How Can We Implement Single-Case Experimental Designs in Group Therapy and Using Digital Technologies: A Study with Fibromyalgia Patients

Carlos Suso-Ribera[1(✉)], Guadalupe Molinari[2], and Azucena García-Palacios[1,2]

[1] Jaume I University, 12007 Castellón de la Plana, Castelló, Spain
{susor,azucena}@uji.es
[2] CIBER of Physiopathology of Obesity and Nutrition CIBERobn, CB06/03 Instituto de Salud Carlos III (Spain), Madrid, Spain
molinari@uji.es

Abstract. Single case designs (SCDs) have been argued to reduce or eliminate some of the problems of large-scale, randomized controlled trials, including the focus on average scores, the need for control groups, the difficulties in modifying treatment protocols after study onset, and the use of a reduced number of assessment points. To date, however, SCDs have been rare due to methodological difficulties (i.e., need for repeated assessment), which is now feasible with technology. It is also rare to find SCDs in group therapy research, again due to methodological and conceptual barriers. Our aim was to set up a SCD within the context of a group delivery psychological intervention for fibromyalgia patients (FM). An app developed by our team, Pain Monitor, was used for ecological momentary assessment. The treatment protocol integrates CBT techniques with positive psychology, pain acceptance, and mindfulness exercises. In this study, we intend to discuss how SCDs can be construed in the context of group therapy. We will present benefits and shortcomings of this methodology in this context and finally we will expose a real case with FM patients from our on laboratory which is currently running. In this investigation, a multiple baseline design was selected, but examples using other designs, such as ABAB (A = baseline; B = treatment), changing criterion, or alternating treatments, will be discussed with the same sample to provide an overview of different possibilities to address group treatment research using SCDs.

Keywords: Singe case experimental design · Smartphone app · Fibromyalgia

1 Introduction

Clinical research in the past decades has been dominated by large-scale, randomized controlled trials that investigate the effectiveness of one or more interventions compared to a control condition (i.e., waiting list or a well-established treatment to be used for comparison). In such designs, a number of assessment points (i.e., pretreatment, posttreatment, and a varying number of follow-ups) is usually included to demonstrate

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treatment effectiveness. By doing this, because of the reduced number of evaluation points, treatment effectiveness is compared at the mean level at the group level [1].

While randomized controlled trials have certainly contributed to the advance of clinical research, important limitations of this methodology should not be ignored. For instance, the limited number of assessment points frequently included in large-scale studies affects the reliability of measurements at the individual level, especially when outcomes can easily fluctuate (i.e., mood). Additionally, the focus on the average level of change makes the validity of findings limited for the individual and the need for a control group results in ethical concerns. Finally, the use of this methodology is problematic when disorders or outcomes of interest are infrequent in daily practice or not prevalent in the population and when a new treatment for which there is no previous evidence is to be tested, as there is risk for low efficacy or even side effects that would affect large samples [2].

Single case designs (SCDs) are an alternative to large-scale, randomized controlled trials in clinical research. Different to large-scale interventions, SCDs require repeated assessment over time (at least five measurements in the baseline phase and five measurements in the treatment phase), evaluate the effectiveness of interventions in the individual as opposed to averaging group scores, eliminates the need for control conditions (each individual acts as his/her own control in the baseline phase), and is suitable when disorders or outcomes are infrequent or when a new treatment is being tested (it can be used with a single individual). Regarding the latter, while SCDs are usually seen as having limited external validity because they can be applied to a single individual, replications of the single effect in an increased number of subjects is perfectly possible (and recommended), thus increasing the generalizability of findings [3, 4].

Despite the use of SCDs in clinical research has important benefits, their use has been limited, arguably due to methodological difficulties. For instance, repeated assessment was initially made using paper diaries and more recently with telephone calls. Both procedures are problematic as resulted in frequent missing or unreliable information (i.e., paper diaries) or they were very time- and cost-consuming (i.e., phone calls). The explosion of smartphones and the increasing use of apps have renewed interest in SCDs as they facilitate ecological momentary assessment with reduced costs. The previous has resulted in a significant increase in the number of single case investigations in clinical research in a variety of conditions [5].

The application of SCDs in group therapy, however, is still rare, which we believe is due to the difficulties in designing a study that fits the assumptions and requirements of SCDs in a group delivery context. For instance, SCDs need three attempts to replicate treatment effect, so AB (A = baseline; B = treatment) and ABA designs are not considered adequate experimental studies. Only ABAB, multiple baselines with three baselines, changing criterions with three criteria, and alternating treatments with three treatment effect replications would be acceptable [6].

