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The Remote Testing in Abbiategrasso (RTA) Study Protocol: A Counter-Balanced Crossover Trial to Assess the Feasibility of Direct-to-Home-Neuropsychology with Older People

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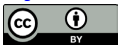

Abstract

Background: The Sars-Cov-2 pandemic has accelerated the spreading of telemedicine, including TeleNeuroPsychology (TNP). Also in a non-pandemic scenario, TNP gives the advantage of reaching older subjects, which often have mobility or transportation limitations. Previous studies on the feasibility, acceptability and reliability of TNP provide promising indications. However, it remains unclear how elderly populations in Italy welcome this practice, in particular when carried out "direct-to-home" (DTH neuropsychology—DTH-NP), hence without assistance in setting up, *i.e.*, the videoconference, and which tests validated in Italian populations show good comparability between remote (either by voice phone call or videoconference) and face-to-face administration. **Aims**: Here we present a study protocol aimed at assessing: 1) the recruitment rate in a study on DTH neuropsychological assessment through voice calls or videoconference, 2) the feasibility and acceptability of a DTH neuropsychological assessment, 3) the comparability between DTH and face-to-face neuropsychological assessments. **Methods:** Fifty-eight older adults (65 - 85 years) were recruited among donors of the Abbiategrasso Brain Bank and will undergo both a face-to-face and a DTH neuropsychological assessment in a counterbalanced cross-over design (Group 1: remote session first; Group 2: face-to-face session first). Recruitment rate will be first evaluated. Then, the responses to an acceptability ques-

tionnaire will be compared between the two administration modalities. Finally, the DTH-face-to-face comparability will be evaluated as good reliability of a DTH neuropsychological assessment and agreement between scores obtained in the two modalities. **Discussion and Conclusion:** This study protocol aims at describing the procedures allowing a more reliable implementation of DTH-NP in the Italian clinical and research contexts. The inclusion of both phone-call and videoconference DTH neuropsychological assessment will give the opportunity to evaluate the feasibility of DTH-NP also in older adults with low digital skills. The results of the comparability analysis will offer the first evidence in the Italian context on which neuropsychological tests can be reliably delivered DTH, by phone call or videoconference.

Keywords

Telehealth, Neuropsychological Assessment, Feasibility Study, Counterbalanced Cross-Over Design

1. Background

Teleneuropsychology (TNP), including voice phone calls or videoconferencing, has recently taken hold because of the need of protecting older people from unnecessary risk exposure to Sars-Cov-2 virus [1]. Also in a non-pandemic scenario, TNP gives the advantage of reaching older subjects with mobility or transportation limitations [2]. Hence, this practice has pivotal importance both in dementia care and research contexts. To date, there is evidence of acceptability, feasibility, and reliability of assisted TNP, in which a neuropsychologist at the subjects' home or in a satellite clinic arranges and controls the setting [3] [4] [5] [6]. However, the pandemic has forced what has been called "direct-to-home-neuropsychology (DTH-NP)" [7], where the neuropsychologist calls or video calls patients at their home, hence without direct contact with them. Even though numerous guidelines on DTH-NP have been published [1], [8] [9], and there is evidence of good feasibility and acceptability of DTH-NP [10] [11] [12], there are still multiple issues to consider when approaching this practice, especially with elderly populations: limited access to technology, poor familiarity with it (e.g., knowledge of videoconference platforms, difficulties in setting up the equipment), the non-controlled environment during the in-home evaluation (e.g. presence of other people, sounds and animals), the management of technical problems (e.g. connection speed, audio-video interruptions,), a difficult extraction of non-verbal cues, a feeling of distance that may hinder the construction of a therapeutic alliance [11]. Furthermore, there is scarce evidence on the feasibility and acceptability of DTH-NP carried out through voice phone calls only: Caze *et al.* [13] found that a telephonic neuropsychological assessment increased attendance to the evaluation, in particular, because of the diminished cost of the service. According to Lacritz *et al.* [10], telephonic assessment also

resulted in good patients' satisfaction.

