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THE IMPORTANCE OF CLINICAL RESEARCH WITHIN MUSCOLOSKELETAL REHABILITATION USING QUALITATIVE STUDIES AND SINGLE-SUBJECT DESIGNS: FUTURE PERSPECTIVES.

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ABSTRACT

Qualitative Studies and Single-Subject Designs are valuable clinical research tools for Physiotherapists and valid source of clinical information to improve our practice. Qualitative approach has gained increasing credibility in the last decade as well as single subject research has become increasingly acknowledged in rehabilitation literature. However a lack of knowledge and some misconceptions regarding these approaches still exist and make these research designs under-represented in Rehabilitation and Physiotherapy.

Qualitative Research Methodology explores human behaviour and social interaction, focusing on individuals' lived experiences, aiming to develop knowledge based on participants' own beliefs and experiences.

Single-Subject Designs are experimental research designs involving multiple measurements over time on a single subject. Single system design is suited for studying the time course, variability or effect of an intervention or treatment on a single patient.

Qualitative Research and Single-Subject Design are still relatively uncommon in the field of physical rehabilitation. This article contribute to overcome the gap outlining the major characteristics of both and giving applications and examples. The use of these two tools for muscoloskeletal practice and manual therapy research is proposed.

CINAHL, EMBASE and MEDLINE are the main sources using "single subject" and "single system", and "qualitative" as key words, yielding articles related to rehabilitation, and muscoloskeletal rehabilitation.

Studies were selected for review either if dealing with the rationale of one of the two approach or if describing a research design application.

Studies exemplifying adherence to methodological rules or illustrating errors that results in threats to the validity of stated findings were identified.

Results demonstrate the increasing application in the rehabilitation field and illustrate that such research designs properly applied can support evidence to clinicians interventions.

More studies are needed using these two approaches to establish further development of evidence-based manual therapy.

Manual therapy needs physiotherapists to collaborate in multi-disciplinary efforts to conduct, review and disseminate high quality qualitative and quantitative research. Physiotherapy publications have an opportunity to educate clinicians about the value of qualitative evidence as well as quantitative evidence through publishing high quality research and engaging critical expert reviewers. The aim of is article is to provide a basis of knowledge and discusses the potential contribution of qualitative studies and single-subject design as valuable sources of clinical evidence in muscoloskeletal rehabilitation field.

INTRODUCTION

Qualitative Studies and Single-Subject Designs are valuable clinical research tools for Physiotherapists. Interest in this field has increased recently.

Qualitative research methods could help us to improve our understanding of medicine. Rather than thinking of qualitative and quantitative strategies as incompatible, they should be seen as complementary. Although procedures for textual interpretation differ from those of statistical analysis, because of the different type of data used and questions to be answered, the underlying principles are much the same(1). Qualitative Research Methodology explores human behaviour and social interaction, it focuses on individuals' lived experiences as they are presented in thoughts, ideas, feelings, attitudes and perceptions. The aim of qualitative methodology is to develop knowledge based on participants' own beliefs and experiences, not on pre-defined, testable hypotheses. It is different from quantitative research. It is inductive rather than deductive, and it is interpretative rather than predictive. If the goal of Physiotherapy, according with WHO's ICF, is to improve patients' lives by addressing impairment, activity and participation, then research agenda must include questions that relate not only to relieving impairments and improving function but also to understanding patients' lived experiences. Qualitative approaches often offer the most appropriate methods and framework for considering these latter questions.

In this paper definition of qualitative methodology and the rationale for using this approach are presented as well as research design, sampling techniques and data collection methods. A short presentation of how to establish scientific rigour in qualitative research is included. We explore also the differences between qualitative and quantitative methodology and analyse the criticism which those unused to qualitative approach consider qualitative research with. Applications are suggested and examples are illustrated. The second manual therapy research tool we propose is the often overlooked single subject research design. The use of this experimental research design is proposed to develop evidence to manual therapy practice. This design involving multiple measurements over time on a single subject (n = 1) can be used to study the time course, variability, or effect of an intervention or treatment on a single patient. It has been labelled as a clinical trial of n = 1, a randomised clinical trial in a single patient, a within subject design, patient care study, A-B, or a single subject design (2).