Our goal is to discuss how SCDs can be effectively implemented within a group therapy context. An example of an ongoing study from our group using multiple baselines with fibromyalgia patients will be presented, but the remaining designs will also be described for the same sample to provide the reader with different design options for group treatment. Fibromyalgia is a prevalent and disabling syndrome

characterized by generalized pain, fatigue, and stiffness which presents with a high comorbidity of affective disorders [7]. Fibromyalgia patients were selected because psychological intervention, such as cognitive behavioral therapy, mindfulness-based treatments, or acceptance and commitment therapy, in a group format is very frequent in this population [8, 9] and because a new treatment including components of other well-established interventions was to be tested. The feasibility of using this methodology including apps for repeated assessment is also discussed in the paper according to our experience.

2 Method

2.1 Participants

Five patients were referred by a rheumatologist from the Rheumatology Unit of the General Hospital of Castellon, Spain. After the screening interviews, three patients were accepted into the study (two of them had difficulties in attending group sessions weekly) and further assessments were conducted. The three patients were women. P1 has 62 years old and a disease duration of 10 years. She is married, has basic levels of education, and is an active worker. P2 has 44 years old and a fibromyalgia (FM) duration of 2 years. She is married, has basic levels of education, and she currently does not work due to a sick leave. P3 has 36 years old and a disease duration of 2 years. She is single, has a university degree, and is an active worker.

2.2 Measures: Ecological Momentary Assessment with Pain Monitor

Assessment was made with a smartphone app developed and validated by our team [10]. In the app, the initial evaluation consists of a set of sociodemographic and pain- and health-related outcomes, including pain localization, average pain intensity and interference in the past two weeks, and overall perceived health status, among others. This group of questions is administered once after downloading and using the app for the first time.

EMA begins the day after the first evaluation and occurs twice a day (10 am and 7 pm with two-hour response flexibility) throughout the study duration. Morning and evening evaluations share a number of items, such as pain intensity and mood (i.e., sadness, anxiety, anger, and happiness), because these variables can vary within the same day. Other constructs are either evaluated in the morning (i.e., interference of pain on sleep) or in the evening only (i.e., interference of pain on daily activities, use of rescue medication during the day, and symptoms experienced during the day). Finally, psychological variables (i.e., pain acceptance, catastrophizing, and fear of pain) are either included in the morning or the evening administration to balance the duration of the evaluations.

At the end of study (i.e., after the 11 weekly sessions), a final assessment is made. Similar to the initial evaluation, this final assessment is administered once only. This includes some sociodemographic information to explore changes compared to the initial assessment (i.e., marital and job status), but also explores additional variables

that are important for the evaluation of the treatment effectiveness (i.e., perceived change after treatment and stressful life events experienced during the study).

2.3 Treatment

The psychological treatment program integrates CBT techniques with positive psychology, acceptance, and mindfulness tools, which have shown evidence in the treatment of chronic pain [11]. The therapeutic components of the program are: Motivation for Change, Psychoeducation, Cognitive Flexibility, Behavioral Activation, Positive Psychology strategies, Mindfulness, Self-compassion, and Relapse Prevention.

The first session of the treatment is "Motivation for Change" and it was delivered individually in order to establish the multiple baselines. This session focused on each participant's motivation to participate in the psychological treatment. Participants set individual goals to be achieved during and at the end of treatment. The rest of the treatment consists of 11 weekly sessions of an approximate duration of 2 h applied in a group format. Every session is held at the University and is conducted by a psychologist. A more detailed description of this multicomponent treatment can be seen in Table 1.

2.4 Procedure

The rheumatologist of the local public hospital provided the participants' with general information about the study and referred FM patients interested in participating. Patients had to fulfill the American College of Rheumatology criteria for primary FM [12]. Also important for the present study, inclusion criteria included having access to a smartphone using Android operating system, having Internet connection, and not presenting a severe psychiatric condition.

