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# Effectiveness of an institution-based adapted physical activity programme versus a home-based self-management programme for chronic poststroke adults: protocol for a randomised controlled study

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## ABSTRACT

**Introduction** Physical activity (PA) protects the cardiovascular system and reduces the risk of stroke recurrence. However, most stroke survivors have significantly lower daily PA levels than those recommended. Adapted PA programmes provide a useful means of increasing the daily PA levels of this population. PA programmes designed to encourage people walking have been found to be more effective than no intervention. Some programmes have been applied in institutional settings while others are done on an independent basis. The aim of this study will be to compare the two methods in terms of their impact on the daily walking rates of subjects with spastic hemiparesis following a chronic stroke. Secondary outcomes will include effects on walking ability, endurance, balance, quality of life and motivation for exercise.

**Methods and analysis** This French single-centre randomised (1:1), controlled, two-arm, parallel, single-blind study will include 40 adults with chronic stroke spastic hemiparesis who are able to walk for 6 min. The primary outcome will be the participants' daily activity measured via the number of steps performed per day using a Stepwatch device. We expect to establish that the institution-based programme will be more effective than a self-managed programme as a means of increasing the PA of chronic stroke subjects.

**Ethics and dissemination** The protocol was approved by an independent National Ethics Committee (Comité de Protection des personnes Est IV). Participants will be asked to provide their signed informed consent prior to the study. The results will be disseminated via publications in the scientific literature, oral and poster presentations by partners at international scientific meetings and associations of patients.

**Trial registration** NCT06061770.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Randomised controlled trial to compare an institution-based adapted physical activity programme with a home-based self-management programme in chronic poststroke adults.
⇒ Adapted physical activity programmes designed to meet the recommendations for physical activity after stroke.
⇒ Reliability and reproducibility of the Stepwatch assessments.
⇒ Evaluator blinded from the intervention, but no double-blinding, which is not possible in this context.
⇒ No assessment of the long-term effects.

## INTRODUCTION

Stroke is a major public health concern, not only due to its high annual mortality rate (estimated at 5.5 million individuals per year) but also because of its significant morbidity rate. It is estimated that 50% of surviving stroke individuals are permanently disabled,[1] making it the leading cause of acquired motor disability in adults.[2] The consequences of stroke include medical complications, greater functional impairment, psychological disorders and musculoskeletal problems.[3–6] Loss of motor skills is one of the most common complaints of stroke survivors. Stroke is responsible for gait disorders in 75% of survivors.[7] Interestingly, the incidence rate of stroke includes a high recurrence rate approaching 25%, as reported in a recent study in the USA.[8] The Interstroke study published in 2016, conducted in 32 countries, identified 10 modifiable risk factors which need to be included in stroke prevention strategies. Physical activity (PA) was found to be a protective factor against stroke, with an OR of 0.58 in men and 0.65 in women.[9 10] The identification of modifiable risk factors can

facilitate the improvement of prevention strategies, which represent one of the main objectives of the 2018–2030 European Stroke Prevention Plan.[11] In this population, the American Stroke and Heart Association recommends that individuals engage in 20–60 min of aerobic activity 3–5 days a week and muscle-strengthening and stretching exercises 2–3 days a week in order to prevent cardiovascular disease and stroke recurrence.[12] However, the level of daily PA in chronic stroke individuals appears to be significantly below the recommended guidelines.[13] It is worth noting that the most frequently cited barriers to participation in PA among poststroke individuals are not solely physical, such as musculoskeletal disorders, obesity or joint pain. Rather, environmental difficulties, including access, transport and cost, as well as lack of motivation and fear of relapse, also play an important role.[12] Adapted PA (APA) programmes could be developed to address some of these barriers.

Walking is an accessible and cost-effective method of increasing PA and preventing chronic diseases.[14] One of the main parameters used in the literature to assess PA programmes has been walking ability based on the 6-min walk test (6MWT). Although the results of 6MWT and daily step counts are closely linked, the former test explains only about 50% of the variability observed in walking in real-life situations.[15 16] Other factors have been reported in the literature to influence the PA of individuals in the chronic stroke phase, including intrinsic factors such as age, PA before stroke onset, the presence of cognitive disorders,[17] motivation and anxiety.[18] On the other hand, extrinsic factors such as the physical and social environment have been found to account for about 10% of the variability observed in walking in real-life situations.[19] The meta-analysis published by Lee *et al*[20] has suggested that walking ability improves more in supervised programmes than in autonomous programmes. However, no studies have been published so far to our knowledge in which the effects of a home-based APA programme are compared with those of a supervised institution-based APA.