A recent meta-analysis demonstrated that brief global cognitive assessments (*i.e.* Mini Mental State Examination—MMSE and Montreal Cognitive Assessment—MoCA), letter fluency and digit span tests showed good reliability for remote administration (meaning that the scores obtained in the two administration modalities, face-to-face and remote, show high correlations) in older populations [5]. Accordingly, Parks *et al.* [14] recently demonstrated that performances obtained at tests assessing auditory attention, verbal fluency, and verbal episodic memory delivered DTH and face-to-face were not significantly different and showed good validity in differentiating between different clinical populations. However, the fact that these data were obtained from a retrospective clinical sample, previously assessed in-person, introduced considerable variability (e.g. different time intervals between sessions, different neuropsychologists).

In the Italian context, only brief global cognitive assessment tools (e.g. MMSE, Telephone Interview for Cognitive Status) seem to have good psychometric properties making them feasible and valid for remote administration in different populations [15]. To the best of our knowledge, no previous study assessed the feasibility and acceptability of DTH-NP in older populations in Italy and the DTH-face-to-face comparability of cognitive tests typically used in second-level neuropsychological assessments in Italy. Proposing such assessment in a non-assisted remote modality to older subjects without diagnosed neurocognitive disorders would allow better understanding that which procedures could be adopted for a successful implementation of DTH-NP, which tests are well accepted, and which show good comparability between the two administration modalities. Furthermore, since waiting times for neuropsychological assessments in Italy are particularly long (even longer after the SarS-Cov-2 pandemic that forced to stop this service), the possibility to offer a reliable neuropsychological assessment in a DTH modality would possibly make it easier to book an appointment, speeding up the detection of early signals that may be indicative of Mild Cognitive Impairment (MCI).

2. Aims

The overall aim of the current study protocol is then to present a counterbalanced cross-over design that will allow evaluating the feasibility of DTH-NP and the comparability between a face-to-face and DTH neuropsychological assessment in older Italian subjects aged between 65 and 85 years without diagnosed cognitive impairment. The first specific aim of the present study is to assess the recruitment rate of community-dwelling older people in a study on DTH-NP. Participants will have the possibility to choose between a phone voice call and videoconference assessment since according to 2019 demographic data, the 58% of the older population in Italy had poor digital skills [16].

The second specific aim is to describe the procedures for delivering a remote neuropsychological assessment in the natural home environment and collect in-

formation on the acceptability of DTH-NP.

The third aim is to evaluate if scores obtained at selected neuropsychological tests are comparable between DTH and face-to-face administration modalities.

3. Materials and Methods

3.1. Study Design

This study will employ a counterbalanced cross-over design (See Figure 1). Older adults aged between 65 and 85 years and without diagnosed cognitive impairment will be randomly assigned to one of the two conditions: Group 1 will first undergo the DTH session; Group 2 will instead be assessed face-to-face first. Thus, all of the participants will undergo both DTH and face-to-face neuropsychological testing sessions in counterbalanced order. The interval between the two sessions will be of 8 weeks.

3.2. Compliance with Ethical Standards

The study protocol was approved by the Comitato Etico Milano Area 3 (ASST Grande Ospedale Metropolitano Niguarda) on June 9th, 2021 (approval number: 387-09062021). All participants will be informed about the study procedures and give written informed consent for their participation in the study. The videoconference assessments will be conducted using Zoom videoconferencing platform, which ensures protection of highly sensitive data through the user-specific authentication and the real-time encryption of meetings.