A definitions of single-subject design and the four principal designs are illustrated. An overview of the rationale of the design, an introduction to the methodology, strengths, limitations and possible clinical applications are presented. This is an introduction of the broad approach. Those readers who became interested in a deeper understanding are referred to further readings.

PART I: QUALITATIVE RESEARCH METHODOLOGY

DEFINITION OF QUALITATIVE METHODOLOGY

Qualitative research has been used in psychology, sociology, anthropology, education, and more recently in medical science. A number of rehabilitation practitioners have reviewed in more detail the usefulness of qualitative research for rehabilitation medicine and studies using qualitative designs have begun to appear in rehabilitation literature(3).

In the qualitative literature there is now a consensus on how to define qualitative methodology:

Qualitative research is an inquiry process of understanding based on distinct methodological traditions of inquiry that explore social human problems. The researcher builds a complex holistic picture, analyses words, reports detailed views of informants and conducts the study in a natural setting(4).

The research methodology is described as a tradition that is interpretative , understood, experienced and produced by human beings. The designs are flexible and sensitive to the social context in which the study is performed. Methods of analyses and explanations are complex, detailed and contextual.

In summary, qualitative methodology deals with understanding and exploration of human's social lives(5). The quality of a phenomenon is in focus, not the quantity. This definition implies that qualitative research is inductive, moving from concrete data collected in a concrete, social reality towards abstract descriptions and analyses on a theoretical level.

RATIONALE

There are basic assumptions underlying qualitative methodology. It is distinct from statistical analysis usually applied to rehabilitation outcome measures(6).

One basic assumption is that realities are multiple and socially constructed, they will vary between different groups of people and in different social settings. Realities are experienced differently depending on who is experiencing them. Therefore it is the researcher's obligation to find these differences, not to find a single truth.

Another assumption is that the researcher and the informants interact with each other, and the research process goes on between the two and they influence each other.

A third assumption is that qualitative research is inductive, time and context bound and requires an emergent study design. That makes it difficult for the researcher to compare association between different social context. The researcher looks rather for the uniqueness of a social process or phenomenon(19).

All these concepts are used in qualitative research as a basis for viewing and understanding the human interaction.

STUDY DESIGN

The research question has to be suitable for a qualitative design. If it is so, the researcher chooses the most appropriate kind of data collection method(s). The interview guide may change and reflect the ongoing simultaneous process of data collection, so called abduction. Questions in qualitative methodology are more open-ended than those of quantitative research. If they are good they will encourage the informants to tell their story. In quantitative research questions are in a closed format and data collected can be subjected to a statistical analysis. In the thematized qualitative interview guide with open-ended questions, the research use himself as a research instrument in the process of data collection and analysis, building trust in the interview situation so that the informants find it comfortable and relaxing to share their experiences. Data collection continues until redundancy or saturation is reached, which means that no additional information is obtained from the last informants.

When it is suitable to use a qualitative design?

One major block to studying outcomes from the experiential perspective of patients is the view that human experience in itself is subjective, cannot be objectified. Therefore qualitative researchers consider the research individual as a source of understanding rather than as an object of study. This conceptual shift transforms the "research individual" into an "informant" and opens an entirely different, yet complementary, approach to inquiry in medical science. This approach specifically allows for analysis of the meanings informants associate with the events, processes, and contexts of their experiential world.

The primary data gathering tools used by the qualitative researcher are interview and observation. The aim of these methods is to gather the individual's experienced world in themes understandable to others. Initial access to such understanding is through individually conducted open-ended interviews and observation of individuals in everyday activity. The collected narrative and observational data are then organised into elements through a process of thematic analysis.

In well designed qualitative research, a structure that reflects the person's experience of the phenomenon under investigation emerges from this analytic process. When this structure is viewed in the context of personal history and circumstance, a picture of the person's reality as it is experienced comes into focus. When this method is applied to groups of individuals who have experienced a similar phenomenon, an overarching thematic structure can be seen through comparison of individual themes across members in the study group. The method also allows for detailed analysis of individual differences within the group. Many variations on this basic approach have evolved over the 100-yr history of qualitative research.