The objective of this study will be, therefore, to compare the effectiveness of an institution-based APA programme versus that of a home-based programme in increasing the daily PA of chronic stroke individuals, by measuring the step counts using a dedicated device. The most original contributions of this study is the comparison made between two types of PA programmes (institution and home-based), based on the ecological assessment criterion consisting of changes in the number of steps performed per day. On the other hand, it presents PA programmes that have been specially designed to enhance the daily PA rates of poststroke individuals, particularly in relation to their walking abilities. These programmes, which have been developed in accordance with the latest international recommendations,[20 21] include detailed descriptions that align with the guidelines published by Slade *et al*.[22]

## METHODS AND ANALYSIS

### Study design and setting

This randomised, controlled, two-parallel-armed, single-blinded study was designed to compare the efficacy of an institution-based and a home-based APA programme, in terms of their ability to increase the daily PA of chronic stroke individuals. This is a single-centre study which will take place in Marseille, France. The primary objective of this study will be to assess the effects of a supervised institution-based PA programme versus those of a home-based self-managed programme on the daily walking rates of chronic poststroke subjects with spastic hemiparesis. The secondary objectives will be to study the effects on walking ability, endurance, balance, quality of life and motivation for exercise. Primary and secondary endpoints will be assessed by an operator blinded to subject status. The single-blind design which is part of the APA protocol is not feasible in a blinded setting. For ethical reasons, participants will be permitted to pursue their usual medical follow-up and physiotherapy without any restrictions.

### Eligibility criteria

Subjects aged 18 years or above with left or right spastic hemiparesis resulting from their first unilateral haemorrhagic or ischaemic stroke which occurred >6 months previously, and who are able to walk for 6 min with or without technical assistance will be eligible for inclusion. The exclusion criteria will include the inability to walk without human assistance (with or without an assistive device), cognitive impairments preventing informed consent, especially the inability to understand the aims of the study and the methods involved or the inability to communicate with the investigators. The presence of any other neurological disorder or pathology contraindicating PA (such as cardiovascular or respiratory disease, in particular) is another criterion for non-inclusion. Subjects must not be participating in any other clinical research project concurrently. In the event of any adverse event necessitating protocol interruption (eg, fracture, cardiorespiratory failure, etc), subject participation will be discontinued.

### Design of the strokAPA protocol

The present study will compare two APA programmes. Subjects will be randomly assigned to one of two groups. Subjects will be randomly assigned to one of two groups on Day 0. Group 1 will participate in the APA programme at the rehabilitation centre from week 1 to week 12, while group 2 will engage in a home-based self-management programme. Group 2 will conclude the study at week 13, after which they will participate in a compensatory APA programme at the rehabilitation centre. Group 1 will continue with the home-based self-management programme from week 14 to week 25. These programmes will be supervised (in person or remotely) by an APA teacher dedicated to each programme.

A two-arm parallel design will be used with a view to comparing the two APA protocols. The primary endpoint, which has been selected in order to meet the primary objective, will be assessed at W13 in the case of both groups. The addition of a home-based self-management APA programme after the institution-based programme for Group 1 will serve to address a secondary question regarding the comparative efficacy of the home-based self-management programme in isolation or subsequent to the institution-based programme. For ethical reasons and to enhance recruitment, all poststroke individuals enrolled in group 2 will benefit from both types of APA, as they will be able to participate in the institution-based programme as part of routine care, after completing the self-directed programme. The detailed protocols are described in the online supplemental material 1.

### Institution-based APA programme

The programme will be implemented as part of routine care at the rehabilitation centre. It consists of 3 sessions of APA per week (Mondays, Wednesdays and Fridays) for 12 weeks. Each session will consist of 2×60 min APA sessions. The entire programme was designed to meet the recommendations for PA after a stroke.[21] Each session will include 45 min of actual work and 15 min devoted to set-up measures. The programme will be supervised by an APA instructor, who will provide participants with feedback and adapt the exercises to each individual's limitations. At the beginning of each week, a group meeting will be held to take an inventory of each participant's PA for the week.

