Load monitoring on Pilates training: a study protocol for a randomized clinical trial

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Study protocol

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Abstract

Background: Currently there are campaigns to raise the awareness of the need to practice some physical exercise with several objectives, mainly as a preventive character. From this perspective, we can see the use of the Pilates method as an instrument of therapeutic exercise for the protection and promotion of health. However, despite being popularly performed, there is still no scientific evidence on the standardization of the use of the method and its progression to an adequate prescription of physical training. Therefore, the purpose of the study was to develop a protocol to monitor the progression of Pilates loads daily between the basic, intermediate and advanced levels, as well as to analyze the effect of the method on the psychometric, cardiorespiratory and autonomic parameters. Methods: there will be a total of 36 sessions of Pilates mat for 32 healthy men. In each training session, initially, cardiorespiratory parameters, pain through the Visual Analogue Scale (VAS), and a psychometric questionnaire will be collected for the volunteers. Heart rate (HR), subjective perception of effort (SPE), and RR intervals will be measured during the sessions for subsequent use to analyze the progression of the loads by monitoring the internal training load and heart rate variability (HRV), respectively. At the end of the sessions, cardiorespiratory parameters, the VAS, the psychometric questionnaire will be measured again and the participants will only be released after 15 minutes of rest for the final HR analysis and to re-respond to the PSE scale. Before and after the 36 sessions of training, participants will also be evaluated in relation to psychometric, cardiorespiratory, and autonomic parameters. Discussion: this study deserves to be highlighted as it is a parallel randomized clinical trial with standardization of training, with the purpose of monitoring the prescription of loads of the method, as well as verifying its efficacy in clinical, cardiorespiratory, and autonomic outcomes. The easy reproducibility of the protocol from its description, also improves the study, besides providing support for prescribing the method to the professionals involved.

Background

The Pilates method can be proposed as an alternative therapeutic exercise for the protection of risk factors and health promotion (1). However, in the current scientific scenario there is only one literature review that investigates the Pilates method (2), based on references of low methodological quality, which evidences the lack of standardization of the use of the method and its progression of loads as a form of physical training (2). Thus, for the prescription of resistance exercises, as in the Pilates method, monitoring of physiological variables, such as heart rate (HR) (3), cardiac autonomic modulation (4, 5), and subjective variables such as subjective perception of effort (6) become useful for safe practice.

Thus, the search to find simple and low-cost methods that are able to control the intensity of various types of exercises is important due to the adaptations that the psychobiological system suffers through training, improving exercise tolerance and influencing physical performance (7). Therefore, it would be useful to use subjective perception of effort together with HR to quantify the training intensity of the Pilates method, as well as to use cardiac autonomic modulation to assess the oscillations of the cardiac autonomic nervous system during its execution, since heart rate variability (HRV) is considered an early

and sensitive indicator of health impairment, indicating good or poor adaptability of cardiac autonomic control against some stimulus (8, 9).

Although the Pilates method is becoming more widespread and showing promising clinical and functional outcomes in the areas of rehabilitation (10, 11), there is a need for quality clinical trials in order to analyze the intensity of the training. The results of these trials will offer greater support for the use of tools that can assist in the moment of prescription and progression of load in Pilates practice, besides demonstrating the effects of the method on the cardiovascular system and autonomic control.

Therefore, the objective of this protocol is to monitor the progression of loads daily between basic, intermediate, and advanced levels through HR, subjective perception of effort, and HRV for 12 weeks, as well as to analyze the effect of the method on psychometric, cardiorespiratory, and autonomic parameters. It is hypothesized that the protocol proposed by the study will be able to be prescribed clinically, proving that PSE, HR, and HRV are useful tools for monitoring the progression of the loads of the method, in addition to presenting favorable results for the psychometric, cardiorespiratory, and cardiac autonomic modulation parameters after 12 weeks of training.

