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Efficacy of Soft palatal augmentation prosthesis for oral functional rehabilitation in patients with dysarthria and dysphagia: a protocol for a randomised controlled trial

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Abstract

Introduction: Palatal augmentation prosthesis (PAP) is used in patients with articulation and swallowing disorders caused by postoperative loss of tongue tissue due to tongue cancer, cerebrovascular disease sequelae, and age-related hypofunction. We have previously reported a newly designed Soft PAP fabricated using an thermoelastic material that is particularly appropriate for early intervention. However, the effect of Soft PAP on oral function improvement remains to be elucidated. The aim of this study is to investigate whether Soft PAP can improve dysarthria and dysphagia occurring as cerebrovascular disease sequelae.

Methods and analysis: This prospective, randomised, controlled trial will compare the immediate and training effects of rehabilitation using Soft PAP with those of rehabilitation without using it. Primary outcomes are the single-word intelligibility test score and pharyngeal transit time (PTT). Secondary outcomes are tongue function (evaluated based on maximum tongue pressure, repetitions of tongue pressure, and endurance of tongue pressure), articulation function (evaluated based on speech intelligibility, oral diadochokinesis, Voice-Related Quality of Life [V-RQOL]), and swallowing function (evaluated using Eating Assessment Tool-10). The study results will help determine the efficacy of Soft PAP in improving functional outcomes of word intelligibility and PTT. We hypothesised that early rehabilitation using Soft PAP would more effectively improve articulation and swallowing function compared to conventional rehabilitation without using Soft PAP.

Ethics and dissemination: Ethical approval was obtained from the Okayama University Certified Review Board. The study findings will be published in an open access, peer-reviewed journal and presented at relevant conferences and research meetings.

Registration details: CBR20-007 (jRCTs062200054)

Strengths and limitations of this study

- A randomised controlled design will minimise bias and allow for a direct comparison between the groups.
- To test the difference between Soft PAP and normal training effects, the control group will receive normal training.
- The articulation function will be evaluated by non-experts under the assumption of routine conversation.
- The limitation of this study is that only the evaluator is blinded to allocation results, not the therapist or participants.

Keywords: Soft palatal augmentation prosthesis, tongue, articulation, swallowing, prospective study

INTRODUCTION

Palatal augmentation prosthesis (PAP) is used in patients with articulation and swallowing disorders caused by postoperative loss of tongue tissue due to tongue cancer, cerebrovascular disease sequelae, and age-related hypofunction.[1] The Japan Council for Quality Health Care guideline for PAP states that it enhances the rehabilitation effect when fabricated and used appropriately.[1] PAP use has been recommended in the PAP guidelines issued by the Japanese Society for Prosthodontics.[1] PAP can be used to improve dysphagia or dysarthria caused not only by tissue loss after glossectomy but also by posterior movement disorders occurring as cerebrovascular disease sequelae.[2] In patients requiring upper and/or lower limb rehabilitation, early initiation of rehabilitation effectively improves the prognosis of movement disorders.[3] However, an early intervention protocol involving PAP use for rehabilitation therapy has not yet been established. This might be partly attributable to the practical difficulties faced by general dental practitioners in fabricating and adjusting PAP during the acute stage of the primary disease. Therefore, medical and dental interprofessional collaboration in acute-care-oriented hospitals in this field is required for PAP use in early rehabilitation therapy.

Most studies reporting the effect of PAP on dysphagia and dysarthria occurring due to stroke and neuromuscular diseases are either case reports or retrospective studies.[4] Moreover, the methods used for evaluating clinical efficacy in these studies were not well structured; therefore, a meta-analysis could not be performed.[4] Thus, prospective cohort studies

examining the effect of rehabilitation using PAP on patients with stroke and neuromuscular disease are needed.

Conventionally, PAP has been fabricated using acrylic resin.[5-8] Acrylic resin is a denture base material and exhibits stable mechanical properties that are appropriate for long-term use, even after repeated clinical adjustment. To achieve the best effect on patients' oral function, frequent adjustments by a skilled dentist are usually required, even when PAP is fabricated at a rather stable or chronic stage of the primary disease. However, given the atmosphere of acute care units providing early intervention in hospitals, a device that is easy to fit and requires less adjustment might be easily accepted. We have previously reported a newly designed Soft PAP fabricated using an elastic thermoplastic material that is particularly appropriate for early intervention (figure 1).[9, 10] Soft PAP is a simplified PAP that has a flat palatal surface. Although a major disadvantage of Soft PAP is that it may not be fully adjustable to exactly reproduce patient's oral function, it provides a mechanical target point as a *terminus ad quem* for tongue movement during rehabilitation. Its inherent properties of ease of fabrication and no requirement of adjustment to provide a mechanical target point are expected to benefit patients undergoing rehabilitation.[11] Early rehabilitation interventions using this simplified type of PAP may improve dysarthria and dysphagia occurring as cerebrovascular disease sequelae. We conducted a preliminary study using a small sample size to ascertain the effect of early intervention using Soft PAP.[12] The results of this preliminary study suggest

that early rehabilitation using Soft PAP improves the functional speed of the tongue tip during articulation movements. We hypothesised that early rehabilitation using Soft PAP would more effectively improve articulation and swallowing function compared to conventional rehabilitation without using it. Therefore, our null hypothesis is that the effect of rehabilitation using Soft PAP on articulation and swallowing function is not different from that of conventional rehabilitation without using Soft PAP.

METHODS AND ANALYSIS

Trial design

This study will be a prospective, randomised, controlled trial comparing the immediate and training effects of rehabilitation using Soft PAP (SP group) with those of conventional rehabilitation without using Soft PAP (NSP group) on patients with dysarthria and dysphagia. Figure 2 shows the flowchart of this clinical trial. Two PAPs with different palatal plate thicknesses will be fabricated for each participant. One will extend up to the height of the flat palatal surface at the cervical line of the upper posterior tooth, whereas the other one would be half as thick as the previous one (figure 3). The participants will select the PAP they feel most comfortable with. They will be instructed to wear Soft PAP for as long as possible, except during meals and sleep, with each participant maintaining a record of the actual duration of wearing the PAP. Each group will be provided the same articulation training during the study

period. The patients will be assessed at baseline and at 2 and 8 weeks postintervention. Enrolment in the study will be performed by a medical doctor or dentist. Soft PAP will be fabricated by a dentist, and video fluorography (VF) assessment will be performed by a medical doctor, radiologist, and speech–language pathologist. Other evaluations will be performed by medical doctors, dentists, and speech–language pathologists. The criteria for stopping the trial include deterioration of patients' condition and a request to stop.

Patient and public involvement

Patients admitted to Kawasaki Medical School Hospital who meet the inclusion criteria receive an explanation for this study. They are not involved in the design or conducting of the study. Results of the study will be disseminated to the participants who want to know the results. In addition, they are not asked to assess the burden of the intervention and time required to participate in the research.

Study sites

This study is funded by the Department of Occlusal and Oral Functional Rehabilitation, Graduate School of Medicine, Dentistry and Pharmaceutical Sciences, Okayama University.

Study participant recruitment will take place at the Kawasaki Medical School Hospital.

Ethical approval

The study protocol is under review by the Okayama University Certified Review Board.

Study population

Study participants will be selected from among patients admitted to the Kawasaki Medical School Hospital with a primary diagnosis of stroke, neuromuscular disease, or head trauma and with a speech articulation disorder score of ≥2.[13] Speech intelligibility will be evaluated by recording the patient reading a text aloud and assessed by three speech–language pathologists with at least 3 years of experience. The following paragraphs provide a detailed description of the inclusion and exclusion criteria.

Inclusion criteria

Patients fulfilling the following five conditions will be enrolled in the study:

1) Those who are acutely hospitalised for stroke, neuromuscular disease, head injury, or other related diseases in the Kawasaki Medical School Hospital

2) Those suffering from dysarthria with a speech intelligibility score of ≥2 or dysphagia with problems in the preparatory, oral, or pharyngeal phase

3) Those within 2 weeks of being allowed to receive articulation or swallowing rehabilitation

4) Those aged ≥20 years at the time of obtaining informed consent

5) Those who have been fully informed about the study and completely understand their participation and have provided voluntary written consent for enrolment

Exclusion criteria

Patients fulfilling one or more of the following five conditions will be excluded:

1) Those diagnosed as having impaired consciousness (a score of ≥10 on the Japan Coma Scale)

2) Those unable to wear Soft PAP due to edentulous maxillae

3) Those with residual tooth mobility that makes it difficult to obtain dental arch impressions

4) Those unable to follow movement instructions due to mental deterioration

5) Those deemed inappropriate for inclusion by the principal investigator or sub-investigator

Enrolment

Enrolment will start after the approval of application for a specific clinical trial. The target completion year is 2026.

Randomisation

Participants will be assigned to either the SP or NSP group according to their sex and age (over and under 65 years) using a web application that automatically achieves stratified randomisation.[14]

Blinding

Randomisation will be reported to the researchers on the basis of the allocation table by someone not involved in the study, with the allocation table strictly controlled. Although participants cannot be blinded to the assigned intervention, they will be blinded to all data analyses, including expected treatment outcomes.

