

Augmentative and Alternative Communication Intervention for in-patient Individuals With Post-stroke Aphasia: Study Protocol of a Parallel-group, Pragmatic Randomized Controlled Trial

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Study protocol

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Abstract

Background: People with post-stroke moderate to severe aphasia commonly receive speech-language therapy (SLT). However, the outcomes of SLT sometimes is limited. Augmentative and alternative communication (AAC) has been reported as an effective treatment approach to improve communication effectiveness, language performance, decreasing depression, and improving quality of life for this population. However, little evidence has demonstrated the use of AAC intervention (AACT) in early recovery from people with post-stroke aphasia in in-patient rehabilitation settings. Besides, only a few studies use a randomized controlled trial (RCT) to compare AACT with SLT to date. The present study focuses on the effect of including AACT in regular SLT for people with post-stroke moderate to severe aphasia (PWAs) in an in-patient rehabilitation setting. The present study aims to compare the potential effectiveness of AACT combined with SLT on communication effectiveness and language recovery with SLT alone for PWAs in in-patient rehabilitation settings.

Methods: We strive to include 30 PWAs, enroll in an in-patient program, a single-blind, randomized controlled trial with two parallel groups, and a 2-week follow-up. Patients receive a one-hour treatment session, including either both AAC and SLT or SLT alone daily for ten consecutive sessions. Three assessment points include baseline, after intervention sessions, and after the 2-week follow-up to compare the two groups' intervention effectiveness. The primary outcome measure is the score differences on the Communication of Basic Needs of Functional Assessment of Communication Skills for Adult (FACS) pre- and post- intervention. The secondary outcome measures include the results of the Chinese Standard Aphasia Battery (ABC), the 10-item Hospital version of the Stroke Aphasic Depression Questionnaire (SADQH-10), and the Stroke-Specific Quality of Life Scale (SS-QOL) as well as a patient and caregiver satisfaction questionnaire.

Discussion: This RCT of AACT in an in-patient rehabilitation setting will contribute to new scientific evidence to the field of aphasia rehabilitation in early recovery during the in-patient period. The paper describes the trial, which will explore the effect of combining AACT and SLT and SLT only, our choice of primary and secondary outcome measures, and proposed analyses. The study results will provide information for implementing AACT in the regular in-patient SLT of future RCTs.

Trial registration: This trial is registered in the Chinese Clinical Trial Registry database (ChiCTR) as ChiCTR2000028870. Date registered: 5 January 2020.

Background

Stroke is one of the most common neurological disorders with a high incidence globally [1] and a leading cause of disability worldwide [2]. Nearly one-third of patients with stroke have post-stroke aphasia [1, 3], which is defined as an impairment of the complex process of interpreting and formulating language symbols affecting auditory comprehension, reading, and oral-expressive language and writing [1]. People with aphasia (PWA) commonly experience different levels of expressive language impairments, ranging

from occasional word-finding difficulties to severe verbal communication difficulties [4]. The impairment further reduces PWA's verbal communication efficiency in daily life [5]. Therefore, aphasia is also related to greater emotional distress levels, like frustration and depression. It also can negatively impact the quality of life, health outcomes, and participation in daily and medical encounters [6–9].

Considerable recovery may occur during the first year, even possible for those with severe aphasia [1, 10]. However, about 60% of the patients show consistent communication impairment one-year post stroke [10]. Speech-language therapy (SLT), focusing on reducing the severity of language impairment [11], is the primary therapeutic approach to improve the language and communication abilities for PWA [4, 12, 13]. A meta-analysis in a Cochrane review suggests that there is some effectiveness of SLT for people with post-stroke aphasia in terms of improved functional communication, reading, writing, and expressive language compared to those without SLT [4]. However, PWA often do not recover sufficient language capability to communicate functionally in acceptable ways to themselves or others in their environments [14, 15]. Therefore, some systematic reviews advocate that different approaches other than SLT might be used alone or adjunct to SLT to optimize the therapeutic effect for this population [4, 16].