Methods

Study Design

A parallel randomized clinical trial will be conducted at the Center for Studies and Assistance in Physiotherapy and Rehabilitation of the Universidade Estadual Paulista (FCT/UNESP), Presidente Prudente, SP, Brazil. The trial was registered at ClinicalTrials.gov (NCT03232866) and approved by the Research Ethics Committee of FCT/UNESP, Presidente Prudente, SP, Brazil (Protocol no. 061942/2017). The study protocol follows the *checklist* of SPIRIT 2013 *(Standard Protocol Items: Recommendations for International Trials)* (36) and the *TIDieR (Template for Intervention Description and Replication)* (37), indicating that the information and quality of the reports of the interventions are well described (38). Prior to the procedures the volunteers will receive oral and written instructions and will sign a consent form agreeing to participate in the study. All personal data will be confidential. It is also worth noting that, although very unlikely, participants who suffer any kind of damage resulting from the collections will receive free evaluation and physiotherapeutic treatment.

Participants will be divided into two groups: Pilates group and control group. Participants of the Pilates group will undergo 12-weeks Pilates method training, which will be held three times a week for approximately 60 minutes each session, totaling 36 sessions. During this training period, participants will be required to pass through the three levels of the Pilates method: basic, intermediate, and advanced. The control group will be oriented to maintain their daily activities without the inclusion of any type of training. The flowchart of the study design and group composition is shown in Figure 1.

Participants

A total of 32 healthy male volunteers will be recruited from the local university (UNESP) through pamphlets, online media, personal invitation, telephone, SMS. These procedures are recommended by Treweek *et al*. (12) as strategies to improve participant recruitment.

The inclusion criteria will be: male, 18 to 35 years of age, healthy (self-report), not having practiced the Pilates method prior to the study, not being smokers or alcoholics, not presenting metabolic, cardiac, and/or endocrine disorders, having no arrhythmias, not using drugs that influence the autonomic modulation of the heart, and not presenting physical limitations such as musculoskeletal, inflammatory, and/or neurological diseases that prevent the performance of Pilates.

Individuals with an episode of musculoskeletal injury during training, adherence to training of less than 85% of sessions, failure to progress between the three levels of the Pilates method, not able to respond adequately to subjective scales, and who present errors in the captured RR intervals will be excluded from the study. Participants will be instructed to maintain their daily dietary routine and abstain from anti-inflammatory medications and analgesics, as well as not performing any other type of exercise during the collection period. This information will be reinforced during the training period and monitored by self-report (13).

Randomization

Prior to the randomization process, baseline data will be collected from participants who meet the eligibility criteria and sign the informed consent form. To ensure hidden allocation, randomization by groups (Pilates group or control group) will be performed by another researcher not involved in the recruitment using a computer-generated randomization schedule.

Details of procedures Study outline

The evaluations will be carried out at FCT/UNESP, Presidente Prudente, SP, Brazil, in a room with controlled temperature and humidity, at the same time of day. For the initial evaluation, after completing the personal information, the participants will receive a psychometric questionnaire (14). After, the anthropometric parameters of each participant will be collected and posteriorly the body mass index (BMI) will be calculated.

In addition, systolic (SBP) and diastolic blood pressure (DBP), HR, respiratory rate, and oxygen saturation will be measured. After this stage, the participants will be sent to a quiet room where a cardiofrequency meter (Polar Electro Oy, Kempele, Finland - model V800) will be placed for 20 minutes, recording HR beat to beat for later analysis of HRV.

The Pilates method training will begin the week following three sessions of familiarization. In each training session, initially cardiorespiratory parameters (SBP, DBP, respiratory rate, HR and oxygen saturation), pain (VAS), and psychometric questionnaire will be collected for basal control. For the progression of the loads, the HR, subjective perception of effort, and vagal indices of HRV will be used. These parameters will be collected during the exercises, the HR being verified and applied to the

subjective perception of effort scale every five minutes, and the RR intervals recorded during the whole session. At the end of each session, the cardiorespiratory parameters, VAS, and psychometric questionnaire will again be measured, and volunteers will only be released after 15 minutes of rest for the final HR analysis and after re-responding to the subjective perception of effort scale.

At the end of the 36 training sessions of the Pilates method, the final evaluation containing the cardiorespiratory parameters, psychometric questionnaire, and HRV will be carried out. The control group will only perform the initial and final evaluations identical to the Pilates group. For better understanding, the study design scheme is shown below (Figure 2).

Pilates method exercise protocol

The exercises that will from part of the protocol are shown in Appendix 1. The exercise sequences will be divided in different ways in order to make the training more dynamic and avoid sample losses (Appendix 2).