At the start of the first week, participants attended an individual information and assessment session on different days to establish the multiple baselines. In this initial session they were informed about the characteristics of the study and were asked to download the app. All participants attended voluntarily and received no economic compensation to participate. All the sessions took place in a therapy room at the Jaume I University and all the appointments were set at the same day to fulfil the requirements of this type of design. Once the participants gave written informed consent to participate, a brief structured interview was conducted in order to assess pain history and previous treatments. After this initial assessment, the psychologist and lead author, GM, who has been trained and is experienced in this type of treatments and population, explained the use of the Pain Monitor App to the patients and helped them to download it from the Google Play Store. Once the Pain Monitor App was installed on the participants' smartphone, they completed the initial assessment with the support of the psychologist. No technical or usability problems were detected at this stage, so further assessments were made without the supervision of the lead researcher.

Previous to recruitment, all participants were randomly assigned to one of the three study conditions (i.e., 5 days, 7 days, or 9 days of baseline assessment). This meant that participants recorded their responses to the app daily in their natural environments for 5, 7, and 9 days prior to the treatment onset. The random assignment of the participants

Table 1. Description of each of the sessions of the psychological treatment

Session	Content	Objective
Session 1	**Motivation for change**	To analyze the advantages and disadvantages of change, emphasizing the importance of being motivated
Session 2	**Psychoeducation**	Provide information about fibromyalgia taking into account related medical, psychological and social aspects. Explanation of the rationale of treatment and group therapy rules
Session 3	**Acceptance**	Recognition of one's own physical limitations and changes in habits caused by fibromyalgia. Learn to be in contact with one's own experience, even when it is not pleasant, and accept it as it is. Acceptance of this "new self"
Session 4	**Activity Programming**	Increase the number and intensity of positive emotions through an appropriate level of activity to better cope with pain. Each participant has to select a list of meaningful activities to perform during the treatment
Session 5	**Mindfulness**	Practice of mindfulness meditations to lower the perception of pain, reduce tension, and improve functioning and well-being
Session 6	**Cognitive flexibility**	Learn to identify and modify maladaptive thoughts, and to generate other alternative interpretations to different situations
Session 7	**Communication strategies**	Learn to identify the main communication problems to move towards more effective communication. Improve interpersonal relationships, self-esteem and put into practice assertiveness
Session 8	**Self-compassion**	Learn the need to take care of ourselves, to be kind to ourselves, seeking well-being and the relief of suffering
Session 9	**Relapse prevention**	Review all the skills learned during treatment and see how to maintain and continue with the progress made so far. Assess the way to act in future risk situations

to the different experimental conditions was generated by an independent researcher according to a randomization list created by an online randomizing program [13].

After the baseline assessment period, participants attended to the first treatment session individually (i.e., "Motivation to Change" session) after 5, 7, or 9 days of study onset in order to establish the multiple baselines (see Fig. 1 for a summary of the design). Participants set individual goals to be achieved during treatment. The following week, participants started group treatment. Weekly sessions were also held at the University and had an approximate duration of 2 h. All sessions were conducted by a clinical psychologist.

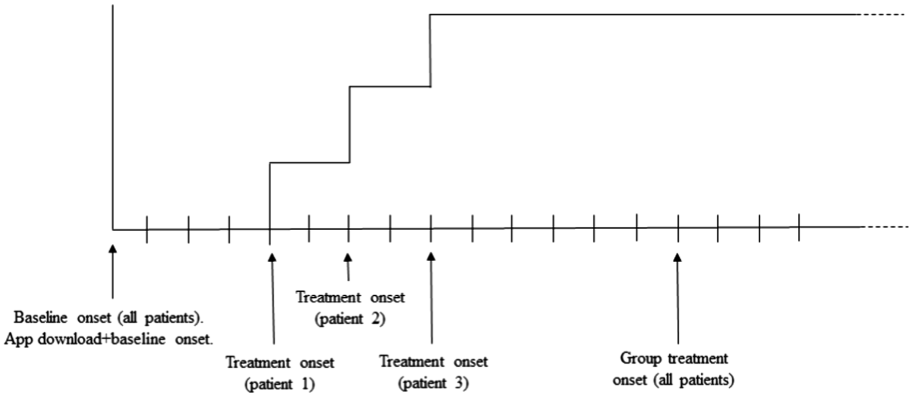

Fig. 1. Graphical representation of the multiple baseline study design. The first treatment session, which occurs at different moments to establish the multiple baselines, is individual and addresses content related to motivation to change. After the group treatment onset, the subsequent group sessions occur on a weekly basis and are not shown in the Figure to facilitate its interpretation. The x axis represents days and the y axis represents each participant.