Outcome measures

Figure 4 shows outcome measures and time points. The following three types of functional data will be collected:

1. Motor function of the tongue

The maximum tongue pressure, maximum number of repetitions of tongue lift-up movement （Repetitions of tongue pressure), and maximum duration of maintaining tongue pressure (Endurance of tongue pressure) will be measured using a tongue pressure measuring device (TPM-01, JMS, Hiroshima; figure 5).

1) Maximum tongue pressure (Pmax)

After positioning the device probe in the mouth, the subject will be instructed to press the probe against the hard palate as strongly as possible using the tongue. This measurement will be performed twice, and the maximum value of the two measurements will be defined as Pmax.

2) Repetitions of tongue pressure (RTP)

RTP will be defined as the maximum number of repetitions performed to press the probe to increase the pressure from 0 kPa to >50% of Pmax in 5 s (figure 6).[15] Real-time visual feedback of the applied tongue pressure with the target value will be provided on a computer screen to the patient during the measurement. The number of times the tongue pressure reaches the target pressure will be defined as RTP, and the number of times it does not reach the target pressure will be defined as failed RTP. The above measurements will be performed three times, with a 30-s break between each attempt.

3) Endurance of tongue pressure (ETP)

ETP will be defined as the maximum duration for which the patient can maintain a tongue

pressure ≥ 50% of Pmax.[16] Two measurements, with a 1-min break between them, will be performed. For the offline measurement of ETP from the waveform, the starting point of the duration will be defined as the moment at which tongue pressure exceeds 50% of Pmax. The endpoint of the duration will be defined according to the following three settings (figure 7):

A: Tongue pressure decreases between 40% and 50% of Pmax for 2 s with subsequent pressure recovery to >50% of Pmax

B: Tongue pressure decreases below 40% of Pmax for 0.5 s with subsequent pressure recovery to >50% of Pmax

C: Tongue pressure decreases below 50% of Pmax without any subsequent recovery to >50% of Pmax

The earliest time point for the above three settings will be regarded as the endpoint.

2. Articulation function

1) Oral diadochokinesis (Oral DDK)

Patients will be instructed to repeat each of the three target sounds (/ta/, /ka/, /taka/) as quickly as possible for 5 s, and the sounds will be recorded using a digital voice (integrated chip; IC) recorder (Sony ICD-SX850, Tokyo, Japan). Two measurements will be performed for each sound. The average of the two measurements will be considered the oral DDK for each sound.

2) 40-Word intelligibility test

Ishihara's 40-word list will be used for a 40-word intelligibility test, with the words listed in a

randomised order. Participants will read out the words from the list, and their voices will be recorded using an IC recorder. The assessment will be completed by three healthy adults without hearing impairment whose native language is Japanese. The average percentage of correct responses by the three examiners will be calculated.

3) Speech intelligibility

Patients' speech will be recorded in two conditions: i) reading aloud a fairy tale, 'Jack and the Beanstalk', and ii) 'routine conversation about patients' events of the day' in 1 min. The assessment will be completed by three healthy adults without hearing impairment whose native language is Japanese. Speech intelligibility will be rated on a five-point scale for each recording.[17] Conventional criteria will be used for this scale in all cases, as in Taguchi's method. The conventional criteria and scores are as follows: 1 = intelligible, 2 = partially intelligible, 3 = intelligible when the topic is known, 4 = mostly unintelligible, and 5 = unintelligible. The average of the three examiners' ratings will be calculated.

4) V-RQOL

V-RQOL is a questionnaire used for examining the voice-related quality of life.[18] Patients will fill in a self-assessment V-RQOL sheet using the following five-point scale for each of the 10 questions about their voice: 1 = none, not a problem; 2 = a small amount; 3 =a moderate (medium) amount; 4 = a lot; and 5 = problem is 'as bad as it can be'.

3. Swallowing function

1) Swallowing VF

The patient will sit in a chair and swallow 5 mL of thickened barium twice. During this task, VF will be recorded in the lateral and frontal views and assessed using the following parameters:

Oral transit duration: time elapsed between the start of swallowing motion of the tongue and the arrival of the bolus head at the ramus of the mandible

PTT: time elapsed between the bolus head crossing the ramus of the mandible and its passage through the upper oesophageal sphincter

Stage transition duration: time elapsed between the bolus head crossing the ramus of the mandible and the onset of hyoid bone elevation

Hyoid movement distance: the maximum elevation of the hyoid bone from the resting position to an anterior and superior position during the swallowing reflex, with the lower border of the spinous process of the fourth cervical vertebra used as the reference point.

Videofluoroscopic dysphagia scale: assessment of VF recordings obtained for evaluating dysphagia according to the report by Han et al.[19]

2) Questionnaire on swallowing

Patients will answer a questionnaire on swallowing function (Eating Assessment Tool-10 [EAT-10]) that comprises 10 items on swallowing-related quality of life.[20]

Sample size calculation

Sample size was determined using the results of a previous study on PTT, which is the primary endpoint, as reference. [21] Matsubara et al.[21] reported an improvement in PTT after 4 weeks of a high-speed jaw-opening exercise in elderly patients with mealtime malaise ($p = 0.01$; Cohen's $d = 0.57$). Using an unpaired two-tailed t-test with Cohen's $d = 0.57$, $\alpha = 0.05$, power = 0.8, and allocation ratio = 1, the sample size will be 50 patients per group. Thus, the target study participants are estimated to be 100. We will be collaborating with our research partners for participant recruitment.

Data processing and analysis

We will follow the intention-to-treat (ITT) principle and perform data collection and analysis based on the treatment assigned to patients by stratified random allocation. ITT analysis is an analytical method based on the allocation determined before the start of the intervention. Missing data will be statistically analysed using the last observation carried forward method. The obtained data will be entered into a dedicated database for collection and analysis. The background and functional test results of participants as well as adverse events experienced by them will be compared between the SP and NSP groups. The primary outcomes are the single-word intelligibility test score and pharyngeal transit time (PTT). The secondary outcomes are tongue function (evaluated based on maximum tongue pressure, RTP, and ETP), articulation function (evaluated based on speech intelligibility, oral diadochokinesis, V-RQOL), and swallowing function (evaluated using EAT-10). The immediate effect will be assessed under

paired conditions. Training effects will be assessed using two-way analysis of variance. All statistical analyses will be performed using SPSS version 22 (IBM, Chicago, State of Illinois, USA). A p-value < 0.05 will be considered significant.

ETHICS AND DISSEMINATION

Ethical approval was obtained from the Okayama University Certified Review Board. The trial registration number is CBR20-007 (jRCTs062200054). Study findings will be published in an open access, peer-reviewed journal and presented at relevant conferences and research meetings. Any changes or revisions to the research protocol or consent explanatory document will be approved in advance by an accredited clinical research review committee.

Data Management

The principal investigator or sub-investigator will explain the study in writing to participants and obtain their consent. Furthermore, a case report form (CRF) has been prepared. The data collected in this study will be entered into and analysed using the researcher's computer (not connected to the Internet) to protect participants' personal information; moreover, the data will be stored in a DVD-R as a password-protected file. The data will remain in a locked cabinet in the Division of Oral Surgery, Kawasaki Medical School Hospital, for 5 years after study completion. Subsequently, the DVD-Rs will be destroyed and the consent forms shredded.

Data monitoring

On-site monitoring of this study is conducted by a person designated by the principal investigator in accordance with the protocol. The monitoring manager has no conflicts of interest to declare.

All adverse events will be recorded on the CRF that will include information on the nature and timing of onset and resolution, severity, treatment, and outcome of the adverse event as well as assessment of its severity. Follow-up investigations will be performed if deemed necessary.

Compensation

The study will be covered by clinical research insurance in case of liability for compensation in the event that study participants experience health problems.

Discussion

Acute rehabilitation is usually primarily achieved through functional training and compensatory methods; therefore, prosthesis use has rarely been incorporated into acute rehabilitation. Studies reporting the starting point of rehabilitation interventions for cerebrovascular diseases have shown that patients starting rehabilitation within 72 h of hospitalisation had a shorter hospital stay and better gait at discharge than those starting rehabilitation later than 72 h.[22] Furthermore, Takashima and Abe have reported that early construction of a knee-ankle-foot orthosis during the acute phase of stroke improves gait independence at an early stage.[23] Accordingly, using prosthetic orthotics to support functional movement may contribute to early

rehabilitation of patients with central nervous system-related locomotor disability. Moreover, as Soft PAP is easy to fabricate and use, it may become a widely used training device for early intervention. Future research will help identify the optimal timing of initiating a Soft PAP intervention and its duration and other impacts.

ACKNOWLEDGMENTS

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AUTHORS' CONTRIBUTIONS

TY and SM conceptualised the original study and drafted the manuscript. KT, TM, TH, NA, JY, HN, KH and NK contributed to refining the study design. YM is the monitoring manager. NK and SM critically revised the manuscript. TM and SM are the principal investigators. SM is the lead researcher. All authors have approved the final draft of the manuscript.

FUNDING

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COMPETING INTERESTS

The authors declare no conflicts of interest.