It is worth mentioning that the proposed exercise protocol was elaborated by the researchers of the project based on an extensive bibliographical survey about the exercises and their respective progressions; this protocol was based on the degree of difficulty of each exercise as well as the volume/intensity interdependence of training.

Primary outcome

Quantification of the internal load of the training will be evaluated daily through the subjective perception of effort (6), HR (15), and HRV (15). The subjective perception of effort consists of a scale proposed by Borg where the participants choose the descriptor and number that best represents their psychophysiological stress about the training session in question (6).

Prior to the sessions, participants will be instructed to respond to the subjective perception of effort scale. It will be explained to the participant that during the exercise it is necessary to perceive how much effort they are using so that every five minutes of each session they can respond according to their individual perception on how exhausting the exercises are. In addition, 15 minutes after the end of each session, the participant's subjective perception of effort will be collected again (6).

The participants will respond by looking at the scale ranging from 6 to 20 points, where 6 means "no effort" and 20 means "maximum effort." To avoid biases in the questioning, the following question will be standardized: “From 6 to 20 points, how do you rate your perception of effort now?”. All responses will be recorded in individualized records and all participants will be previously familiarized with the scale (6).

In each session the value obtained from the subjective perception of effort scale 15 minutes after the end of the session will be multiplied by the duration of the session in minutes, and the product represents the internal load given in arbitrary units (A.U.). The intensity of the session will be divided into three zones according to the Borg scale used in the study of Moreira *et al.* (16). In addition, during the sessions the

internal load will also be monitored by means of the subjective perception of effort scale every five minutes.

Quantification of the internal load training by the HR will be performed using the TRIMP method that evaluates the volume and intensity of the session through specific scores in each training zone, as proposed by Edwards (17, 15)

In addition to these methods of monitoring loads, the analysis of HRV will be used. The weekly mean of rMSSD (rMSSDmean) expressed in milliseconds and the weekly intra-individual coefficient of variation of rMSSD (rMSSDcv) expressed in percentages will be used (18, 19). These indices will be transformed in to a logarithm to avoid outliers and simplify their analysis.

Secondary outcomes

The HRV analysis will be performed from the series of RR intervals captured by the cardiofrequency monitor and linear methods, analyzed in the time and frequency domains, and the Poincaré plot will be used for analysis. All HRV indices will be obtained through Kubios HRV software version 3.1.0.

For this analysis the time series of RR intervals will initially be subjected to digital filtering with moderate filtering using Kubios HRV software version 3.1.0, supplemented by manual filtering for the elimination of premature ectopic beats and artifacts and only series with more than 95% of sinus beats will be included in the study (20). Through the visual analysis of the time series, the absence of artifacts or ectopic beats will be observed that can interfere in the analysis of HRV.

The RR interval series will be analyzed in the moments before and after the 12 weeks of training with 1000 RR intervals in each analysis. In addition, daily tracking of each session will be analyzed, with established stretches of RR intervals every five minutes. In these stretches, 256 consecutive RR intervals will be obtained. In both analyzes the stretches of greatest stability will be observed in order to avoid bias of analysis and data interpretation (5).

The time domain (rMSSD and SDNN) (21), frequency (low frequency [LF] and high frequency [HF]) (22,23), and Poincaré plot (SD1 and SD2) (24, 25) HRV indices will be used (28) for the analyzes before and after the 12 weeks of training. For daily tracking, only the time domain indices and the Poincaré plot will be used.

Heart rate (20, 26), respiratory rate measurements (26) and oxygen saturation will be captured (27). Blood pressure will also be checked (28) as well as subjective pain assessment will be obtained through visual analog pain scale (29, 30, 14). Volunteers will be asked to fill out a psychometric questionnaire (14) before and after the training ends, as well as fill it out before starting training on all training days.

All these outcomes will be collected in the initial evaluation and in the final evaluation after the end of the 12 weeks of training, in addition to being collected daily in the initial and final moments of each session of the Pilates method. The description of the specific outcome collection moments can be seen in Table 1.