Augmentative and alternative communication (AAC) helps PWA participate in communication activities in alternative ways [5, 14, 15]. An AAC system is defined as an integrated group of components to enhance communication. These components include AAC forms (aided or unaided), symbols to present languages, selection techniques, and AAC usage strategies [18]. PWA can use either aided forms (such as communication books and high-tech devices) or unaided forms (such as facial expressions and gestures) for different communication situations [7, 17], and improve (a) communicate basic needs, (b) deliver information, (c) maintain social closeness, and (d) use social etiquette by AAC [5, 17]. Therefore, AAC is considered as a treatment option for PWA. AAC can be used to compensate for expressive communication impairments, facilitate communication effectiveness, and to support traditional SLT [7, 17].

Historically, AAC intervention (AACT) focused on primarily supporting PWA's communication function but not restored PWA's language abilities. Currently, few studies reported that AACT could facilitate PWA's language recovery. Evidence has shown that PWA can acquire alternative means of expression and comprehension to make proper requests and respond to their conversation partner(s) [19–23]. Several AAC treatment studies have documented improvements in aphasia test scores and spoken discourses to unfamiliar listeners [24–26]. Moreover, it has been reported that PWA may self-cue with the letter on an AAC device or a communication board to facilitate spoken language during communication breakdowns [24, 27, 28]. While this positive evidence of AACT in PWA is encouraging, a randomized controlled trial (RCT) for AACT is needed to investigate further the difference between AAC and other means of intervention, and finally increase acceptance of AAC as a valid treatment approach [24].

In in-patient rehabilitation settings, people with moderate to severe aphasia usually receive all-day care from an interdisciplinary team of professionals [9]. In these situations, PWA need to communicate effectively about goal setting, preferences, and medical decision making with health care providers [29].

However, PWA often complain that communication in hospital settings is challenging due to reduced comprehension and expression abilities. Meanwhile, caregivers and healthcare professionals also reported difficulties when communicating with PWA [30]. Therefore, when PWA work with speech-language pathologists (SLPs), SLPs help PWA identify communication needs and introduce different communication strategies to maximize their communication skills within desired life roles [29]. SLPs teach PWA how to use available AAC systems (e.g., paper-based communication boards) to promote communication in daily activities [9, 24]. However, little is known about the effectiveness of AAC practices in in-patient rehabilitation settings. Thus, an understanding of AAC practices and supports related to serving individuals with post-stroke aphasia within in-patient rehabilitation settings is essential to develop evidentiary AAC intervention in in-patient rehabilitation settings.

It is also important to note that there is limited evidence of AACT for Chinese-speaking people with aphasia until now. PWA in in-patient rehabilitation settings in China are mainly in acute rehabilitation or subacute facilities. Their communication demands may include expressing basic wants and needs and specific needs (e.g., asking a nurse to call a family member). On the other hand, they need to share information and feelings with their family members and interact with medical professionals about needs and concerns regards to their healthcare. Evidence indicated that this population could learn to use AAC systems, such as yes/no cards to answer questions, use a rating scale to rate their feelings or opinions on a particular subject, and use communication boards that include pictures and words to participate in specific activities or conversational topics [5]. While the previous studies supported the concept of using AAC in hospital settings, there is still no evidence to support this approach in Chinese-speaking PWA. Therefore, an AACT RCT study is needed to investigate the feasibility of the AACT and build up the foundation of research evidence.