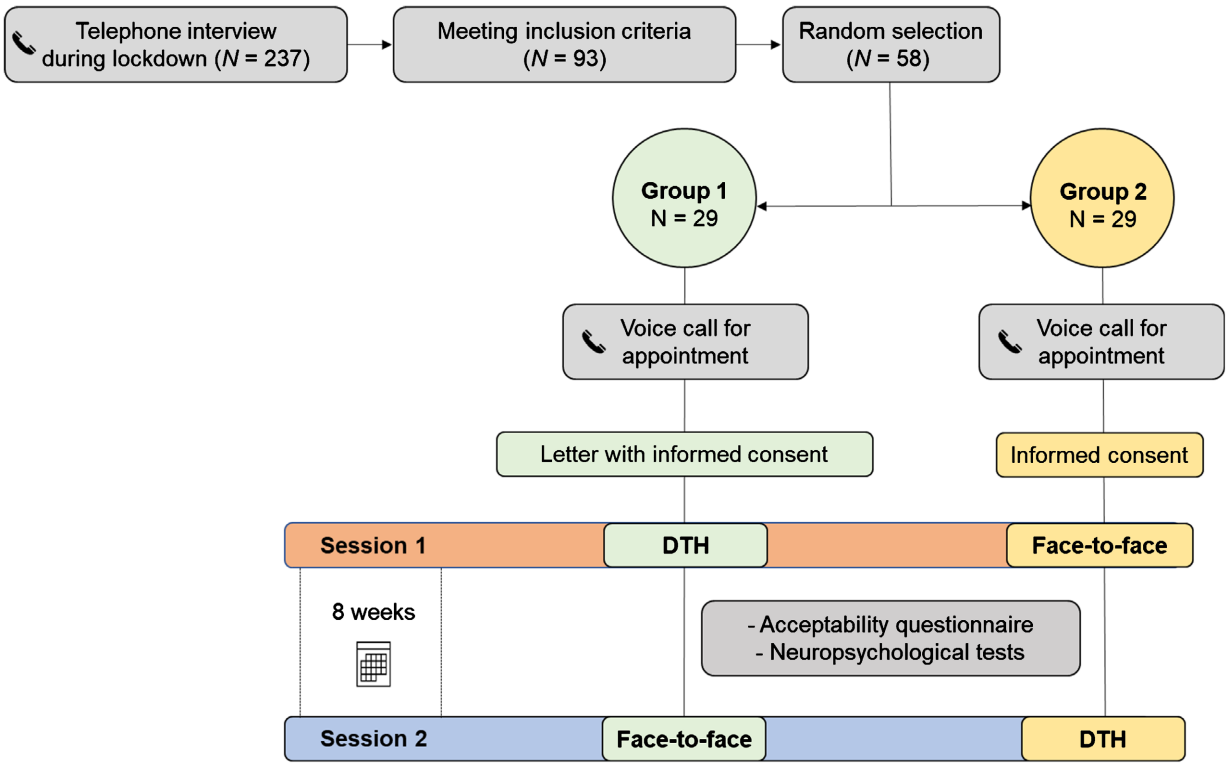

Figure 1. Flowchart of study design. DTH = direct-to-home.

3.3. Participants

Participants in this study were recruited among donors of the Abbiategrasso Brain Bank. This donation program includes periodic multidimensional assessments from enrolment to death, in order to prospectively collect social, lifestyle, neuropsychological, clinical and biological information to enrich the characterization of donors' life trajectories [17]. These activities were discontinued during the riskiest phases of the Sars-Cov-2 pandemic, between March 2020 and April 2021, to avoid social contacts with vulnerable individuals. However, a telephonic survey was conducted in April 2020 as a mean to maintain contacts and to collect information on participants' health, social and psychological consequences of the pandemic [18]. A second survey was then scheduled a year apart. Thus, in February and March 2021, 237 donors of the Abbiategrasso Brain Bank were interviewed by phone. The purpose of the survey was to collect information on how they experienced the isolation due to the pandemic in the last year, on health conditions and sleep, daily habits (nutrition, movement, and leisure activities), internet and social networks use as a way to maintain contact with their network, and loneliness feelings [19]. In this context, the willingness to participate in a study on remote neuropsychological assessment by phone, personal computer (PC) or tablet was explored. The inclusion criteria were: normal cognition (absence of a neurocognitive disorder, psychiatric or neurological diagnosis, a memory disorder with impact on the daily life reported by the person or detected by the interviewer) and not being scheduled for follow-up of the donation program in 2021 (since this included a similar neuropsychological assessment). Eligible participants were 107 and among which 93 expressed their interest to participate in the present study during the telephonic survey. Among these donors, 58 were randomly extracted (see Statistical Methods paragraph for sample size calculation) to take part in the present study and randomly assigned to one of the two groups.

3.4. Study Procedure

A healthcare assistant will call the selected subjects (N=58) to receive confirmation of their participation in the study, furnishing general instructions on the testing procedure and checking the preferred remote modality (phone call or videoconference).

In case of acceptance, Group 1 subjects (DTH assessment first) will be sent a letter containing the disclosure note on the study, the informed consent and the detailed instructions for the remote testing session (e.g., choose a quiet room, close any open programs on their PC, use earphones if possible, install Zoom, etc...) and numbered sheets on which to draw the stimuli (if in videoconference mode). Group 2 (face-to-face assessment first) will instead receive the information note and the informed consent on the day of the appointment at the Golgi-Cenci Foundation; at the end of the session, they will receive paper instructions and numbered sheets on which to draw the stimuli (if in videocon-

ference mode).