A hallmark of high-calibre qualitative research is that primary data are used to further refine and focus the research process itself as well as the emerging picture of the experiential worlds of the informants. The qualitative research process is thus inductive and iterative, consisting of a preliminary premise that is shaped and refined through the research process itself. Repeated returns to collected data for reanalysis are the rule, and additional data are gathered as needed. Thus, in contrast to traditionally based hypothesis-driven research in which data-gathering processes are specified before beginning the research, data-gathering in qualitative research is in part driven by the research process itself. Results of qualitative inquiry include, for example, narratives that elucidate meanings and processes of the informants' worlds as well as hypotheses and new variables that can be incorporated in standard statistical research designs.

SAMPLING TECHNIQUES

Sampling in qualitative methodology differs from sampling in quantitative research. Whereas random sampling is a gold standard in quantitative studies, non-probabilistic samples are preferred in qualitative research. The choice of study subject is purposive and strategic. During a first data analysis the researchers may realised that more information are needed from a few of the participants in order fully to understand their meaning. The researchers may judge these informants as having additional information that are theoretically important for the development of the final result and so may conduct other research interview. The researcher use a flexible, emergent research design, the questions develop throughout the study and the sampling procedure is not defined beforehand.

The sampling strategy is called theoretical sampling as it follows and changes along with the emerging theory.

The World Health Organisation has suggested several sampling techniques for qualitative research. Maximum variation, for instance, means that the chosen informants are different from each other in as many aspects as possible. Another technique is called chain sampling. This can be used when researchers don't know how to reach the people they want include in the study and start interviewing a firsts informant then ask him for others whom the informant believes will provide further information.

In other study one may want to include those who have extreme opinions, then it will be useful a deviant sampling techniques.

Other sampling techniques recommended in qualitative methodology can be used and the authors have to justify their choice.

QUALITATIVE DATA COLLECTION METHODS

In a qualitative study design the detailed aspects of human life and the depth people's thoughts and experiences can be at best investigated by qualitative research interviews(7). The qualitative research interview is usually performed on a conversational basis, using rather loose, broad and open-ended questions or interview themes in a thematic interview guide. The aim is to encourage the informant to talk. Sometimes the researcher may use a semi-structured interview form with more or less closed questions. The interviews are often tape recorded and transcribed

verbatim directly afterwards. However, sometimes researchers prefer to use the tape without a transcription, as a basis for analysis.
Another tool for data collection is the focus group discussions. It is used when the aim of the research is to develop knowledge about how groups of people think and act.
A third method for data collection is to conduct participants observations. This is use when the aim is to explore people's behaviour in their specific social context. The observations can be conduct covertly or overtly. Observational studies may use videotaping to help the analysis of human interaction.
There are other forms of data collection as reflective diaries or medical records, the choice depending on study design and aim.

QUALITATIVE DATA ANALYSIS
In qualitative health research there are 3 methods for analysis most frequently adopted: content analysis; phenomenology and grounded theory. We briefly describe the grounded theory method.
Grounded theory (8) is a frequently used approach for data analysis, which seek to develop theory and hypothesis from qualitative data. The theory should thus be grounded in data.
The first step is to read the transcript and write down concepts and terms that capture the context of the text. This initial process is called open coding. Next step is to find common features among the open codes, to group these codes together and label the groups. This is a process labelled categorising. Once identified the categories, the researchers decide which of them is the most important and reflect the core of data. This one becomes the core category. In the third step the transcripts are re-readed to selectively search for the categories and the core category. This is the selecting coding. The categories may have certain characteristics such properties and dimensions. Next step is to find relations between the categories, the linking process. The final result is usually presented as a model, a theory or a hypothesis. However the model is theoretical and the association between categories should not be seen as a correlation from a statistical perspective.