Masking/Blinding

Outcomes will be collected at baseline prior to randomization and in the final evaluation by trained evaluators blinded to group allocation. In addition, data will be collected throughout the training period of the Pilates method by other independent evaluators. The statistician of the study will also be blinded. In this study design it will not be possible to blind the participants and therapist who will minister the sessions of the Pilates method due to the control condition.

Sample size calculation

The sample calculation was carried out based on Barbosa *et al.* (31) in which the variable SDNN was selected. The clinically relevant difference was 25.13 ms and the standard deviation 24.00 ms. The significance level for the sample calculation was 5%, the power of the test 80%, and the two-tailed hypothesis test. The value obtained from the sample calculation was 14 volunteers. 10% of the total value of n was added to statistically suppress the analyzes if there were withdrawals during collection dynamics, thus obtaining a sample of 16 volunteers per group.

Statistical analysis

For analysis of the data of the population profile, the descriptive statistical method will be used and the results presented as values of means, errors and standard deviations, percentages, and absolute numbers. The normality of the data will be evaluated through the Shapiro-Wilk test. For the comparison of the population profile and the cardiorespiratory, autonomic, and psychometric parameters in the initial and final evaluations, the paired t test will be used for normal data or the Wilcoxon test for non normal data and for the comparison between the groups, the unpaired t test or Mann-Whitney test will be used depending on the normality of the data, with the significance level set at $p < 0.05$. The differences based on magnitudes (Δ = final value - initial value) will also be collected (32, 33) to verify the differences between the initial and final moments.

For analysis of the internal training load, the Pearson or Spearman correlation will be used, according to the normality of the data, to correlate the dependent variables rMSSDmean, rMSSDcv, subjective perception of effort, and HR with the variables of the psychometric questionnaire and VAS. The threshold used to quantitatively evaluate the correlations will be based on Hopkins (33) using the following criteria: <0.1 trivial; 0.1 ≥ 0.3 small; 0.3 ≥ 0.5 moderate; 0.5 ≥ 0.7 large; 0.7 ≥ 0.9 very large; and> 0.9 almost perfect.

The definition of the cutoff points for load increments with the HRV indices and PSE will be obtained by the Receiver Operating Characteristic (ROC) curve. The sensitivity, specificity, positive predictive value, and negative predictive value for each level of the Pilates method will also be recorded. The area under the curve will be considered significant when values ≥ 0.65 are obtained (34), in addition to which, a comparison will be made between the ROC curves of each HRV index to detect which is the most representative index to determine the internal load training of the Pilates method.

Statistical analysis will be carried out through the *Statistical Package for the Social Sciences* – version 15.0 (SPSS Inc., Chicago, IL, EUA) and *MedCalc Software bvba* – version 14.10.2 (Oostende, Belgium). The data will be typed twice. All participants included in the initial assessment will be considered under the intent-to-treat approach in which the worst outcome obtained by the study group will be selected to ensure the power of the data analysis.

Discussion

Previous systematic reviews report a beneficial effect of the method on risk factors for various diseases, as well as positive responses in outcomes such as strength, flexibility, low back pain, and quality of life, among others (2, 34, 35). However, the low methodological values of the quality of the existing studies and the lack of load monitoring for the exercise prescription do not yet allow definitive conclusions about the real effect of the Pilates method, besides the lack of studies investigating the effects on cardiac ANS in the individuals who practice it.

Methodological characteristics commonly found in studies published in the literature include lack of concealed allocation, and an absence of the intention-to-treat approach when analyzing data, blind assessors, and standardization of training respecting biological principles, and familiarization of participants with the method. This study deserves to be highlighted as it is a parallel randomized clinical trial which has the purpose of verifying the effectiveness of the Pilates method for the cardiac ANS and, mainly, to monitor the prescription of the method loads.

The protocol created in this study was based on the most recent literature on the subject. In addition, another strong point of the study is to present a parallel randomized clinical trial design, which addresses intention-to-treat. The easy reproducibility of the protocol from its description, meaning it can be reproduced anywhere, also enhances the study. However, one limitation of this study is the inability to blind participants to the application of the method.

This study will contribute by providing information on the real autonomic benefits provided by this type of physical exercise and can be used to guide practitioners in prescribing the method, as well as offering more support to practitioners.