Previous studies have reported that PWA and their families often reject to accept AAC strategies with the fear that AAC may interfere with or impede the restoration of their natural language system [24, 31, 32]. In the meantime, early AACT combined with SLT may result in an increased acceptance of AAC and better long-term participation outcomes. SLT allows PWA to recover as many language abilities as possible and reduce overall aphasia severity. Meanwhile, AACT may simultaneously strengthen communication by reducing the pressure to retrieve target concepts using impaired language functions [24]. Since the present study aims to introduce a new approach (AACT) in an in-patient rehabilitation setting, considering PWA's potential concern and their families becomes essential. Therefore, instead of comparing AACT and SLT exclusively, the present study aims to compare AACT's effect along with regular SLT to SLT only in individuals with post-stroke moderate to severe aphasia in an in-patient rehabilitation program.

Objective

The present study focuses on the effectiveness of AACT combined with SLT for individuals with moderate to severe aphasia in in-patient rehabilitation settings. The primary aim is to evaluate whether PWA who receive AACT with SLT have more improvement in functional communication and language performance than those who received only SLT.

Methods

Study design and procedure

The study is a single-blind, pragmatic randomized controlled trial with two parallel groups and a 2-week follow-up. Participants will participate in ten one-hour treatment sessions (see Fig. 1). During each intervention session, participants will receive 30 minutes of AACT in addition to 30 minutes of SLT (experimental group) or 60 minutes of SLT (control group). Participants in the AACT + SLT group will learn to use a paper-made (low-technology) communication board to express themselves. The communication board includes 30 pictures relating to basic needs, moods, medical conditions, and daily activities. Except for the two experimental conditions above, participants' regular rehabilitation interventions, such as physical and occupational therapies, remain the same. To our knowledge, a parallel design has not been used before in the AAC literature. This design allows measurements pre- and post-intervention, thus providing information on improvement over time within one subject.

Setting and study population

PWA who are receiving in-patient stroke rehabilitation services, are screened for eligibility. These participants are enrolled in in-patient service in Yueyang Hospital of Integrated Traditional Chinese and Western Medicine Shanghai University of traditional Chinese medicine, Shanghai, China (YY Hospital). Table 1 lists the inclusion and exclusion criteria. We strive to include 30 participants, based on a power analysis (see Data analysis section). Before inclusion, all participants and their family members review the written information and an oral explanation from the research staff. Participants are required to review the information and sign the consent form before participating in the study. This study has been approved by the Medical Ethics Committee (MEC) of YY hospital (reference number: 2019-118, approval received in November 2019). The researchers will report serious adverse events to the MEC. The events will be managed based on institutional policies.

Table 1
Inclusion and exclusion criteria

<p>Inclusion criteria</p> <ol style="list-style-type: none">1. Diagnosis of aphasia, after stroke, as confirmed by a qualified speech-language therapist ascertained with the Chinese Standard Aphasia Battery (ABC) test [33]2. Moderate to severe information reduction of Verbal production (percentile score of 50 or lower on the ABC verbal production subtest)3. First onset of stroke, anytime post-stroke4. Age 20–80 years5. Mandarin Chinese as the first language. (the first) native language6. Able to participate in intensive therapy <p>Exclusion criteria</p> <ol style="list-style-type: none">1. Acute stroke with unstable vital signs2. Premorbid speech and language disorders caused by a neurological deficit other than stroke3. Premorbid cognitive impairment, mood disorders, mental disorders affecting communication4. Severe non-linguistic cognitive disturbances impeding language therapy5. Presence of serious heart, liver, kidney, infectious disease and uncontrolled medical problems6. Concomitant neurological diseases other than stroke

Randomization and blinding

Participants who meet the inclusion criteria will be randomly assigned to the experimental group or the control group after the baseline assessment. To randomize participants to the experimental or control condition on the ratio of 1 to 1, we use a list of two-number codes based on a computer-generated sequence. Then these codes are ordered from the smallest to the largest and transferred to new numbers. Odd numbers are allocated to the experimental condition (AACT + SLT), and even numbers are allocated to the control condition (SLT only). A researcher, who is not involved in the assessment and training process, seals these new numbers in numbered opaque envelopes. At the beginning of each participant's first intervention session, an SLP will open one of the envelopes, so he/she knows a participant's assigned condition. Therefore, all participants are blinded to their treatment condition.