SCIENTIFIC RIGOUR IN QUALITATIVE RESEARCH
Qualitative research is still relatively uncommon in the field of physical rehabilitation and it is criticise as subjective and lacking reliability and validity by those unused to this approach. Another critical difference is reproducibility. Although this is a primary test of reliability in quantitative research, in qualitative research it is neither a goal, nor possible: "For the human science it is not necessary that a phenomenon to be investigated be duplicated identically (even if it was possible) but simply that its essential theme can be identified through its varying manifestations. To demand that the essential theme of a phenomenon and its manifestation be constant is an unnecessary reduction that not only does violence to the phenomenon, but also prohibits a correct understanding of it because the various ways it manifests itself also shed light on its essential nature" (Giorgi A. 1971).
Traditionally 4 questions are in focus to assess scientific rigour, and than quality, in research(6). It is of course as important in qualitative methodology as in quantitative tradition to establish trustworthiness. These questions in quantitative research are called internal validity, external validity, reliability and objectivity. As the basic assumptions differ, qualitative methodology uses slightly different terms and strategies to establish trustworthiness.
Lincoln & Guba (1985) present the term of credibility to answer the question about the truth value or internal validity of a study. The qualitative methodology assumption that realities are multiple reflects on the concept of credibility as the research's ability to capture these realities. Several techniques have been developed in order to increase credibility in a qualitative study, of which the most frequently used are prolonged engagement, triangulation, peer debriefing and member checking (9).
The concept of applicability, which refers to external validity or generalisability in quantitative research, relates to the concept of transferability in qualitative methodology. As qualitative samples are small, non-probabilistic and as the research deals with detailed, in-depth analyses rather than large-scale population-based studies, it is not possible to generalise the findings using traditional statistical inference. The qualitative findings aim at obtaining analytical generalisation and generating knowledge transferable to other similar social context. Qualitative researchers never deal with the question of generalisability. The readers of qualitative publications are the ones judging the value and the applicability of the findings (9).
Instead of reliability, qualitative researchers talk about dependability. The researchers and the study subjects are interrelated and interacting with each other, thus also influencing each other. And as perceived realities are constantly changing, questions of replicability are not in focus.
The last question is that of objectivity or neutrality, which become the concept of confirmability in qualitative methodology. This concept refers to the researcher's ability to be neutral to data. Confirmability is also checked by an audit trail, meaning that the auditor should be able to find the derived qualitative results well grounded in data.

Rehabilitation researchers require an expanded repertoire of research tools. Qualitative research offers a valuable and time-tested approach to the study of subjective experience. Although qualitative methods have been used in the social sciences for more than 100 years, they are only beginning to be embraced by medical investigators. Researchers have recently articulated a clear rationale for use of these methods in health-related research and demonstrated their usefulness.

OBSTACLE. QUALITATIVE IS BETTER THAN QUANTITATIVE? EXPLORING THE DIFFERENCES
Although there are good reasons to use qualitative inquiry in rehabilitation research, there are also obstacles to its use(2). One is lack of models that include the subjective meanings that patients attribute to their illness experiences. As a result, subjective meaning (and the unique context and chronological flow within which it is embedded) is not recognised as a legitimate focus of inquiry. Standard disablement models such as those developed by the World Health Organisation, although they include objective features, they do not include disablement's more subjective features, and this hampers the assessment of overall rehabilitation outcomes.
A second obstacle to the qualitative approach in medical research is lack of understanding of this approach's fundamental assumptions and the inability to differentiate them from assumptions underlying quantitative approaches to inquiry(18). Differences between qualitative and quantitative research are not only methodological but also point to different ways of knowing the world. Exploration of these differences has led to a creative dialog among researchers from the medical and social science research traditions, and a growing body of literature shows how qualitative and quantitative approaches can be effectively integrated into a single research protocol. More recent works explore the limits and potentials of "mixed-method" approaches to inquiry (10) and suggest integration of qualitative and quantitative research (11), (12).
Qualitative research is a democratic process that gives informants a voice, for instance patients in healthcare settings. Doing qualitative research is very much an innovative and open-minded activity. One disadvantage is that it is a younger research tradition than the quantitative one, at least within the field of health and rehabilitation. Therefore it is not tested as quantitative methods. It is sometimes regarded as very time-consuming, that is another disadvantage. Finally combining the two research approaches may help bridge the gap between qualitative and quantitative methodology.
Qualitative research offers an appealing approach to studying the perspectives of persons with disabilities on the quality of their lives, the effectiveness of rehabilitation interventions, and the meaning of disability(13). Rather than exploiting differences between qualitative and quantitative research to promote one approach as superior to the other, educating ourselves about the values of each offers the potential reward of effectively addressing complex rehabilitation issues in ways impossible by use of either method alone (4).