3 Discussion

3.1 Advantages and Barriers to the Implementation of a Multiple Baseline SCD in a Group Format Supported by Technologies

The present study is currently ongoing (four therapy sessions have been delivered so far), but positive aspects and difficulties in the design and implementation of a SCD in a group format supported by an app have been already revealed. First, an advantage of using a SCD has been that the study could be implemented with a reduced number of women and that a control group was not required (the baseline phase is used as the control for each individual). We calculated that, with an anticipated effect size of 0.40, an alpha level of .005, a power of .80, two conditions (treatment vs control), and 10 measurement points only (5 for the A phase and 5 for the B phase), we would need more than 110 patients using a traditional randomized controlled trial [14]. Additionally, this would mean having a control group, which is ethically problematic. Another advantage of the SCD is that treatments can be modified if an issue emerges (i.e., the treatment is causing side effects or not being effective). In the present study, this has not been necessary, but the treatment could be adapted for the whole group if required. Finally, repeated assessment tends to be a challenge in SCDs, which was efficaciously minimized with the use of a smartphone application. In the past, paper diaries and telephone calls have been used but proven to be unreliable or inefficacious. Our experience in the present and past research is that the use of apps finally makes EMA feasible.

While acknowledging the benefits of this design for group psychological treatment in particular and clinical research in general, we also noted some difficulties in the present investigation. For instance, the multiple baseline design, which we believe best suited the study goals (see the next point for further discussion), implies that

participants had to start the treatment phase on different days, which might be difficult in group treatment. We have proposed a solution for this problem, but other studies might need a different strategy to manage this requirement. Another limitation that we have observed when implementing a SCD in a group psychological treatment for FM is that technology is still a barrier for a number of individuals, especially older ones. The physicians who referred the patients to us indicated that some potential participants had very old phones with no Internet connection, so their inclusion was not possible. This is certainly a problem we will face in the next years when using technology for research, but the increasing availability of smartphones is likely to minimize this difficulty [15].

3.2 Alternatives to a Multiple Baseline Design for Group Delivery Using Technologies

In the present investigation, a multiple baseline SCD was selected because we believed this design had the best fit to the study purposes and characteristics. However, we will now present other SCDs and discuss how they could be implemented in the same study presented above (i.e., group psychological treatment of FM patients), together with their advantages and disadvantages.

ABAB Design. An ABAB design is a straightforward SCD that consists of a baseline phase (A), followed by treatment phase (B), a withdrawal phase (A), and a final treatment phase (B). Simpler forms of this design are AB or ABA designs, but these do not meet the requirements for adequate SCDs (i.e., three replications of the treatment effect). In the present investigation, an ABAB design for the psychological treatment of FM patients in a group format with the help of technology for EMA could have been easily implemented [16]. First, all patients should have started the baseline assessment with the app on the same day. Next, at least five days after the initial assessment (five assessments are the minimum to meet the requirements of excellent SCDs) [6] all patients would start the treatment in a group format (note that this is largely different from the multiple baseline design). After a number of treatment sessions (this might vary depending on the treatment), the treatment would be withdrawn and a return to baseline scores in the outcome measure (i.e., mood or pain intensity or interference) would be expected. A new treatment phase is then started to obtain the third evidence of treatment effect (improvement from A to B, worsening from B to A, and new improvement from A to B).

As described above, this is a straightforward design to be used in group (and individual) format is one is to implement a SCD, which is one of the strengths of this design. However, in the present study an ABAB design would have been problematic because the return to baseline levels after treatment withdrawal is rare in psychological treatments [17]. In fact, increasing the patient's ability to deal with difficult situations outside the therapy context and in a large number of settings (i.e., generalization) is one of the main goals of psychological interventions, so this design is not suitable when a return to baseline levels is not expected in the transition from B to A.

Changing Criterion Design. In the changing criterion design, participants are required to reach a specific goal (i.e., criterion) that changes at different stages of the study (i.e., when the goal is repeatedly met). Similar to the previous design, three

replications of a treatment effect are required to meet the standards for SCDs, which means that at least three different criteria are needed [6]. In the present investigation, the three criteria could have been: a reduction of 10% in pain interference compared to baseline levels, a reduction of 20% in pain interference compared to baseline levels, and a reduction of 30% in pain interference compared to baseline levels. This means that a first study goal would be to achieve and maintain a reduction of 10% in pain interference during five or more days after the onset of treatment. Once this was achieved, a more difficult criterion of 20% reduction would be set and, again, this should be maintained for five days or more. Finally, the third replication of treatment effect should be achieved with a 30% reduction of pain interference.