On the day of the remote session, participants who choose the voice phone call assessment will be called on their phone. In contrast, a link to access the Zoom videoconference will be sent one day prior to the appointment to participants in the videoconference mode. To ensure stability of videoconference, speed of internet connection will be assessed prior to the testing session [1] and considered appropriate if ≥50 - 150 kbps as advised in Zoom guidelines. For tests involving visual stimuli, the experimenter will share the screen to make them visible to subjects, and will take a screenshot of the paper on which the subject will draw.

Data collection, both remotely and face-to-face, will be carried out in a quiet room of the Golgi Cenci Foundation. All the neuropsychological tests will be administered by the same trained psychologist (VA).

3.5. Neuropsychological Tests Battery

The neuropsychological tests were selected to assess the main cognitive domains. Some of them (MoCA 5-minute and MoCA Audiovisual, Digit span and Fluency tasks, described in detail below) were selected because they showed good reliability for remote administration based on previous studies performed in other countries [4] [5] [20] [21].

In order to assess global cognition, two versions of the MoCA were used: the MoCA 5-minute for telephonic administration [20] and the MoCA Audiovisual for videoconference administration [22]. The MoCA 5-minute is a brief version of the MoCA test including only verbal tasks: 5-word learning (attention), phonemic fluency (language, executive function), 6-item orientation, and delayed recall (memory). The MoCA 5-minute has been translated into Italian and it is commonly used in clinical settings because of its good validity, but normative data for the Italian population are still missing. The MoCA Audiovisual is the version of the MoCA test used for video administration with little adaptation (in the orientation question, subjects are asked to close their eyes before retrieving the date and to answer the question "Which clinic am I calling you from?", instead of "Where are we?"). Normative data in an Italian population obtained for the MoCA test can be used for the Audiovisual version [23].

For the assessment of verbal learning and memory (including retention, encoding, retrieval and subjective organization), the Rey Auditory Verbal Learning Test (RAVLT) was included in the battery. The subject hears a list of 15 words, for five times, and is asked, each time, to recall as many words from the list as possible (Immediate score = sum of words recalled in the 5 learning trials; range 0 - 75). After a 15-minutes delay (performing interfering non-verbal tasks), the participant is asked to recall the words from the list (Recall score = sum of the words recalled after 15 min; range 0 - 15). A parallel version was used in the second session to avoid a learning effect [24]. The Italian version of the RAVLT showed good psychometric properties [24]. Notwithstanding its reliability for remote administration has not yet been assessed, similar verbal learning tasks

showed good reliability [5]. A parallel version will be used in the second session to avoid a learning effect.

In order to assess short-term memory and working memory, the Digit span forward and backward, and two subtests of the Wechsler Adult Intelligence Scale (WAIS) were selected. Participants are asked to repeat sequences of numbers of increasing length in straight order (Digit span forward) or reverse order (Digit span backward). Longest Digit Span Forward (LDSF) and Longest Digit Span Backward (LDSB) were used as raw scores to indicate the maximum length of the sequence correctly repeated. This test, with minimal verbal requirements, will be delivered in the interval between the RAVLT immediate and Recall, together with the Mental Alternation Test [25], which was merely employed to fill the 15-minutes interval and hence not scored.

Verbal fluency tests are measures of spontaneous verbal production, although they have a strong association with executive function, processing speed and memory. The alternate phonemic/semantic fluency test has been validated for face-to-face administration in the Italian population [26] and consists of three subtests, administered in the following order: letter-cued (phonemic) fluency, category-cued (semantic) fluency and alternate phonemic/semantic fluency. In the phonemic fluency, it is asked to produce words beginning with a specified letter ("F", "A" and "S"). In the semantic fluency, it is asked to produce words belonging to a specified category ("colours", "animals" and "fruits"). In the alternate phonemic/semantic fluency, it is asked to continuously alternate letter-cued words with category-cued words as follows: trial 1) letter "A" and "Colours"; trial 2) letter "F" and "Animals"; trial 3) letter "S" and "Fruits", hence assessing shifting mental set ability, a pivotal aspect of the executive functioning. The final score for each subtest (phonemic, semantic and alternate) is the sum of the correct responses produced for each letter, category or letter/category alternance, within 60 seconds.