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FIGURE LEGENDS

Figure 1 Soft palatal augmentation prosthesis

Figure 2 Study flow chart

Figure 3 Soft palatal augmentation prosthesis (Soft-PAP) used in the SP group: type 1 and type 2

Figure 4 Outcome measures and time points

Figure 5 The tongue pressure measurement device (TPM-01, JMS, Hiroshima) is connected to a personal computer. Measurements are performed with real-time visual feedback on the screen.

Figure 6 An example of measurements obtained when 50% of Pmax is considered the target tongue pressure

Figure 7 Measurement of the endurance of tongue pressure (ETP): A, B, and C show a schematic sample of the endpoint of ETP. A: Tongue pressure decreased between 40% and 50% of Pmax for 2 s with subsequent pressure recovery to >50% of Pmax. B: Tongue pressure

decreased below 40% of Pmax for 0.5 s with subsequent pressure recovery to >50 of % Pmax.

C: Tongue pressure decreased below 50% of Pmax without any subsequent recovery to >50% of Pmax.

Fig. 1

Fig. 2

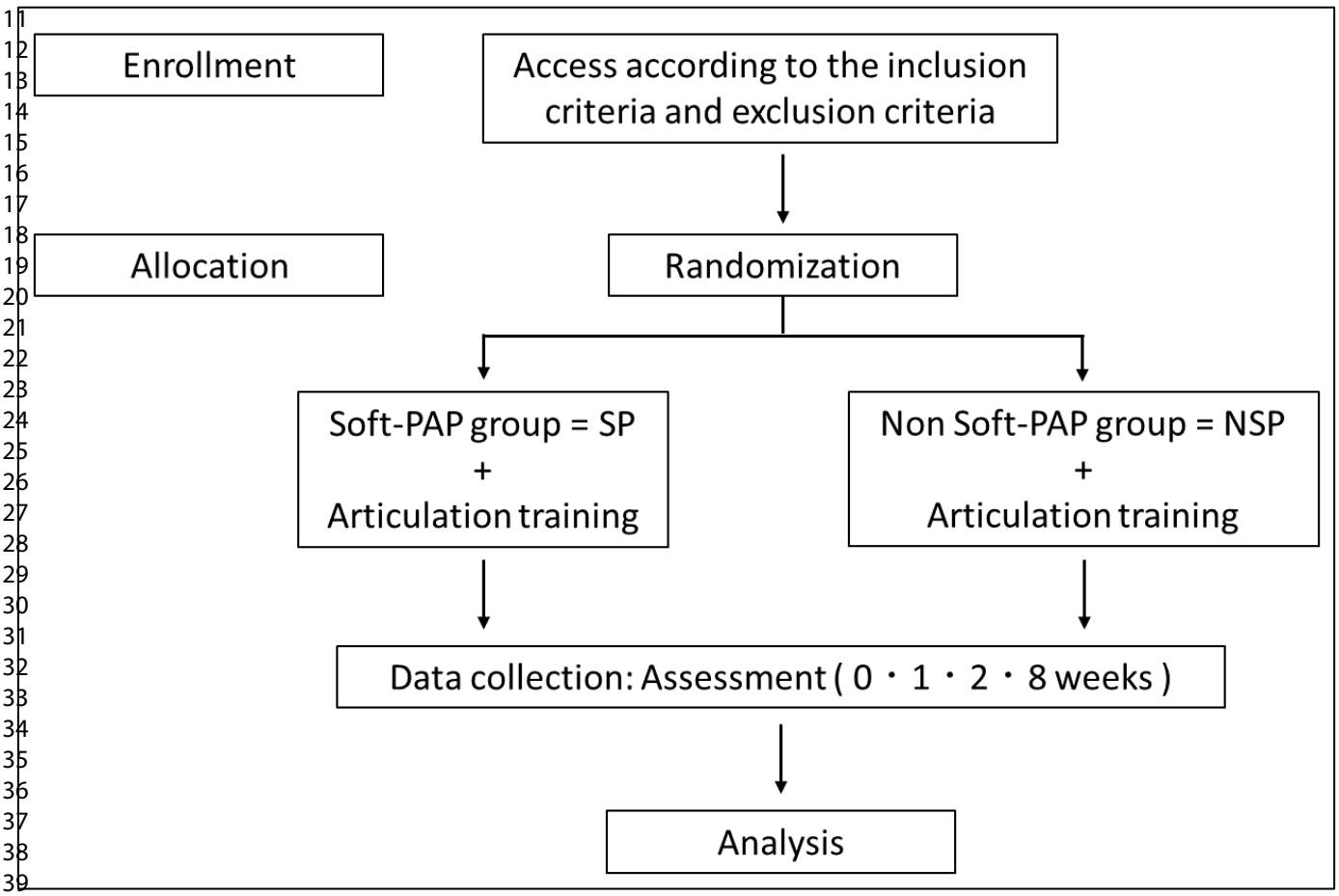

Enrollment
Access according to the inclusion criteria and exclusion criteria
Allocation
Randomization
Soft-PAP group = SP + Articulation training
Non Soft-PAP group = NSP + Articulation training
Data collection: Assessment (0・1・2・8 weeks)
Analysis

Fig. 3

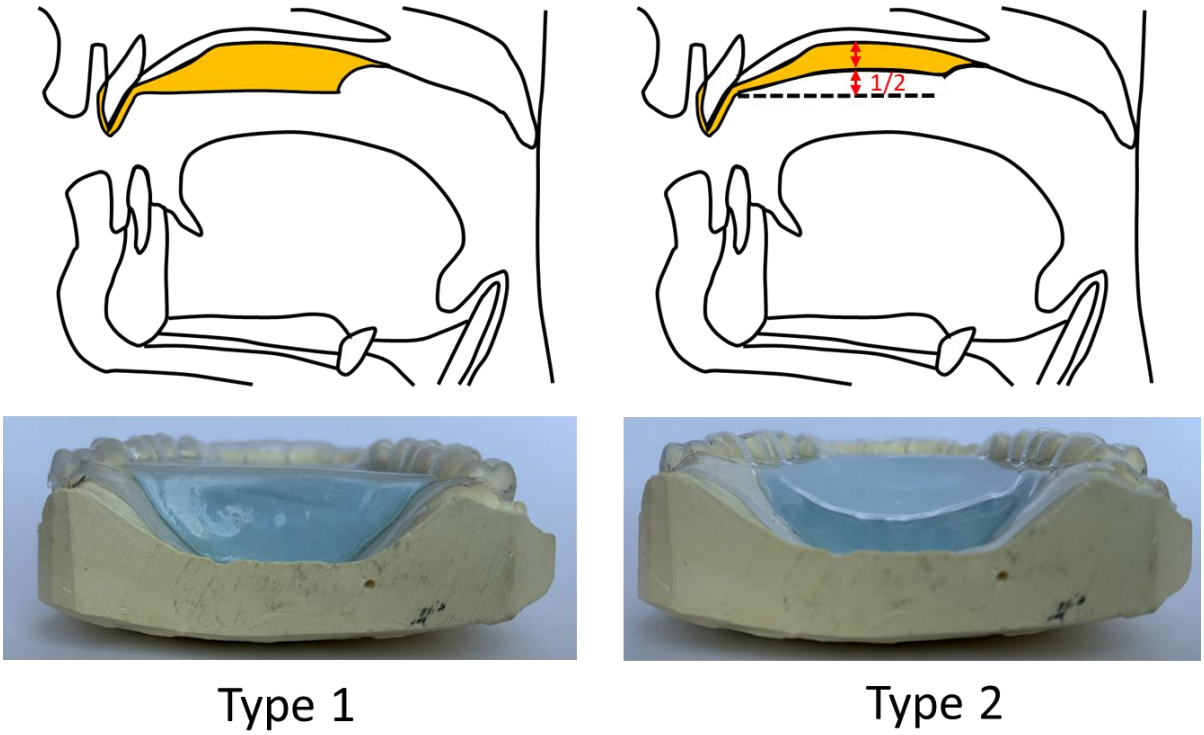


Fig. 4

	Enrollment	Allocation	Baseline	Weeks after Treatment		
Time Point	Prior to allocation	Befor 3day−0	0	Week 1	Week 2	Week 8
Eligibility screen	◎					
Informed consent	◎					
Allocation		◎				
Tooth impressions		◎				
Fabrication of Soft-PAP		□				
Intervention			←	—	—	→
Assessment: Motor function of tongue			○	○	○	○
Articulation function			○ □■	○ □■	○ □■	○ □■
Swallowig function			○ □■		○ □■	○ □■
Conscious Evaluation of Soft−PAP			□	□	□	□

※ The ◎ is performed by all participants. ○ = NSP group, □ = SP group, ■ = unattached condition for SP