While this design is perfectly feasible for the present investigation and has important benefits (i.e., only one participant or group of participants are needed), a barrier for using this method is that goals have to be successively achieved at the established criterion, but not further [18]. Therefore, if a patient or group of patients showed a large reduction in pain interference of 30% in the first step (when the criterion was 10%), we could not conclude that the reduction was due to the effect of treatment or due to an external event that occurred at the same time as treatment onset (i.e., obtained a sick leave or there was a change in the tasks assigned at work). Therefore, if the treatment was "too effective", this would become an AB design which prevents us from drawing causal conclusions. Because we anticipated that the change obtained with our treatment would be difficult to restrict to a specific criterion (i.e., it is difficult to indicate pain patients in the group that they should improve functioning despite the pain, but to a certain extent only), a changing criterion design was not felt like the most appropriate design for our purposes.

Alternating Treatments Design. In an alternating treatments design, two or more interventions are provided alternatively after a baseline phase. Next, the treatment that appears to provide the smaller effect (i.e., when graphically representing the evolution on the outcome of interest or after overlap calculations) is withdrawn and the most effective treatment is left alone to ensure that the efficacy revealed when both treatments were provided together is maintained when the arguably most effective one is presented alone [19].

In the present investigation, our goal was not to compare the effectiveness of two interventions, so this design was not suitable. However, we discuss how this could have been implemented if two treatments, such as cognitive behavioral-therapy (CBT) and acceptance and commitment therapy (ACT), were to be compared. After a baseline phase, CBT and ACT sessions would be randomly alternated (2 CBT sessions, 1 ACT session, 1 CBT session, 2 ACT sessions, 2 CBT sessions, 3 ACT sessions, etc.) until the full treatment is delivered. All group members would attend all sessions. Assessments would be made during the whole study duration and a graphical representation would evidence whether the outcome of interest (i.e., depressive symptoms) was more largely improved after the delivery of one of the treatments (e.g., CBT). Finally, to ensure that the effectiveness of CBT was not due to the interaction with ACT, CBT would be provided alone and the graphical analysis would indicate whether the effect on the outcome was maintained after removing ACT.

3.3 Analytic Strategies

An in-depth discussion of the analytic strategies for SCDs is out of the scope of the present investigation. However, we believe that a brief overview of this topic, including some recommended references will be important for the reader. Early studies using SCDs mostly relied on visual analysis (i.e., analysis of changes in trend and slope) between phases, with an emphasis on clinically meaningful changes in outcomes [6, 20]. While graphical visualization is clearly informative, more rigorous procedures have emerged in the past decades. Note, first, that the presence of autocorrelation in SCDs (time series data) means that traditional tests, both parametric and non-parametric, are not appropriate for the calculation of treatment effects, so a different analytic approach is required for SCDs. Some of the most frequently used analytic strategies in SCDs include calculations of overlap between baseline and treatment phases [21]. Several overlap methods exist, which mostly differ in the number of baseline measurement points included in the analyses (i.e., some take the median, while others use non-overlapping data only). However, the *non-overlap of all pairs*, a strategy that includes the comparison of every measurement in the baseline phase and every measurement in the treatment phase, is the procedure that has shown to be more robust to bias [22]. In addition to an analysis of overlap, randomization in SCDs (i.e., of both participants and duration of baseline phases), as performed in the present investigation, allows for more sophisticated calculations, such as the analysis of randomized tests, a nonparametric of treatment effect size [23, 24].

4 Conclusions

The present study aimed at presenting a SCD for group psychological treatment of patients. The use of SCDs is gaining ground in clinical research, arguably to the explosion of smartphones, which have made EMA a feasible alternative to episodic, onsite assessment. Despite this increasing interest in these designs, the literature in this field is still scarce, especially in relation to group treatment formats. We have presented the four most commonly used SCDs and we have provided an example of how group psychological treatment of FM could be implemented with each design. In doing so, we have discussed the advantages and barriers to implementing each design in a group format, as well as the methodological requirements for each method.

We believe the present work will provide new light into clinical research using group formats and SCDs and will encourage researchers to implement these designs in future research.

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