The individual's ability to reason, *i.e.* solve problems, draw inferences and classify, based on previous own knowledge, was investigated by the Verbal judgments test [27]. The test consists of four subtests: differences (e.g., "What is the difference between a glass and a plate?"), proverbs (e.g., "What is the meaning of the sentence *The dress does not make the priest*"?), nonsenses (e.g., "What's wrong with the following story?") and classifications (e.g., "What do Milan, Rome, Naples and Venice have in common?"). Items scoring is based on predefined criteria, so that each subtest score varies between 0 and 15 (total range score 0 - 60).

Copy figure tasks are generally included in most of the common screening tests and batteries administered remotely for the evaluation of visuospatial abilities although a high level of variability between studies [1]. In the Constructional Praxis test [27], there are 8 figures, of different complexity, to copy. Each is rated from 0 to 2. The final score is the sum of scores obtained for each copy.

The abilities to attribute mental states to others and to predict, describe, and explain behaviour on the basis of such mental states, *i.e.* the Theory of Mind (ToM) [28], are recognised as cognitive and affective processes involved in social

functioning and affected in neurodegenerative diseases. To our knowledge, no previous research on feasibility and comparability of such measure in a video-conference setting has been conducted. We hence chose to adopt the Italian version of the Reading the Mind in the Eyes test (RME) [29] [30]. This test consists of 36 black and white photographs depicting the eye region of adults, young and old people of both sexes. The subject is asked to indicate the term, among four adjectives placed under the photograph, best describing the emotion expressed in the image (range 0-36). To adapt the administration to the DTH modality, the images were projected on the shared screen.

4. Outcome Measures

The primary outcome will be the actual recruitment rate among the 58 Abbiategrasso Brain Bank donors selected to participate in our study. The reason of refusal, if any, will be collected.

The acceptability of DTH-NP will be assessed through the systematic collection, on an acceptability module, of information on tests not completed, the reason of non-administration or non-completion (e.g., refusal, exhaustion/anxiety, impairment of function, hearing impairment, and motor problems) and a questionnaire investigating feelings of anxiety and perceived difficulty on a 5-point Likert scale. At the end of the second session, participants will be also asked to state their preferred modality and reasons for their choice ("If we were to call you back again for a neuropsychological evaluation, would you prefer to come to the Foundation or do it remotely? Why?").

For the reliability aim, the raw scores obtained at the selected neuropsychological tests in the two sessions (DTH and face-to-face) will be correlated and compared for each subject (see Statistical Analyses for detailed information).

5. Statistical Methods

5.1. Sample Size

Based on Backx *et al.* [31], a sample of 45 would provide adequate power to detect an Intraclass Correlation Coefficient (ICC) indicative of fair reliability (ρ = 0.40) and a sample size of 52 is required to detect an effect size of 0.40 at 0.80% of power in a paired-sample test with a normal distribution. We planned an increase in sample size of 6 participants (hence getting a sample size of 58), since the expected drop-out rate due to possible acute clinical conditions interfering with the participation in the study, or death, is 10%.

5.2. Statistical Analyses of Baseline Data

To ascertain whether the two groups were comparable for relevant socio-demographic characteristics, an Independent Sample T-test for continuous variables and a Chi-square test for categorical variables have been performed. **Table 1** shows that the groups were not different for age, sex, education and preferred DTH administration modality.

Table 1. Socio-demographic characteristics and preferred DTH modality of the 58 randomly extracted participants stratified by group. Values denote mean (standard deviation) for continuous variables, counts (percentages) for categorical variables, p-values (Chi-square test for categorical variables, t-test for continuous variables).

	Group 1 (N = 29)	Group 2 (N = 29)	p
Sex			0.565
Females	22 (75.9)	19 (65.5)	
Males	7 (24.1)	10 (34.5)	
Age	80.21 (6.05)	79.62 (6.21)	0.713
Education	9.14 (3.66)	9.57 (3.36)	0.687
Remote modality			0.747
Phone voice call	17 (58.6)	19 (65.5)	
Videoconference	12 (41.4)	10 (34.5)	

5.3. Planned Statistical Analyses

All analysis will be performed on SPSS Statistics 20.0 (IBM SPSS Statistics for Windows, Version 20.0, IBM Corp. Released 2011, Armonk, NY, USA).