It is also worth mentioning that this study contemplates the checklist items for protocol studies in order to minimize bias and has been prospectively registered. The outcomes will be disseminated through publications in scientific journals and presentations at area congresses.

Trial Status

Number protocol: NCT03232866

Patient recruitment is currently underway.

Study start date: September 1, 2018

Primary completion date: February 2019

Study Completion date: December 2019

List Of Abbreviations

ANS: autonomic nervous system; HR: heart rate; HRV: heart hate variability; RPE ratings of perceived exertion; SMS: Short Message Service; RR: R-R interval; BMI: body mass index; SRP: systolic blood pressure; DBP: diastolic blood pressure; VAS: Visual Analog Scale; rMSSD: Root mean-square of successive differences of adjacent RR intervals; SDNN: Standard deviation of all RR intervals; LF: low frequency; HF: high frequency; SD1: Standard deviation of data against the axis x=y in Poincaré plot; SD2: Standard deviation of data against the axis, which is orthogonal to the axis x=y (crosses this axis at the mean value of the data) in Poincaré plot.

Declarations

Ethical approval and consent to participate

Ethical approval was granted by the Ethics Committee of Universidade Estadual Paulista FCT/UNESP (061942/2017). Informed consent will be obtained from all study participants.

Consent for publication

The patient consented to the publication of his images.

Availability of data and materials

Not applicable

Conflict of interests

The authors declare no conflict of interest.

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Authors' contributions

APSC and FMV are responsible for the study design. APSC, EPJ, AFM, TMB, CMP, and FMV commented on the various versions of this study protocol. APSC, EPJ, TMB, AFM, and FMV will be involved in recruiting participants and collecting data. All authors approved the final manuscript.

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Table

Due to technical limitations the table is only available via download with the supplemental material.