Fig. 5

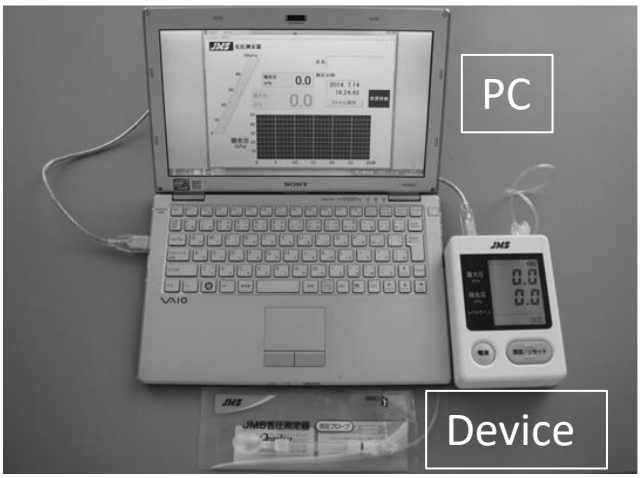


Fig. 6

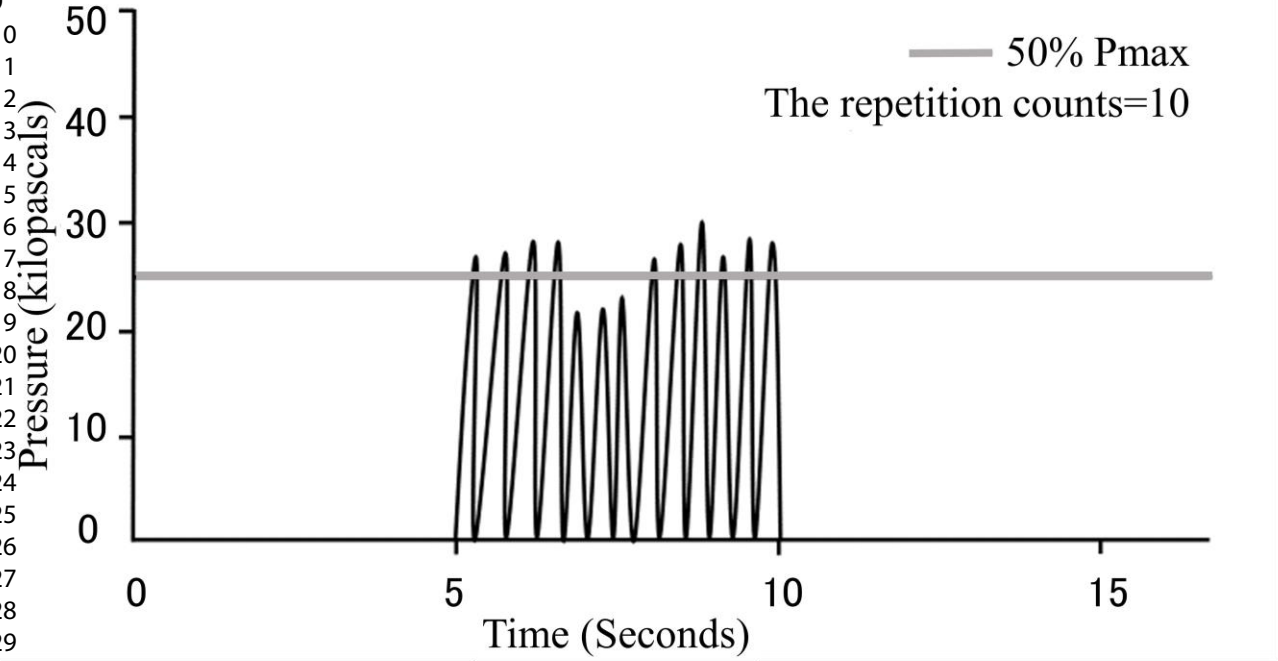
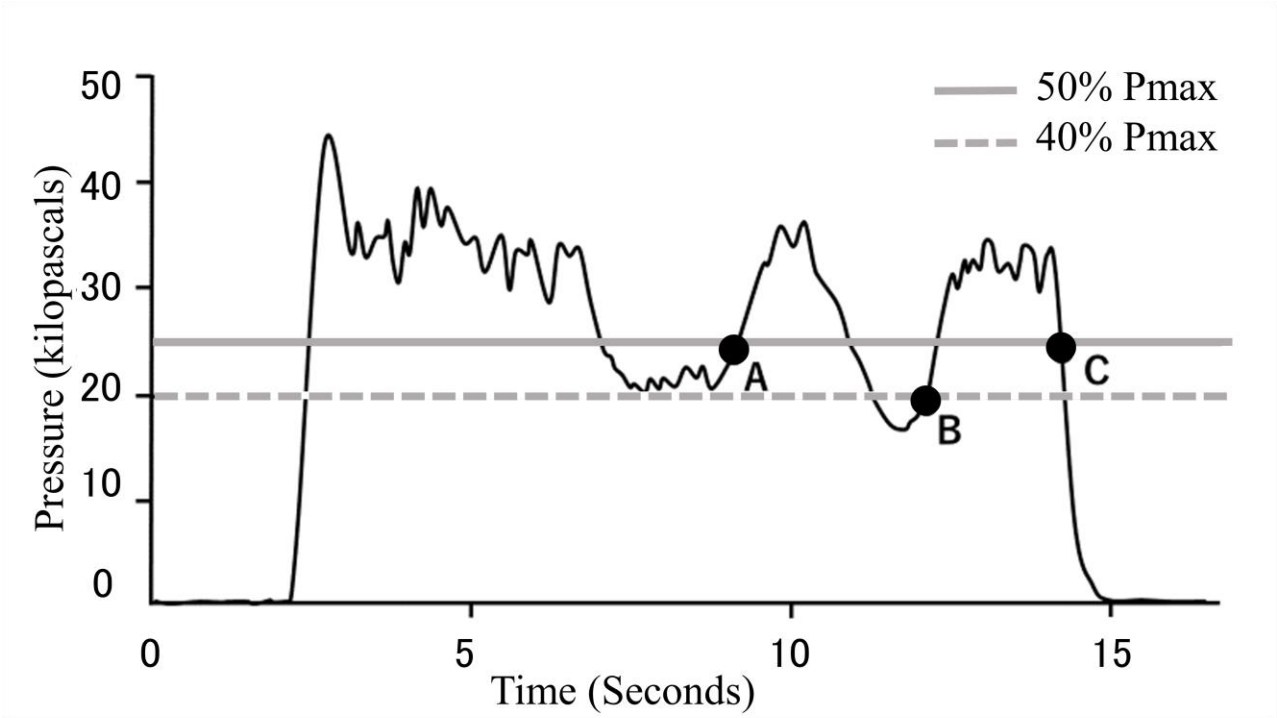

50% Pmax
The repetition counts=10
Pressure (kilopascals)
50
40
30
20
10
0
0
5
10
15
Time (Seconds)

Fig. 7


50% Pmax
40% Pmax
Pressure (kilopascals)
50
40
30
20
10
0
A
B
C
0
5
10
15
Time (Seconds)

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	ItemNo, Number of page	Description
Administrative information		
Title	1 P1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
Trial registration	2a P4	Trial identifier and registry name. If not yet registered, name of intended registry
	2b P4	All items from the World Health Organization Trial Registration Data Set
Protocol version	3 P4	Date and version identifier
Funding	4 P18	Sources and types of financial, material, and other support
Roles and responsibilities	5a P1,P18	Names, affiliations, and roles of protocol contributors
	5b P18	Name and contact information for the trial sponsor
	5c P18	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities
	5d -	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
Introduction		
Background and rationale	6a P6-8	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention

	6b P5-7	Explanation for choice of comparators
Objectives	7 P7-8	Specific objectives or hypotheses
Trial design	8 P7-8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)
Methods: Participants, interventions, and outcomes		
Study setting	9 P8	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained
Eligibility criteria	10 P9-10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)
Interventions	11a P7-8	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
	11b P8	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)
	11c -	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
	11d P7-8	Relevant concomitant care and interventions that are permitted or prohibited during the trial
Outcomes	12 P10-15	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
Participant timeline	13 P7	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
Sample size	14 P14-15	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
Recruitment	15 P15-16	Strategies for achieving adequate participant enrolment to reach target sample size

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a P10	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions
Allocation concealment mechanism	16b P10	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
Implementation	16c P10	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
Blinding (masking)	17a P10	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
	17b P10	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial

Methods: Data collection, management, and analysis

Data collection methods	18a P10-14	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
	18b P15	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols
Data management	19 P16-17	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol
Statistical methods	20a P15-16	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
	20b -	Methods for any additional analyses (eg, subgroup and adjusted analyses)

	20c P15	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)
Methods: Monitoring		
Data monitoring	21a P16-17	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed
	21b -	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
Harms	22 P17	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
Auditing	23 –	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor
Ethics and dissemination		
Research ethics approval	24 P16	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
Protocol amendments	25 P16	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
Consent or assent	26a P16	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
	26b -	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
Confidentiality	27 P16	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
Declaration of interests	28 P17	Financial and other competing interests for principal investigators for the overall trial and each study site
Access to data	29 P17	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
Ancillary and post-trial care	30 P17	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation

Dissemination policy	31a P16	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
	31b -	Authorship eligibility guidelines and any intended use of professional writers
	31c -	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code
Appendices		
Informed consent materials	32 P16	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens	33 P16	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Efficacy of Soft palatal augmentation prosthesis for oral functional rehabilitation in patients with dysarthria and dysphagia: a protocol for a randomised controlled trial

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Efficacy of Soft palatal augmentation prosthesis for oral functional rehabilitation in patients with dysarthria and dysphagia: a protocol for a randomised controlled trial

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Abstract

Introduction: Palatal augmentation prosthesis (PAP) is used in patients with articulation and swallowing disorders caused by postoperative loss of tongue tissue due to tongue cancer, cerebrovascular disease sequelae, and age-related hypofunction. We have previously reported a newly designed Soft PAP fabricated using an thermoplastic material that is particularly appropriate for early intervention. However, the effect of Soft PAP on oral function improvement remains to be elucidated. The aim of this study is to investigate whether Soft PAP can improve dysarthria and dysphagia occurring as cerebrovascular disease sequelae.