QUALITATIVE MUSCULOSKELETAL REHABILITATION LITERATURE REVIEW

Ten muscoloskeletal/ chiropratic/ othopaedic/ spinal manipulation, massage, myofunctional therapy related studies abstract (21), (22), (23), (24) were reviewed. Of those, 5 available full text were reviewed (20), of which 3 we report which according with our assessment exemplify well conducted qualitative research.
Adamsem & coll. (14) investigated fatigue's qualitative aspects in 23 cancer patients between 18 and 65 years aged undergoing chemotherapy and concurrently participating in a 6-weeks multidimensional exercise programme, using semi-structured qualitative interviews. Throughout the programme the patients experienced exercise-induced fatigue, which they associated with a sense of improvement energy and well-being, in contrast with the negative chemotherapy-induced fatigue, which they perceived as physical discomfort and uncontrollable exhaustion. The findings of this study supports the theory of exercise as a beneficial intervention strategy in the cancer-related fatigue treatment.
Monninkohof E. & coll. (15) used grounded theory analysis to support the hypothesis of the COPE self-management programme efficacy, which a previous RCT demonstrated not significantly efficacy, despite expressions of satisfaction of patients to healthcare workers. The findings of this study reported an increased self-confidence and coping behaviour as important effect of the COPE self-management programme. The qualitative interviews suggest that the primary outcome measure used in the RCT failed to capture the full experience of patients in self-management studies.

In McBurney H. & coll.s' study(16), the outcomes of a home-based strength-training programme for cerebral palsy affected young people were investigated. Using thematic coding, three categories of outcomes emerged: body function and structure, activity and participation. The study illustrated the programme generated overwhelmingly positive outcomes including benefits such perceptions of strength, flexibility, posture, walking improvement. The study provides useful indications to guide future quantitative studies of outcomes that are meaningful for people with CP.

Otherwise the follow study illustrates methodological errors in a mixed-method approach that result in threats to the validity of stated findings. In Campbell's article(17), which full text is free available on www.BMJ.com , the authors seek for concordance between the outcome validated scale data used in a RCT and the interview data used in a qualitative study. As the resulting level of concordance was less than 50%, the conclusion leaded to erroneous disparity between the quantitative and the qualitative results. Actually using qualitative and quantitative measures in contrast with one another it is incorrect, as well as comparing the two approaches has no meaning and it results in threat to the validity of stated findings. The statistical approach and the interview data are complementary, such those researchers must them use when conducting mixed research(2).

PART II: SINGLE SUBJECT DESIGN

INTRODUCTION

Single-subject research design (SSDR) can provide concrete data to validate existing theories in rehabilitation as well as formulate new ones (25). In the past several years single-subject research has become increasingly acknowledged in rehabilitation literature. However some misconceptions regarding both the design and its implementations still exist. In this issue we aim to review the basic concepts of SSDR. Some recent examples from literature in the field of manual therapy and rehabilitation are reported.

DESIGN OVERVIEW

Single subject designs are ideally suited for research in the rehabilitation practice environment. If properly applied, these designs can help establish the efficacy of rehabilitation practice and contribute to rehabilitation science(26). SSRD is an efficient and cost-effective way to assess the impact of targeted interventions on individual behaviour (27).
Single-subject research is not the same as a case study or case report. A case study provide a detailed description of a patient and the patient's responses to treatment. There is no attempt to define or manipulate an independent variable in order to examine its effects on a dependent variable, as it is required in experimental studies. In contrast, the single-subject experimental paradigm adopts the assumption of the quantitative research paradigm, except that the unit of study is an individual rather than a group.
The process of a single-subject research consists of systematic, repeated measurement of a target behaviour (dependent variable) through one or more baseline and intervention phases(25). Data are gathered for a minimum of three sessions to establish a baseline, followed by the introduction of an intervention (independent variable). Continued repeated measures are taken throughout the intervention phase, which permits cause-effect inferences to be made. If a clinically significant change occurs as a result of the intervention, then the study must be replicated across subject, settings, and practitioners to accumulate evidence to strengthen external validity.
Single-subject research also requires that only one independent variable be changed at a time and stability of the response (or target behaviour) be achieved before introducing the intervention. In practical terms, stability of response is difficult to judge before at least 5 data points because target behaviours tend to have some day-to-day fluctuations in most clinical situations.