### Home-based self-management APA program

The APA home-based self-management programme will be based on detailed exercise cards presenting yoga, Pilates and walking activities. Subjects will be given a booklet of detailed cards with photographs. The main aim of the adapted yoga exercises presented in the booklet is to stretch all four limbs and the trunk. The booklet presents the yoga session used in the institution-based programme. The focus here is on the physical sensation of stretching and working without pain. The Adapted Pilates exercise booklet focuses on general motor strengthening. It presents the Pilates session used in the institution-based programme.

Since the objective is to effectively promote PA in chronic stroke individuals, subjects are encouraged in all these programmes to engage in PAs of their choice, even in activities other than those proposed, and to record them in the registry.

## Time schedule

The study will run for 25 weeks with subjects enrolled in group 1 and 13 weeks with those in group 2, with an additional 12 weeks of participation in the compensatory institution-based APA programme, as routine care. The flow chart of the study is presented in figure 1. The study has not yet commenced, but enrolment is scheduled to begin in September 2024. The study is expected to last for a period of 2 years.

## Enrolment and initial assessment

The inclusion medical visit will take place on Day 0 with the objective of verifying that the inclusion and non-inclusion criteria defined above have been met. This medical visit will also permit the initial assessment to be carried out by an operator blinded to the subjects' group.

The enrolment visit is a medical consultation designed to ensure that there are no contraindications to participating in the programme. The visit provides an opportunity for the subject to provide informed consent and for the relevant data to be recorded recording. This includes the subjects' stroke characteristics (cortical or subcortical and ischaemic or haemorrhagic), comorbidities, body mass index, stroke severity (National Institutes of Health Stroke Scale and injured area if available), the use of any assistive devices, spasticity (modified Ashworth

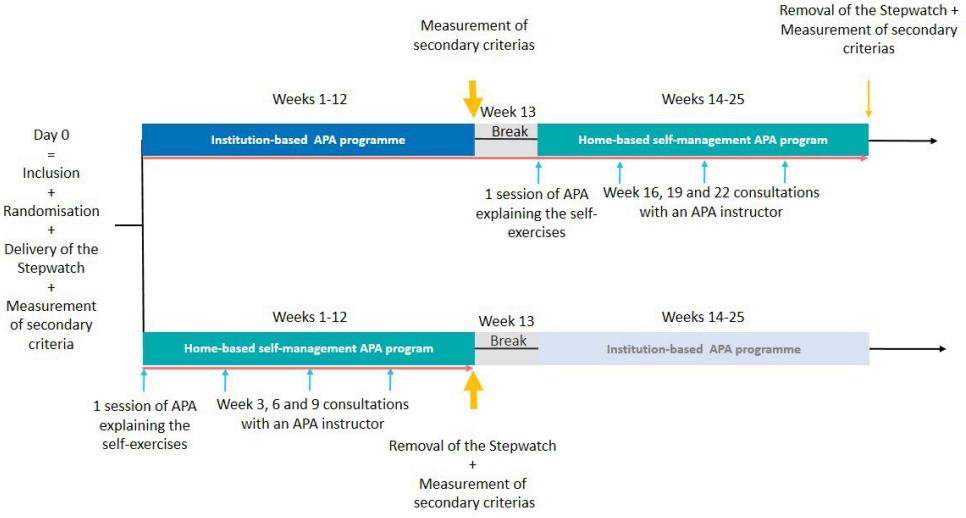


**Figure 1** Study schedule. The red arrows indicate the measurement of the primary endpoint, while the yellow arrows represent the measurement of the secondary endpoints. APA, adapted physical activity.

score), prestroke sports activities, the presence of depressive syndrome (Individual Health Questionnaire 9), pain visual analogic scale and neuropathic pain diagnostic questionnaire (DN4) to assess any neuropathic component present, and the initial assessment. This visit will also be used to fit the Stepwatch daily PA measurement monitor (to be worn at least during the subjects' waking hours for the entire duration of their participation in the study on the ankle of the healthy limb), to provide each subject with the notebook to be used for the written report and to record all the PAs performed during and outside the programme.

A simple randomisation procedure will then be employed to assign the subject to one of the two groups, using a computer-generated table of random numbers.