Methods and analysis: This prospective, randomised, controlled trial will compare the immediate and training effects of rehabilitation using Soft PAP with those of rehabilitation without using it. Primary outcomes are the single-word intelligibility test score and pharyngeal transit time (PTT). Secondary outcomes are tongue function (evaluated based on maximum tongue pressure, repetitions of tongue pressure, and endurance of tongue pressure), articulation function (evaluated based on speech intelligibility, oral diadochokinesis, Voice-Related Quality of Life [V-RQOL]), and swallowing function (evaluated using Eating Assessment Tool-10). The study results will help determine the efficacy of Soft PAP in improving functional outcomes of word intelligibility and PTT. We hypothesised that early rehabilitation using Soft PAP would more effectively improve articulation and swallowing function compared to conventional rehabilitation without using Soft PAP.

Ethics and dissemination: Ethical approval was obtained from the Okayama University Certified Review Board. The study findings will be published in an open access, peer-reviewed journal and presented at relevant conferences and research meetings.

Registration details: CBR20-007 (jRCTs062200054)

Strengths and limitations of this study

- A randomised controlled design will minimise bias and allow for a direct comparison between the groups.
- The intervention group will undertake rehabilitation using Soft palatal augmentation prosthesis, although the control group will receive normal training.
- The study sample size was calculated based on previous study regarding the improvement in pharyngeal transit time.
- The limitation of this study is that only the evaluator is blinded to allocation results, not the therapist or participants.

Keywords: Soft palatal augmentation prosthesis, tongue, articulation, swallowing, prospective study

INTRODUCTION

Palatal augmentation prosthesis (PAP) is used in patients with articulation and swallowing disorders caused by postoperative loss of tongue tissue due to tongue cancer, cerebrovascular disease sequelae, and age-related hypofunction.[1] The Japan Council for Quality Health Care guideline for PAP states that it enhances the rehabilitation effect when fabricated and used appropriately.[1] PAP use has been recommended in the PAP guidelines issued by the Japan Prosthodontic Society [1] PAP can be used to improve dysphagia or dysarthria caused not only by tissue loss after glossectomy but also by posterior movement disorders occurring as cerebrovascular disease sequelae.[2] In patients requiring upper and/or lower limb rehabilitation, early initiation of rehabilitation effectively improves the prognosis of movement disorders.[3] However, an early intervention protocol involving PAP use for rehabilitation therapy has not yet been established. This might be partly attributable to the practical difficulties faced by general dental practitioners in fabricating and adjusting PAP during the acute stage of the primary disease. Therefore, medical and dental interprofessional collaboration in acute-care-oriented hospitals in this field is required for PAP use in early rehabilitation therapy.

Most studies reporting the effect of PAP on dysphagia and dysarthria occurring due to stroke and neuromuscular diseases are either case reports or retrospective studies.[4] Moreover, the methods used for evaluating clinical efficacy in these studies were not well structured; therefore, a meta-analysis could not be performed.[4] Thus, prospective cohort studies

examining the effect of rehabilitation using PAP on patients with stroke and neuromuscular disease are needed.

Conventionally, PAP has been fabricated using acrylic resin.[5-8] Acrylic resin is a denture base material and exhibits stable mechanical properties that are appropriate for long-term use, even after repeated clinical adjustment. To achieve the best effect on patients' oral function, frequent adjustments by a skilled dentist are usually required, even when PAP is fabricated at a rather stable or chronic stage of the primary disease. However, given the atmosphere of acute care units providing early intervention in hospitals, a device that is easy to fit and requires less adjustment might be easily accepted. We have previously reported a newly designed Soft PAP fabricated using an elastic thermoplastic material that is particularly appropriate for early intervention (figure 1).[9, 10] Soft PAP is a simplified PAP that has a flat palatal surface. Although a major disadvantage of Soft PAP is that it may not be fully adjustable to exactly reproduce patient's oral function, it provides a mechanical target point as a *terminus ad quem* for tongue movement during rehabilitation. Its inherent properties of ease of fabrication and no requirement of adjustment to provide a mechanical target point are expected to benefit patients undergoing rehabilitation.[11] Early rehabilitation interventions using this simplified type of PAP may improve dysarthria and dysphagia occurring as cerebrovascular disease sequelae. We conducted a preliminary study using a small sample size to ascertain the effect of early intervention using Soft PAP.[12] The results of this preliminary study suggest

that early rehabilitation using Soft PAP improves the functional speed of the tongue tip during articulation movements. We hypothesised that early rehabilitation using Soft PAP would more effectively improve articulation and swallowing function compared to conventional rehabilitation without using it. Therefore, our null hypothesis is that the effect of rehabilitation using Soft PAP on articulation and swallowing function is not different from that of conventional rehabilitation without using Soft PAP.

METHODS AND ANALYSIS

Trial design

This study will be a prospective, randomised, controlled trial comparing the immediate and training effects of rehabilitation using Soft PAP (SP group) with those of conventional rehabilitation without using Soft PAP (NSP group) on patients with dysarthria and dysphagia. Figure 2 shows the flowchart of this clinical trial. Two PAPs with different palatal plate thicknesses will be fabricated for each participant. One will extend up to the height of the flat palatal surface at the cervical line of the upper posterior tooth, whereas the other one would be half as thick as the previous one (figure 3). The participants will select the PAP they feel most comfortable with. They will be instructed to wear Soft PAP for as long as possible, except during meals and sleep, with each participant maintaining a record of the actual duration of wearing the PAP. Each group will be provided the same articulation training during the study

period. The patients will be assessed at baseline and at 2 and 8 weeks postintervention. Enrolment in the study will be performed by a medical doctor or dentist. Soft PAP will be fabricated by a dentist, and video fluorography (VF) assessment will be performed by a medical doctor, radiologist, and speech–language pathologist. Other evaluations will be performed by medical doctors, dentists, and speech–language pathologists. The criteria for stopping the trial include deterioration of patients' condition and a request to stop.

Patient and public involvement

Patients admitted to Kawasaki Medical School Hospital who meet the inclusion criteria receive an explanation for this study. They are not involved in the design or conducting of the study. Results of the study will be disseminated to the participants who want to know the results. In addition, they are not asked to assess the burden of the intervention and time required to participate in the research.

Study sites

This study is funded by the Department of Occlusal and Oral Functional Rehabilitation, Graduate School of Medicine, Dentistry and Pharmaceutical Sciences, Okayama University.

Study participant recruitment will take place at the Kawasaki Medical School Hospital.

Ethical approval

The study protocol was approved by the Okayama University Certified Review Board.

Study population

Study participants will be selected from among patients admitted to the Kawasaki Medical School Hospital with a primary diagnosis of stroke, neuromuscular disease, or head trauma and with a speech articulation disorder score of ≥2.[13] Speech intelligibility will be evaluated by recording the patient reading a text aloud and assessed by three speech–language pathologists with at least 3 years of experience. The following paragraphs provide a detailed description of the inclusion and exclusion criteria.

Inclusion criteria

Patients fulfilling the following five conditions will be enrolled in the study:

1) Those who are acutely hospitalised for stroke, neuromuscular disease, head injury, or other related diseases in the Kawasaki Medical School Hospital

2) Those suffering from dysarthria with a speech intelligibility score of ≥2 or dysphagia with problems in the preparatory, oral, or pharyngeal phase

3) Those within 2 weeks of being allowed to receive articulation or swallowing rehabilitation

4) Those aged ≥20 years at the time of obtaining informed consent

5) Those who have been fully informed about the study and completely understand their participation and have provided voluntary written consent for enrolment

Exclusion criteria

Patients fulfilling one or more of the following five conditions will be excluded:

1) Those diagnosed as having impaired consciousness (a score of ≥10 on the Japan Coma Scale)

2) Those unable to wear Soft PAP due to edentulous maxillae

3) Those with residual tooth mobility that makes it difficult to obtain dental arch impressions

4) Those unable to follow movement instructions due to mental deterioration

5) Those deemed inappropriate for inclusion by the principal investigator or sub-investigator

Enrolment

Enrolment will start after the approval of application for a specific clinical trial. The target completion year is 2026.

Randomisation

Participants will be assigned to either the SP or NSP group according to their sex and age (over and under 65 years) using a web application that automatically achieves stratified randomisation.[14]

Blinding

Randomisation will be reported to the researchers on the basis of the allocation table by someone not involved in the study, with the allocation table strictly controlled. Although participants cannot be blinded to the assigned intervention, they will be blinded to all data analyses, including expected treatment outcomes.

