon suggests an alternative design, one that combines a retrospective and prospective approach. An example case report is included.

40 Waalen JK. Single subject research. J Can Chiropr Assoc 1991; 35(2):95–95.

This article describes and compares two types of single subject research designs; the case study and the single-case experiment. Also discussed is criteria for evaluating the results. The author points out two issues to consider when engaging in single subject research: replication and evaluating change.