### Organisation of participant follow-up

Follow-up will involve collecting Stepwatch data every 3 weeks at the rehabilitation centre, with the individual responsible for data collection being unable to view or alter the data in any way. Given that the programme for group 1 will be conducted at the rehabilitation centre, data will be collected there during one session at week 3, 6 and 9. The home-based self-management programme will involve visits to the rehabilitation centre every 3 weeks, during which Stepwatch data will be collected at week 3, 6 and 9 on group 2 and at week 16, 19 and 22 on group 1. A final evaluation will take place on week 13, at the end of the first APA period, by an operator who is blinded to the subjects' status. Group 1 will continue the study on an exploratory basis, using the APA home-based self-management programme until week 26, at which point the final assessment of the criteria will be conducted.

### Evaluation criteria

In this protocol, the primary outcome will be the subjects' daily activity in terms of the number of steps measured per day, average per week, which will be recorded throughout the entire duration of the study using a Stepwatch device. This device has been tested and found to show the greatest accuracy at all the walking speeds and step lengths tested.[23] In order to ensure the accuracy of the data collected, the device has to be worn on the ankle of the unaffected limb at least during the subjects' waking hours throughout their participation in the study.

The Stepwatch device will be delivered to the subjects with an instruction manual on day 0. It will then be calibrated by an investigator using the subject's anthropometric data and a 20-step calibration procedure. Data will be collected at week 3, 6, 9 and 13 on both groups and at week 16, 19, 22 and 26 on group 1. These data will be collected by an investigator blinded to the subjects' individual status. The comparison between the two groups with regard to the primary endpoint will be performed at week 13.

The secondary endpoints will be assessed based on the other tests performed to assess walking ability, endurance (6MWT and Borg Rating Scale of Exertion), balance (Berg Balance Scale and Activity-Specific Balanced Confidence Scale), quality of life (Stroke Specific Quality of Life) and motivation for exercise (Behavioural Regulation in Exercise Questionnaire 2).

A written report on the PAs performed by each subject (types of PA and duration) will be recorded by the subjects themselves in a diary distributed at baseline.

The 6MWT will be used to assess subjects' walking ability. Heart rate and systolic blood pressure will be measured at rest and after the 6MWT. Subjects will complete various assessments and questionnaires. The Borg Rating Scale of Exertion[24] will be employed to assess the subjects' perception of their exertion following the 6MWT on a scale ranging from 0 to maximum. The Stroke Specific Quality of Life[25] Scale will be used to evaluate subjects' quality of life. This scale contains several subsections including autonomy, social relationships and character. Subjects will be asked to rate their difficulty in performing an activity or how far they agree with a statement on a scale of 1 to 5. The Berg Balance Scale[26 27] will be used to assess subjects' balance by rating their ability to perform each of the 14 items from 0 to 4. The Activity-Specific Balanced Confidence Scale[28] will be used to assess subjects' confidence in their balance. Subjects are asked to rate their confidence in their balance from 0% to 100% in response to 16 situations. Finally, the Behavioural Regulation in Exercise Questionnaire 2[29] will be used to quantify participants' motivation to perform exercises of 24 kinds, which they will be asked to rate between 1 and 7.

### Statistical aspects

#### Sample size calculations

Assuming the existence of a difference of 1000 steps between the endpoints, an SD of 1500,[30] a 5% risk of the first type and a power of 80%, it would be appropriate to include 28 subjects per group, making a total number of 56 subjects. The present study will include 40 subjects, which will make it possible to specify the precision of the indicators with a power of 70%. The randomisation ratio will be 1:1 in this study.

#### Statistical analysis

Data analysis will be performed by the statistician under the responsibility of the methodologist, using SPSS V.17.0 under Windows. The significance level will be set at 0.05. No interim analyses have been planned. The analysis will be blinded, that is, the statistician will know nothing about the identity of the groups and will initially present the results anonymously to the coordinating investigator and the other investigators. Once the statistical analysis has been completed, the identity of the groups will be revealed.

The methodological and analytical plan will be based on the criteria presented in the Consolidated Standards of Reporting Trials Statement (CONSORT, http:// www.consort-statement.org/consort-statement/).

### Patient and public involvement

The implementation of the institution-based APA protocol, as part of routine care, has been adapted on

the basis of feedback from patients participating in this programme.