Visual analysis of graphed data is the traditional method used in SSDR. Clinical interpretation of visually displayed data can be inconsistent between raters, however it is usually the first level of analysis in SSDR and may suggest the need for additional techniques.. Statistical analysis can quantify and strengthen visual findings. A minimum of 10 data points is recommended before statistical analysis is performed.
A patient care or an experimental single subject research design can have multiple periods of measurement and multiple times for intervention or treatment. At the onset of each of these designs, a series of baseline (A) observations are taken to assess the patient or subject in the initial or diseased state. A course of treatment is prescribed, denoted by the treatment or (B) phase. The patient or subject continues with the treatment, while assessing the effectiveness across time, using the same outcome variables that were used during the baseline phase. This describes the primary A-B single subject design. Other designs might include removal of the intervention or treatment referred to as wash-outs, the second baseline (A), a readministration of the treatment (B), or different treatments (C). The research question of interest should guide the single subject design used in terms of combinations of baselines and treatments (A-B, A-B-A, A-B-A-B, A-B-C, etc). Depending upon the research question of interest, varying combinations of phases of observation consisting of baseline, washout, intervention, and so forth. If more than one treatment is planned, the order of the treatments may be randomised; and, where feasible, the researcher and patient are blinded to the order of the treatments. Within each of these phases, multiple across time observations are obtained. If there are multiple repeating phases, these are considered as periods. One, or more than one, outcome variable(s) may be measured (2) .

ADVANTAGES AND LIMITS

Common criticisms of the single-subject approach have included the lack of generalisation, poor external validity, and the inappropriateness for statistical analysis. These criticisms appear to have little merit, and an alternative position is presented suggesting that single-subject designs hold a great deal of promise for the researcher, educator, and the practitioner in rehabilitation (28).Limitations of the single system design are generalisability (25)of the study conclusions and the methodological and statistical assumptions that are typically needed for inferential statistical tests. A single subject design provides limited support for conclusions regarding populations of subjects. The results of a single subject design may provide positive findings of the effectiveness of an intervention for a particular subject, however the portion of the population that would show this effectiveness and the size of the benefit remain unknown. The non-violation of the methodological and statistical assumptions that are typically needed for inferential tests are difficult to evaluate and test when using a single subject design, because of the limited available data. The evaluation of the validity of the assumptions is more difficult to assess in these small samples. Even with these limitations, estimates and the tests of the effectiveness or intervention effect on the studied subject can be accurately and validly tested using a single subject design. With group based research designs, internal and external validity issues need to be considered and balanced. As the primary questions for a single subject research design concern the investigation of the process of change and whether a treatment would work for a particular patient, internal validity (elimination of bias) issues are paramount. Unfortunately, because of the nature of these designs, external validity (generalisability) when balanced against internal validity is typically left with limited control. As the generalisability of the results from a single subject research study is limited, possible means of increasing the external validity, generalisability of the results, is by choosing a subject that is representative of the general type of patients for which this intervention would be used and by conducting replication studies involving variation in researchers, subjects, or practices. At times, single subject research designs have advantages over more traditional group based designs. Some advantages that are especially applicable to rehabilitation research, include: research situations where research funds are scarce, especially for professionals working in private practice or small clinical settings; research questions that aim to study the process of change; research questions that are driven by clinical work with the crucial question as to whether a treatment would work for a particular patient.