The recruitment rate will be evaluated as the percentage of randomly extracted subjects who agreed to participate in the study, with particular attention to the DTH modality chosen (phone call or videoconference).

Then, we will test the acceptability of DTH assessment by comparing responses to the qualitative questionnaire and the number of completed tasks in the two administration modalities. Normality of data distributions will be tested for choice of the hypothesis tests. A paired sample T-test or the correspondent non-parametric test will be employed to assess differences on the items of the acceptability questionnaire. Differences between preferences expressed by the subjects (remote, face-to-face or no preference) will be assessed through the Chi-square test or the Fisher's exact test. A p-value less than 0.05 will be considered significant (two-sided).

To verify reliability of DTH-NP, the scores obtained in the DTH and face-to-face sessions, for each neuropsychological test, will be correlated by means of the Intra-Class Correlation (ICC) (single-rating, absolute-agreement, 2-way random-effects model). For the interpretation of ICC results, we will follow guidelines by Cicchetti & colleagues [32]. Bland-Altman plots and relative t-tests will be employed to assess the comparability between scores obtained at neuropsychological test DTH and face-to-face. This method allows testing if the Bias, namely the mean difference between scores obtained in the two modalities, is significantly different from zero.

6. Discussion

DTH-NP may be a valid means of assessing cognitive functioning in older adults and its importance became pivotal in the context of Sars-Cov-2 pan-

demic. Even in a non-pandemic scenario, DTH-NP may help to reach more easily those living in rural or disadvantaged areas, or with limited mobility due to health conditions. Challenges to implementing DTH-NP with older adults include: limited access to technology, poor familiarity with it, a non-controlled environment during the in-home evaluation, and difficult management of technical problems.

This study may offer preliminary evidence to address these issues, since the sample that will be assessed has a mean age of ~80 years. This age group, particularly prone to develop cognitive disorders and/or having mobility issues, allows investigating the feasibility and acceptability of DTH-NP, without introducing issues related to diagnosed neurocognitive disorders (e.g. the need for presence of a caregiver). Assessing DTH-face-to-face comparability of neuropsychological tests widely employed in the Italian clinical context will open to the possibility to propose a neuropsychological assessment remotely, hence not requiring journeys to a clinic and allowing diminishing service costs and waiting times, helping in the earlier detection of neurocognitive disorders, in particular MCI.

Another strength of this study protocol lies in the counterbalanced design allows testing the same subjects in two different controlled conditions by limiting order effects. A recent feasibility study on DTH-NP included in fact retrospective results obtained at the clinic, hence introducing higher variability related to intervals between the two sessions [14].

As for the limitations of this study protocol, we are aware that, if given the choice between the two remote modalities (voice phone call and videoconference), older subjects could rather be being tested by phone because of poor digital skills. Nevertheless, this will allow obtaining precious information about the current digital literacy in older Italian populations, and investigate the feasibility, acceptability and reliability of telephonic DTH-NP, which remains currently under-investigated as compared to videoconference DTH-NP, but seems to be feasible and well appreciated by users.

7. Conclusion

We here presented a study protocol aimed at investigating the feasibility of DTH-NP in Italian community-dwelling older adults. The description of the procedures employed to deliver an extensive neuropsychological assessment by phone call and videoconference in the natural home environment (hence without assistance in setting up the environment) will allow testing this practice in the Italian context. The inclusion of an acceptability questionnaire will allow understanding the potentialities and barriers related to DTH-NP in older populations. The comparison between the scores obtained at selected neuropsychological tests in the two administration modalities (face-to-face and DTH) will address the question, so far poorly addressed in Italy, of which tests are the most reliable for DTH administration.

Authors' Contributions

Roberta Vaccaro, Elena Rolandi and Mauro Colombo conceived the study design. Elena Rolandi implemented randomization and sample size calculation. Roberta Vaccaro, Virginia Aglieri and Michele Rossi conceived data analysis plan. Roberta Vaccaro and Virginia Aglieri drafted the manuscript. Antonio Guaita and Mauro Colombo critically reviewed the intellectual content. All authors reviewed the paper, provided significant feedback, and approved the final manuscript.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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