Outcome measures

Figure 4 shows outcome measures and time points. The following three types of functional data will be collected:

1. Motor function of the tongue

The maximum tongue pressure, maximum number of repetitions of tongue lift-up movement (Repetitions of tongue pressure), and maximum duration of maintaining tongue pressure (Endurance of tongue pressure) will be measured using a tongue pressure measuring device (TPM-01, JMS, Hiroshima) (figure 5).

1) Maximum tongue pressure (Pmax)

After positioning the device probe in the mouth, the subject will be instructed to press the probe against the hard palate as strongly as possible using the tongue. This measurement will be performed twice, and the maximum value of the two measurements will be defined as Pmax.

2) Repetitions of tongue pressure (RTP)

RTP will be defined as the maximum number of repetitions performed to press the probe to increase the pressure from 0 kPa to >50% of Pmax in 5 s (figure 6).[15] Real-time visual feedback of the applied tongue pressure with the target value will be provided on a computer screen to the patient during the measurement. The number of times the tongue pressure reaches the target pressure will be defined as RTP, and the number of times it does not reach the target pressure will be defined as failed RTP. The above measurements will be performed three times, with a 30-s break between each attempt.

3) Endurance of tongue pressure (ETP)

ETP will be defined as the maximum duration for which the patient can maintain a tongue

pressure ≥ 50% of Pmax.[16] Two measurements, with a 1-min break between them, will be performed. For the offline measurement of ETP from the waveform, the starting point of the duration will be defined as the moment at which tongue pressure exceeds 50% of Pmax. The endpoint of the duration will be defined according to the following three settings (figure 7):

A: Tongue pressure decreases between 40% and 50% of Pmax for 2 s with subsequent pressure recovery to >50% of Pmax

B: Tongue pressure decreases below 40% of Pmax for 0.5 s with subsequent pressure recovery to >50% of Pmax

C: Tongue pressure decreases below 50% of Pmax without any subsequent recovery to >50% of Pmax

The earliest time point for the above three settings will be regarded as the endpoint.

2. Articulation function

1) Oral diadochokinesis (Oral DDK)

Patients will be instructed to repeat each of the three target sounds (/ta/, /ka/, /taka/) as quickly as possible for 5 s, and the sounds will be recorded using a digital voice (integrated chip; IC) recorder (Sony ICD-SX850, Tokyo, Japan). Two measurements will be performed for each sound. The average of the two measurements will be considered the oral DDK for each sound.

2) 40-Word intelligibility test

Ishihara's 40-word list will be used for a 40-word intelligibility test, with the words listed in a

randomised order. Participants will read out the words from the list, and their voices will be recorded using an IC recorder. The assessment will be completed by three healthy adults without hearing impairment whose native language is Japanese. The average percentage of correct responses by the three examiners will be calculated.

3) Speech intelligibility

Patients' speech will be recorded in two conditions: i) reading aloud a fairy tale, 'Jack and the Beanstalk', and ii) 'routine conversation about patients' events of the day' in 1 min. The assessment will be completed by three healthy adults without hearing impairment whose native language is Japanese. Speech intelligibility will be rated on a five-point scale for each recording.[17] Conventional criteria will be used for this scale in all cases, as in Taguchi's method. The conventional criteria and scores are as follows: 1 = intelligible, 2 = partially intelligible, 3 = intelligible when the topic is known, 4 = mostly unintelligible, and 5 = unintelligible. The average of the three examiners' ratings will be calculated.

4) V-RQOL

V-RQOL is a questionnaire used for examining the voice-related quality of life.[18] Patients will fill in a self-assessment V-RQOL sheet using the following five-point scale for each of the 10 questions about their voice: 1 = none, not a problem; 2 = a small amount; 3 =a moderate (medium) amount; 4 = a lot; and 5 = problem is 'as bad as it can be'.

3. Swallowing function

1) Swallowing VF

The patient will sit in a chair and swallow 5 mL of thickened barium twice. During this task, VF will be recorded in the lateral and frontal views and assessed using the following parameters:

Oral transit duration: time elapsed between the start of swallowing motion of the tongue and the arrival of the bolus head at the ramus of the mandible

PTT: time elapsed between the bolus head crossing the ramus of the mandible and its passage through the upper oesophageal sphincter

Stage transition duration: time elapsed between the bolus head crossing the ramus of the mandible and the onset of hyoid bone elevation

Hyoid movement distance: the maximum elevation of the hyoid bone from the resting position to an anterior and superior position during the swallowing reflex, with the lower border of the spinous process of the fourth cervical vertebra used as the reference point.

Videofluoroscopic dysphagia scale: assessment of VF recordings obtained for evaluating dysphagia according to the report by Han et al.[19]

2) Questionnaire on swallowing

Patients will answer a questionnaire on swallowing function (Eating Assessment Tool-10 [EAT-10]) that comprises 10 items on swallowing-related quality of life.[20]

Sample size calculation

Sample size was determined using the results of a previous study on PTT, which is the primary endpoint, as reference. [21] Matsubara et al.[21] reported an improvement in PTT after 4 weeks of a high-speed jaw-opening exercise in elderly patients with mealtime malaise ($p = 0.01$; Cohen's $d = 0.57$). Using an unpaired two-tailed t-test with Cohen's $d = 0.57$, $\alpha = 0.05$, power = 0.8, and allocation ratio = 1, the sample size will be 50 patients per group. Thus, the target study participants are estimated to be 100. We will be collaborating with our research partners for participant recruitment.

Data processing and analysis

We will follow the intention-to-treat (ITT) principle and perform data collection and analysis based on the treatment assigned to patients by stratified random allocation. ITT analysis is an analytical method based on the allocation determined before the start of the intervention. Missing data will be statistically analysed using the last observation carried forward method. The obtained data will be entered into a dedicated database for collection and analysis. The background and functional test results of participants as well as adverse events experienced by them will be compared between the SP and NSP groups. The primary outcomes are the single-word intelligibility test score and pharyngeal transit time (PTT). The secondary outcomes are tongue function (evaluated based on maximum tongue pressure, RTP, and ETP), articulation function (evaluated based on speech intelligibility, oral diadochokinesis, V-RQOL), and swallowing function (evaluated using EAT-10). The immediate effect will be assessed under

paired conditions. Training effects will be assessed using two-way analysis of variance. All statistical analyses will be performed using SPSS version 22 (IBM, Chicago, State of Illinois, USA). A p-value < 0.05 will be considered significant.

Data Management

The principal investigator or sub-investigator will explain the study in writing to participants and obtain their consent. Furthermore, a case report form (CRF) has been prepared. The data collected in this study will be entered into and analysed using the researcher's computer (not connected to the Internet) to protect participants' personal information; moreover, the data will be stored in a DVD-R as a password-protected file. The data will remain in a locked cabinet in the Division of Oral Surgery, Kawasaki Medical School Hospital, for 5 years after study completion. Subsequently, the DVD-Rs will be destroyed and the consent forms shredded.

Data monitoring

On-site monitoring of this study is conducted by a person designated by the principal investigator in accordance with the protocol. The monitoring manager has no conflicts of interest to declare.

All adverse events will be recorded on the CRF that will include information on the nature and timing of onset and resolution, severity, treatment, and outcome of the adverse event as well as assessment of its severity. Follow-up investigations will be performed if

deemed necessary.

Compensation

The study will be covered by clinical research insurance in case of liability for compensation in the event that study participants experience health problems.

Discussion

Acute rehabilitation is usually primarily achieved through functional training and compensatory methods; therefore, prosthesis use has rarely been incorporated into acute rehabilitation. Studies reporting the starting point of rehabilitation interventions for cerebrovascular diseases have shown that patients starting rehabilitation within 72 h of hospitalisation had a shorter hospital stay and better gait at discharge than those starting rehabilitation later than 72 h.[22] Furthermore, Takashima and Abe have reported that early construction of a knee-ankle-foot orthosis during the acute phase of stroke improves gait independence at an early stage.[23] Accordingly, using prosthetic orthotics to support functional movement may contribute to early rehabilitation of patients with central nervous system-related locomotor disability. Moreover, as Soft PAP is easy to fabricate and use, it may become a widely used training device for early intervention. Future research will help identify the optimal timing of initiating a Soft PAP intervention and its duration and other impacts.

ETHICS AND DISSEMINATION

Ethical approval was obtained from the Okayama University Certified Review Board. The trial registration number is CBR20-007 (jRCTs062200054). Study findings will be published in an open access, peer-reviewed journal and presented at relevant conferences and research meetings. Any changes or revisions to the research protocol or consent explanatory document will be approved in advance by an accredited clinical research review committee.

ACKNOWLEDGMENTS

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AUTHORS' CONTRIBUTIONS

TY and SM conceptualised the original study and drafted the manuscript. KT, TM, TH, NA, JY, HN, KH and NK contributed to refining the study design. YM is the monitoring manager. NK and SM critically revised the manuscript. TM and SM are the principal investigators. SM is the lead researcher. All authors have approved the final draft of the manuscript.