## ETHICS AND DISSEMINATION

### Informed consent and data management

This clinical trial will be conducted in accordance with the Helsinki Declaration. Subjects will be preselected from among those attending our Physical Medicine and Rehabilitation Department, and eligible subjects will be contacted by the investigators. Participants will be asked to give their signed informed consent prior to the study (online supplemental material 2).

The data obtained in this study will be processed by the clinical data manager at the AP-HM Health Research Department, in line with the French legislation. Data will be recorded using an electronic case report form developed using open-source web-based software, namely the Research Electronic Data Capture application (REDCap).

### Ethics approval and trial registration

The protocol used in this study was approved on 2 May 2023 by an independent National Ethics Committee (Comité de Protection des personnes Est IV) under the number 23.00588.000168 and registered in the clinicaltrial.gov registry: NCT06061770. The manuscript meets the requirements of the Standard Protocol Items: Recommendations for Interventional Trials guidelines for reporting protocols.

### Dissemination

The results will be disseminated via publications in the scientific literature, oral and poster presentations by partners at international scientific meetings, wide-audience media outlet and associations of patients and their families.

## DISCUSSION

It is well established that PA is a factor preventing stroke relapse. The daily PA rates of chronic stroke individuals are known to be significantly lower than those recommended by the international health authorities. Consequently, increasing PA in individuals after stroke remains a significant challenge.

The initial rehabilitation management includes early mobilisation and upright positioning in physiotherapy programmes. Moore *et al* have reported that an intensive walking PA programme significantly improved the daily walking rates of the poststroke subjects studied.[30] APA can be employed in the rehabilitation process for individuals after stroke.[31] It helps to maintain their independence, reduces the risk of recurrence and favours their social reintegration when applied in a group setting.[32] APA programmes, which are often carried out as an adjunct to rehabilitation care for a period of 3–12 months, constitute a whole stage in the poststroke recovery process.[32] The duration of these programmes appears to be a significant factor in enabling subjects to increase their activity levels. A meta-analysis conducted by Lee *et al* in 2020 demonstrated that programmes lasting at least 12 weeks had significantly greater effects on muscle strength and walking ability than those lasting for shorter periods.[20] The latter authors proposed that the duration of these exercise programmes contributes importantly to inducing physiological adaptations that improve individuals' walking ability.

The StrokAPA protocol may provide an effective approach to encouraging poststroke individuals to increase their PA. It is noteworthy that the majority of the studies establishing the effectiveness of APA programmes as a means of increasing daily walking are based on direct gait training or at least on incentives to walk.**30 33** Moore *et al* observed an increase of approximately 24% in participants' daily step count after applying an institution-based APA programme in a conventional rehabilitation setting, where they had reached a recovery plateau.[30] The Danks study[33] was a home-based self-management programme that included motivational interviews encouraging subjects to walk with daily step count goals and the use of a pedometer as feedback. The step rates increased significantly from an average number of 5205 to 6372 steps per day. Moore's study was based on the use of an institution-based supervised PA programme, while Danks' study was based on a home-based self-management programme with motivational interviewing and the testing of the use of a pedometer as a feedback tool. Both types of programmes were found to have beneficial effects on PA in ecological settings since they increased the number of daily steps taken by individuals with stroke sequelae. The meta-analysis published by Lee *et al*[20] has indicated that supervised programmes tend to result in greater improvements in walking ability than self-directed programmes. However, to the best of our knowledge, no studies have yet been published that directly compare the effects of a home-based unsupervised APA programme with those of a supervised institution-based APA programme.

The present APA study proposes a comparison of the effects of the institution-based programme versus those of a home-based self-management programme with a view to optimising their use in chronic poststroke individuals. This project aligns with the spirit of the European Stroke Action Plan 2018–2030, which stresses the lack of PA programmes catering for stroke survivors. The objective of the latter action plan is to make PA programmes accessible to all stroke survivors.[11] A recent meta-analysis has demonstrated that participation in a supervised programme combining motor strengthening and aerobic exercise is an effective strategy for promoting individuals' participation in PA and improving their cardiorespiratory fitness, muscle strength and walking ability.[20]