SINGLE-SUBJECT DESIGN RECENT EXAMPLES FROM LITERATURE

We selected a few examples from literature in the last 5 years using CINHAL, EMBASE, MEDLINE single subject or single system and rehabilitation or physiotherapy or physical therapy. Results: 18 studies. We propose the examples below.
Mudge-S and coll. (29) conducted a study aimed to determine the effect of a period of body weight supported treadmill training on gait in a subject with chronic stroke and to see if there was a carry-over to balance, trunk control and function. Conclusions were that a period of treadmill training has significant carry-over to balance in a subject with chronic hemiplegia.
In Hunt-GC and coll.s' (30) study design we have an example of alternating single-subject A-B and A-B-A designs. Objective of this study is to discuss biomechanical and histiological issues related to the development of plantar fasciitis and to evaluate the effectiveness of arch taping in controlling heel pain during deambulation. The study found out that Biomechanical and histiological factors need to be considered for successful management of plantar fasciitis. The arch taping technique applied in these two cases was effective in controlling pain during deambulation and could be considered as a viable treatment option for other individuals with similar clinical presentations. Slower healing time of dense connective tissue such as plantar fascia needs to be protected for longer periods of time to ensure resolution of plantar fasciitis.
Recently sport scientists have proposed the use of SSRD in applied conditioning research to understand how well an intervention (a training method) works and to predict performance for a particular athlete (33).
Other recent applications of SSRD demonstrate the benefits of a functional training for older women to alleviate mobility problems following hip fracture (34); Plant and coll.s (35) evaluated conservative management of a symptomatic flatfoot of a pre-adolescent with flexible pes plano-valgus, using a foot orthotic; the effect of passive range of motion exercises on lower-extremity goniometric measurements of adults with cerebral palsy were investigated by Cadenhead-SL and coll.s (36): this study demonstrated use of a single-subject design to measure the effect of PROM exercises on adults with cerebral palsy.; the authors concluded that the PROM exercise protocol did not have an effect on the lower-extremity goniometric measurements of the participants.

From EMBASE, key words: manipulative medicine, single subject design or single system design. Results: two studies of which one we report as an example of ABAC design applied in muscoloskeletal rehabilitation field.
In this N of 1 ABAC study design Gelfound and coll.s (31) purposed to investigate the results of a rehabilitation program in the conservative management of anterior knee pain. They posed as primary question the following: 'What is the effect of a rehabilitation program, when used in conjunction with manipulation of the lumbar spine and pelvis, for the treatment of patellofemoral tracking dysfunction (PFTD). The study was carried out over 9.5 weeks. The initial baseline (A) was collected on the first two visits. There were two 3-week treatment periods (B, C) with a 3-week period of no treatment (A) between them to establish a new baseline. The first treatment period included manipulation of the lumbar spine, sacroiliac, pubis symphysis and hip joints. The goal of the treatment was to restore mobility to the lumbar spine at the levels of innervation to the lower extremity and to maintain proper motion in the pelvis and hips for normal biomechanics. The second treatment program incorporated the manipulative techniques with an activity-specific rehabilitation program aimed at strengthening the vastus medialis obliquus (VMO) muscle. Hardcopy data, numerical pain scales, and subjective questionnaires were used to measure outcomes. Positive results were obtained in both treatment periods. The addition of a rehabilitation program in the second period produced a greater decrease in the patient's symptoms and an increase in the functional ability of daily activities.
The SSRD are under-represented in muscoloskeletal rehabilitation field and in manual therapy literature.

CONCLUSIONS

Progressions towards evidence-based practice is shaped by what forms of knowledge are counted as evidence. As even clinical reasoning activities can be viewed through two different reasoning processes: hypothetico-deductive reasoning and narrative reasoning, and as these reasoning processes have underlying assumptions parallel to those underlying quantitative and qualitative research paradigms (37), so rehabilitation science has to generate knowledge using both qualitative and quantitative approaches. Rehabilitation outcomes are utterly dependent on patients' attitudes, thoughts and motivation, and as the rehabilitation process in itself builds on social interaction, therefore studies with a qualitative design can be useful tools in the development and improvement of rehabilitation. There is nothing about qualitative research that precludes it from being considered a valid form of evidence. More recent works explore the limits and potentials of "mixed-method" approaches to inquiry. The traditional quantitative research methods represent a confined access to clinical knowing, since they incorporate only questions and phenomena that can be controlled, measured, and counted. The tacit knowing of an experienced practitioner should also be investigated, shared, and contested. (32).

Otherwise single subject designs are ideally suited for research in the rehabilitation practice environment. If properly applied, these experimental designs can help establish the efficacy of rehabilitation practice and contribute to rehabilitation science. They are an efficient and cost-effective way to assess the impact of targeted interventions on individual behaviour.
Qualitative studies and single-subject design can provide a potential contribution as valuable sources of clinical evidence in muscoloskeletal rehabilitation field.

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