FUNDING

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COMPETING INTERESTS

The authors declare no conflicts of interest.

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FIGURE LEGENDS

Figure 1 Soft palatal augmentation prosthesis

Figure 2 Study flow chart

Figure 3 Soft palatal augmentation prosthesis (Soft-PAP) used in the SP group: type 1 and type 2

Figure 4 Outcome measures and time points

Figure 5 The tongue pressure measurement device (TPM-01, JMS, Hiroshima) is connected to a personal computer. Measurements are performed with real-time visual feedback on the screen.

Figure 6 An example of measurements obtained when 50% of Pmax is considered the target tongue pressure

Figure 7 Measurement of the endurance of tongue pressure (ETP): A, B, and C show a schematic sample of the endpoint of ETP. A: Tongue pressure decreased between 40% and 50% of Pmax for 2 s with subsequent pressure recovery to >50% of Pmax. B: Tongue pressure

decreased below 40% of Pmax for 0.5 s with subsequent pressure recovery to >50 of % Pmax.

C: Tongue pressure decreased below 50% of Pmax without any subsequent recovery to >50% of Pmax.

Fig. 1

Fig. 2

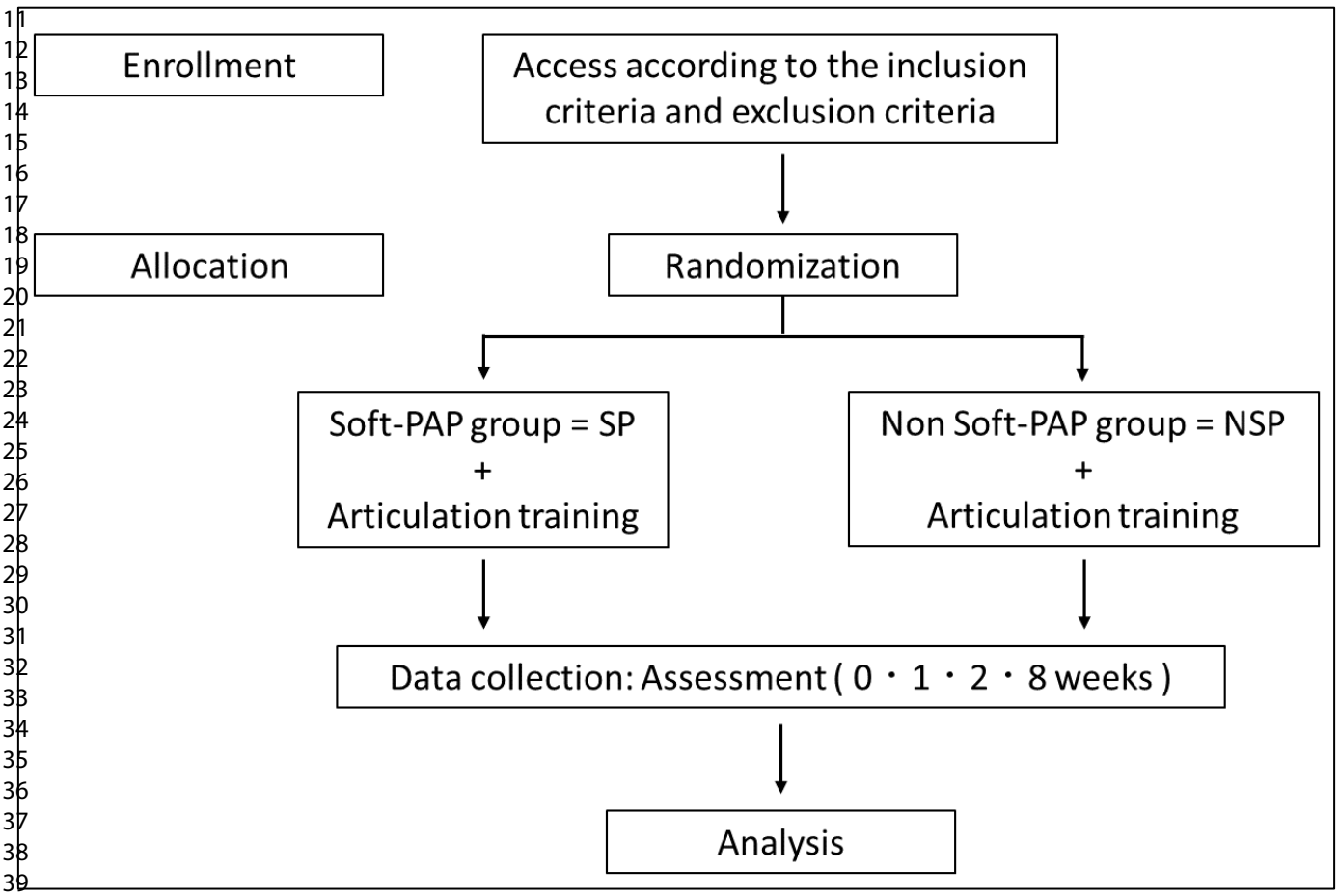

Enrollment
Access according to the inclusion criteria and exclusion criteria
Allocation
Randomization
Soft-PAP group = SP + Articulation training
Non Soft-PAP group = NSP + Articulation training
Data collection: Assessment (0・1・2・8 weeks)
Analysis

Fig. 3

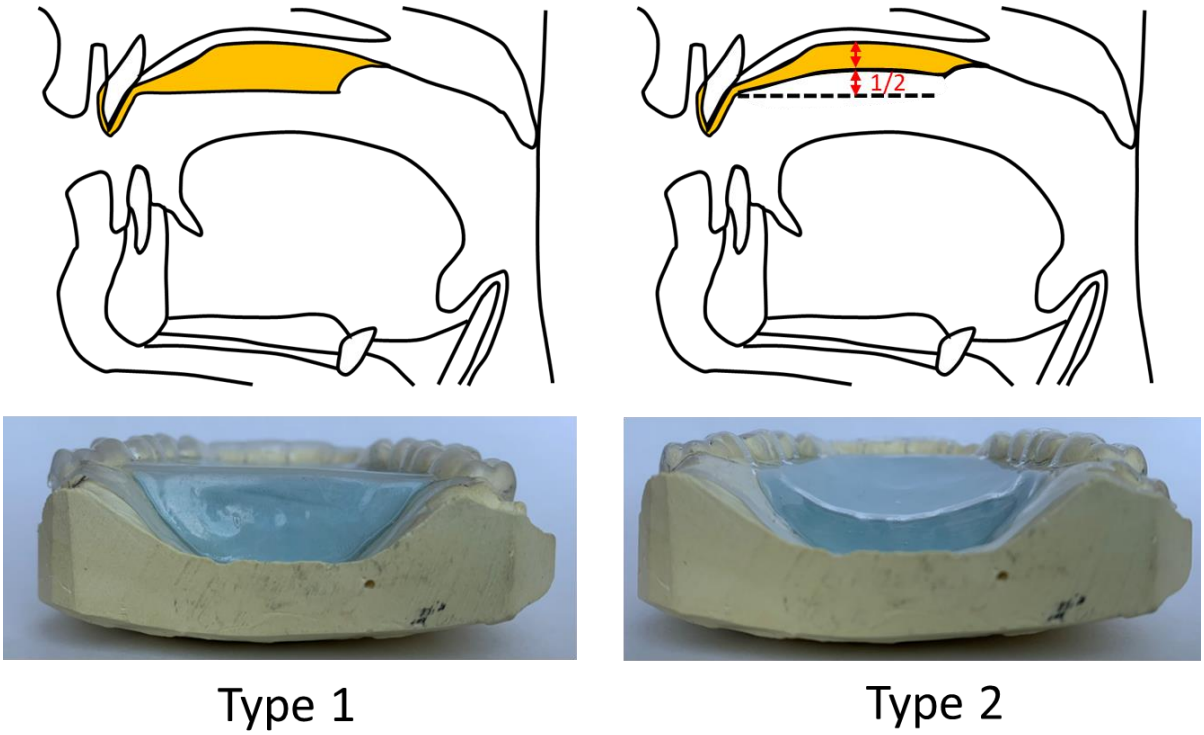


Fig. 4

	Enrollment	Allocation	Baseline	Weeks after Treatment		
Time Point	Prior to allocation	Befor 3day−0	0	Week 1	Week 2	Week 8
Eligibility screen	◎					
Informed consent	◎					
Allocation		◎				
Tooth impressions		◎				
Fabrication of Soft-PAP		□				
Intervention			←	—	—	→
Assessment: Motor function of tongue			○	○	○	○
Articulation function			○ □■	○ □■	○ □■	○ □■
Swallowig function			○ □■		○ □■	○ □■
Conscious Evaluation of Soft−PAP			□	□	□	□

※ The ◎ is performed by all participants. ○ = NSP group, □ = SP group, ■ = unattached condition for SP