Ultimately, we have several aims. First, to establish the value of an institution-based APA programme for chronic poststroke individuals. The main advantages of our programme include the fact that it requires only a straightforward medical examination to ascertain

contraindications and that it can be carried out in conjunction with APA instructors, as it could be done in a centre dedicated to PA. The results obtained here could be of great importance on several levels. For individuals and their families, it would reinforce the feasibility and the interest in programmes of this kind, thereby improving individuals' walking performances in their everyday lives. At present, the daily PA rates of individuals in the chronic stroke phase are known to be well below the international recommendations,[13] and a programme of this kind could greatly improve this situation. From the perspective of the healthcare system, the results of this study could constitute a further step towards optimising the management of individuals with chronic poststroke sequelae. Furthermore, the implementation of an institution-based APA programme would also enable individuals who have suffered from a stroke to interact with people in similar situations. PA helps to maintain independence, reduces the risk of recurrence and encourages social reintegration if practised in a group.[32] This promotes interactions and intergroup emulation, which is conducive to motivation for PA and promotes the pursuit of PA at the end of the programme. Adapted group PA can also have disadvantages, such as the risk of exercising at the intensity of the least active participant, thus minimising the benefits for most participants. Conversely, the intensity of the exercise may be too high, increasing dropout rates. To avoid these issues, our group programme is supervised by an APA professional who ensures that the exercise proposed is appropriate for each participant and can adjust it if necessary.

Conversely, the implementation of an institution-based programme prior to a self-managed programme seems likely to result in sustained PA rates in chronic stroke individuals, thus increasing the effectiveness of the self-managed programme. This would increase the value of generalising programmes of this kind so as to lead post-stroke individuals to increase their PA rates, which could then be maintained independently, requiring only periodic follow-up visits. Consequently, it would be worth conducting a medico-economic study on the benefits of such programmes in reducing disability and secondary complications in a population of chronic poststroke individuals. In fact, the aim of such programmes of this kind would be to enable individuals to modify their lifestyles by including regular PA, thus reducing the risk of recurrence, which would naturally also reduce public health costs.

Walking appears to be an accessible and beneficial form of PA that prevents chronic diseases.[14] One of the most innovative aspects of this study is that it involves assessments that are as similar as possible to what individuals often do in real life, namely measuring the number of daily steps they take, in this case, using the Stepwatch. The authors of some recent studies have used this method[30–34] to measure the number of steps taken per day. The results obtained with this device have been found to show particularly good reliability and reproducibility, regardless of the wearers' stride speed and stride length.[23] Therefore, the Stepwatch can be considered a reliable and reproducible ecological means of assessing the effectiveness of PA programmes.[13] Nevertheless, the selection of primary outcome measures obtained via technology and not through standardised clinical scales may be open to question, given that it could be susceptible to issues of poor reliability and replicability across studies. To address this, standard clinical tests were incorporated as secondary objectives.

One of the principal limitations of the present study is the absence of double-blinding, despite the inherent difficulties in achieving this in studies of this kind. We have attempted to mitigate bias by ensuring that the assessor was unaware of the subjects' status.

The potential for underuse or misuse of the Stepwatch device represents a risk inherent to this study. Any issues with the device would be addressed during the scheduled visits for the group undergoing rehabilitation at the centre, as well as during the interviews scheduled every 3 weeks for the group undergoing rehabilitation at home. Additionally, participants can contact the provided telephone number if they encounter any problems.

All participants are authorised to continue physiotherapy rehabilitation. The intention is that APA should be carried out in addition to the usual rehabilitation for stabilised patients. The objective is to study stabilised patients in their ecological conditions, without modifying them. The two groups will be comparable on this point.

Another limitation is that there was no provision for long-term assessments of the impact of the programme. It would certainly be of interest to conduct a study on the long-term effects, as well as on the medico-economic benefits of programmes of this kind.

This study represents a significant contribution to the field of PA research, as it presents a novel comparison between the efficacy of two distinct types of PA programmes: institution-based versus home-based self-management. The study's findings will provide valuable insights into the impact of these programmes on the daily lives of individuals with chronic poststroke conditions. The findings of this study will corroborate the efficacy of the PA programmes recommended in the 2018–2030 European Stroke Action Plan.

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**Contributors** Conceptualisation: MC and LB; methodology: MC, LB and PA; writing—original draft preparation: ES and MC; writing—review and editing: MC,

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**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were involved in the design, conduct, reporting or dissemination plans of this research. Refer to the Methods section for further details.

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