Figures

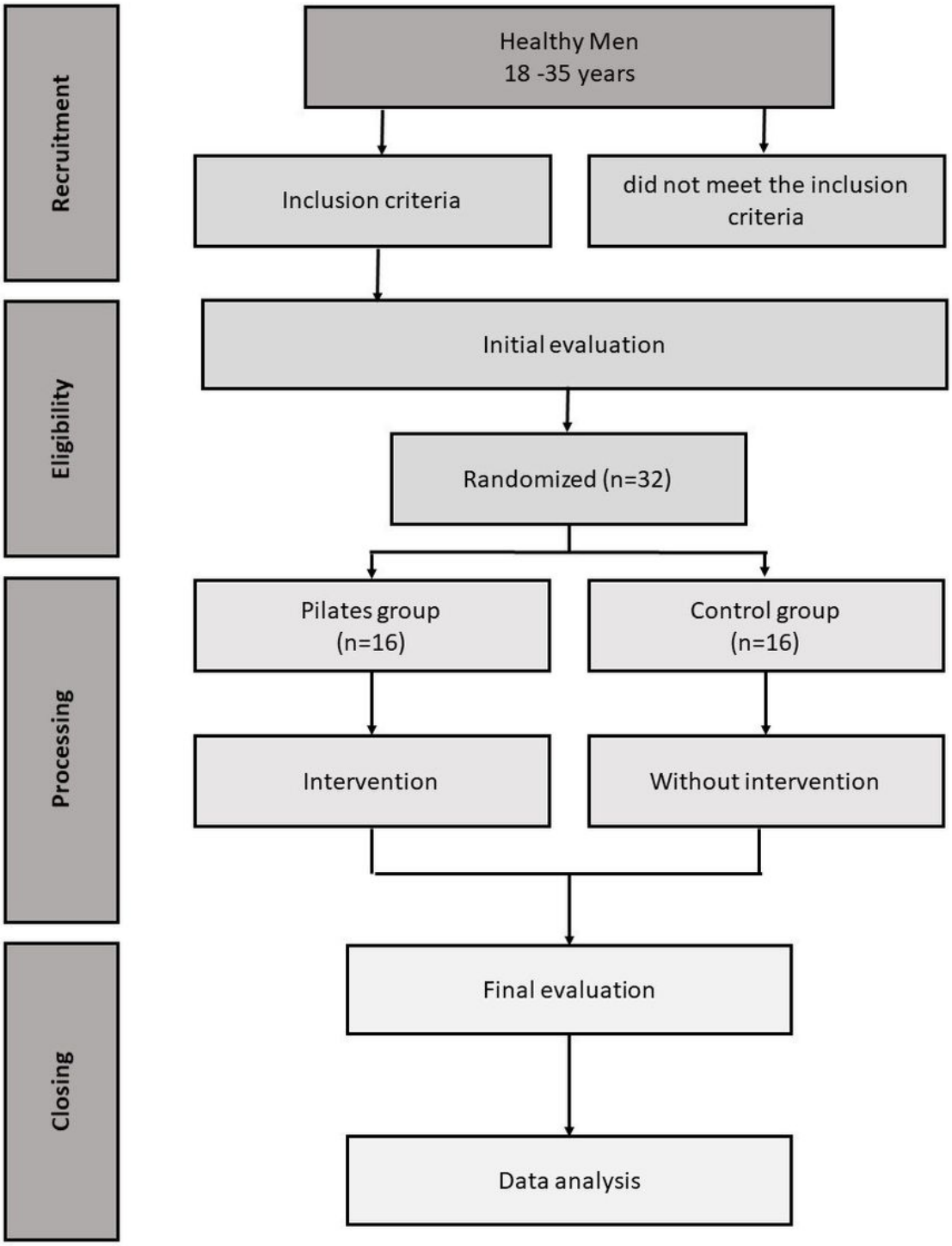

Figure 1

Flowchart of study design.

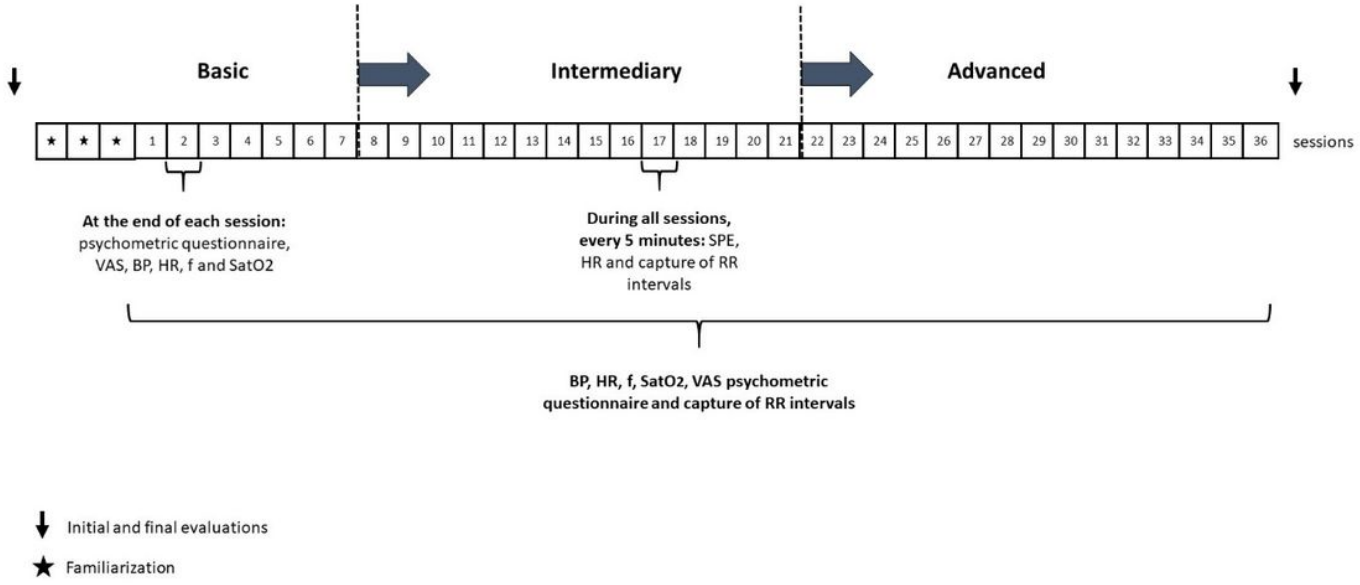

Figure 2

Study outline. Legend: VAS: Visual Analog Scale; BP: blood pressure; HR: heart rate; f: respiratory rate; SatO2: oxygen saturation.

Supplementary Files

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