Fig. 5

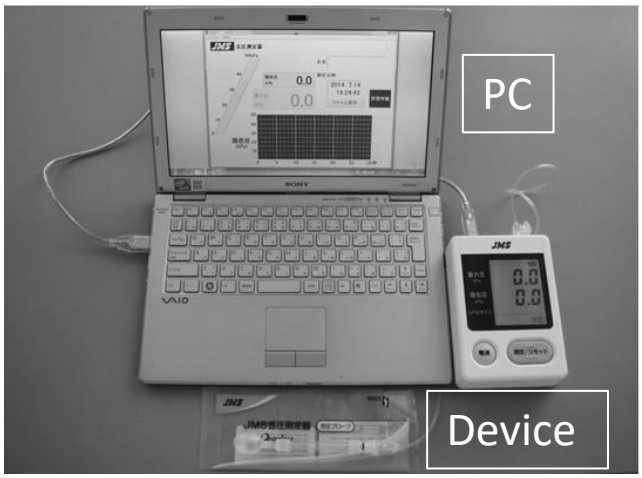


Fig. 6

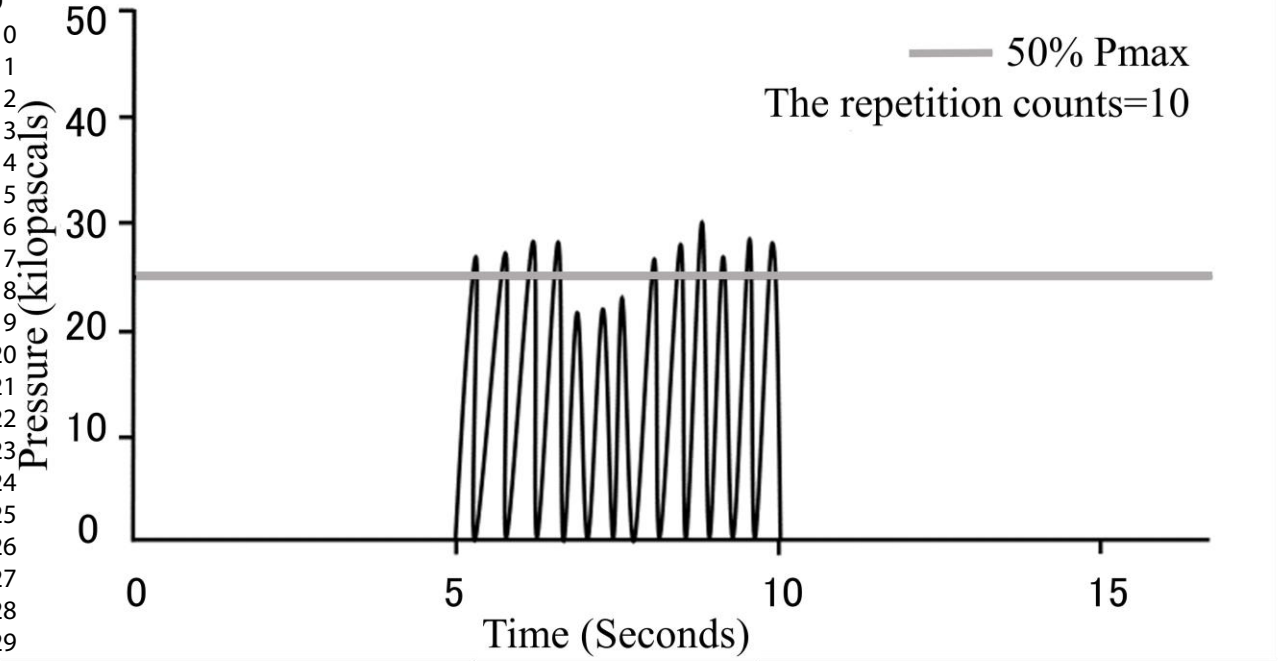
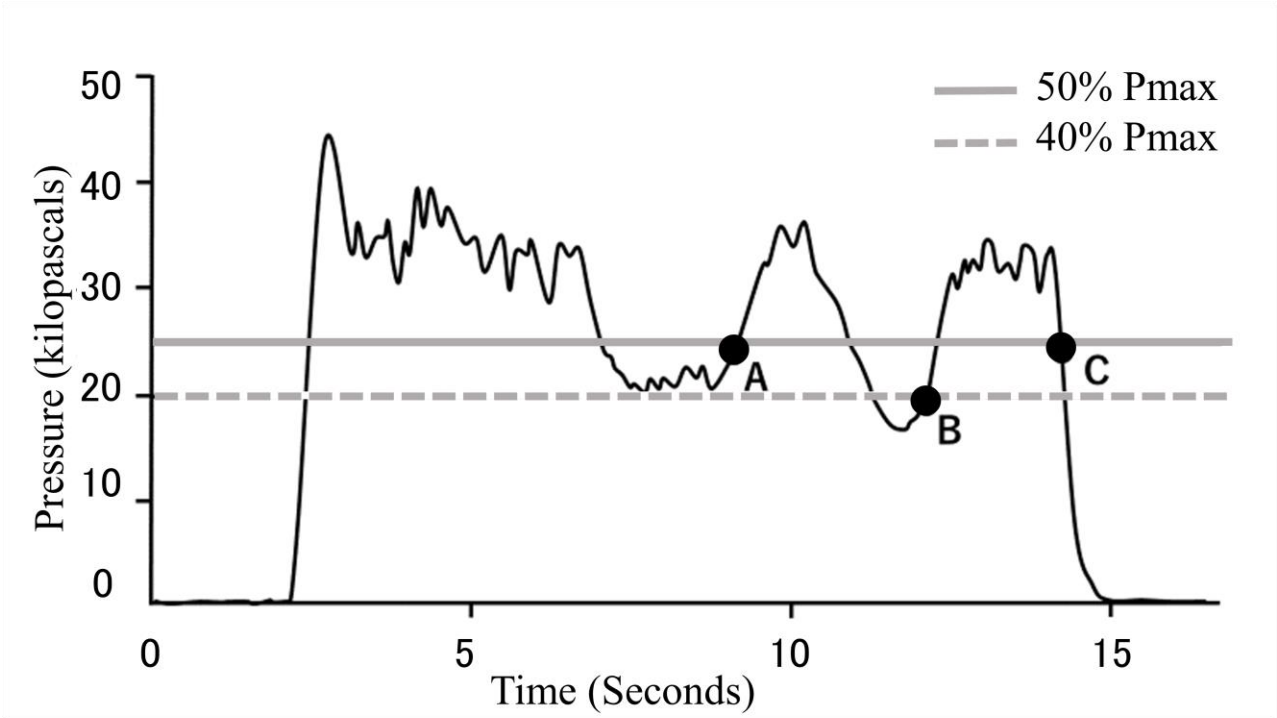

50% Pmax
The repetition counts=10
Pressure (kilopascals)
50
40
30
20
10
0
0
5
10
15
Time (Seconds)

Fig. 7


50% Pmax
40% Pmax
Pressure (kilopascals)
50
40
30
20
10
0
A
B
C
0
5
10
15
Time (Seconds)

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	ItemNo, Number of page	Description
Administrative information		
Title	1 P1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
Trial registration	2a P4	Trial identifier and registry name. If not yet registered, name of intended registry
	2b P4	All items from the World Health Organization Trial Registration Data Set
Protocol version	3 P4	Date and version identifier
Funding	4 P18	Sources and types of financial, material, and other support
Roles and responsibilities	5a P1,P18	Names, affiliations, and roles of protocol contributors
	5b P18	Name and contact information for the trial sponsor
	5c P18	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities
	5d -	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
Introduction		
Background and rationale	6a P6-8	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention

	6b P5-7	Explanation for choice of comparators
Objectives	7 P7-8	Specific objectives or hypotheses
Trial design	8 P7-8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)
Methods: Participants, interventions, and outcomes		
Study setting	9 P8	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained
Eligibility criteria	10 P9-10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)
Interventions	11a P7-8	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
	11b P8	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)
	11c -	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
	11d P7-8	Relevant concomitant care and interventions that are permitted or prohibited during the trial
Outcomes	12 P10-15	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
Participant timeline	13 P7	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
Sample size	14 P14-15	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
Recruitment	15 P15-16	Strategies for achieving adequate participant enrolment to reach target sample size

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a P10	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions
Allocation concealment mechanism	16b P10	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
Implementation	16c P10	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
Blinding (masking)	17a P10	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
	17b P10	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial

Methods: Data collection, management, and analysis

Data collection methods	18a P10-14	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
	18b P15	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols
Data management	19 P16-17	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol
Statistical methods	20a P15-16	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
	20b -	Methods for any additional analyses (eg, subgroup and adjusted analyses)

	20c P15	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)
Methods: Monitoring		
Data monitoring	21a P16-17	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed
	21b -	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
Harms	22 P17	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
Auditing	23 –	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor
Ethics and dissemination		
Research ethics approval	24 P16	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
Protocol amendments	25 P16	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
Consent or assent	26a P16	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
	26b -	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
Confidentiality	27 P16	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
Declaration of interests	28 P17	Financial and other competing interests for principal investigators for the overall trial and each study site
Access to data	29 P17	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
Ancillary and post-trial care	30 P17	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation

Dissemination policy	31a P16	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
	31b -	Authorship eligibility guidelines and any intended use of professional writers
	31c -	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code
Appendices		
Informed consent materials	32 P16	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens	33 P16	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.