Intervention

In each intervention session, both groups will receive a one-hour intervention in total. The experimental group will receive AACT (0.5 hour) + SLT (0.5 hour). The control group will receive a one-hour SLT. The same SLP provides all interventions to all participants. Each intervention session is video recorded.

AACT (experimental condition) is provided by teaching participants to point to the target icons on a paper-based communication board to answer questions (e.g., “Do you have pain?”, “Where is your pain?”) in line with studies that apply AACT for PWA [5,9,34]. The communication board contains 45 icons designed for PWA to communicate with medical professionals and family members in the in-patient setting. These icons are pictures of everyday needs, clinical symptoms, types of medical care, rehabilitation services, name of people around, yes/no signs, and a rating scale, with Chinese written words on the top of each icon.

Each intervention includes three training tasks. These tasks aim to help PWA to learn how to use the communication board [25]. The first task is symbol identification. Participants are asked to identify each icon on the communication board following verbal directions from the SLP. At first, the SLP presents the verbal model plus a demonstration: the SLP saying “point to [target icon]” while physically modeling the desired response by pointing to the target icon on the communication board. After the modeling, participants are asked to follow the same directions. Next, the SLP presents a verbal cue only: the SLP saying “point to [target icon],” and then requires the participant to point to the target icon independently. The second task is to answer yes/no questions. The SLP asks a yes/no question relative to a particular icon (is this a picture of [target icon]) and then asks the participant to respond to the question by pointing to the yes or no icon on the communication board. The third task is to respond to questions with a specific icon. The SLP asks an open-ended question relative to a particular icon (e.g., “if you have a headache, which icon will be selected to tell the people who are surrounding you?”). Then the participant responds to the question by pointing to the target icon.

In SLT (control group), fifty words related to the stroke rehabilitation program's routine are selected. The fifty words include categories as vegetables and fruits, daily supplies, daily actions, body parts, the salutation of surrounding medical professionals and family members (husband/wife, son/daughter, physician, nurse, caregiver). These words are presented with a picture and a written word. The 50 items are divided into five sets (10 items/set) according to categories. Participants will practice one set in every two days.

Participants learn the semantic and phonological knowledge of 10 items and conduct auditory comprehension (selecting target item from two/four items following verbal directions from the SLP), word repetition, and naming tasks of learned items in each session. The tasks and training procedures are the same in each session. The procedures are as follows: 1) participants are taught with the semantic and phonological knowledge of the target item one by one; 2) they are asked to repeat the word with the SLP; 3) they are asked to do auditory comprehension tasks by selecting target items from two or four cards; 4) they are asked to name the target picture based on the Cueing Hierarchy [35].

Measurement instruments

Table 2 gives an overview of the measurement instruments used in the study. The primary outcome measure is the scale of the Communication of Basic Needs (CBN) on the Functional Assessment of

Communication Skills for Adults (FACS) [36]. The scale and the sub-test items are translated into Chinese.

The FACS are used to measure the change of the functional communication skills for basic needs pre- and post- intervention. The FACS is a measure of functional communication for adults, which measures functional communication across four assessment domains: social communication, communication of basic needs, reading, writing, and number concepts, and daily planning. Participants use the scale to rate their performance. The response is scaled from 0 to 7, with the outcome measure from 0 to 49, and lower scores indicate more severe communication disability [37].

The secondary outcome measures are the Chinese Standard Aphasia Battery (ABC), a 10-minute clinician-patient semi-structured conversation (10-min conversation), the 10-item Hospital version of the Stroke Aphasic Depression Questionnaire (SADQH-10) [38], the Stroke-Specific Quality of Life Scale (SS-QOL) [39] and a satisfaction questionnaire. The ABC is a well-known aphasia test for evaluating PWA's language abilities in clinical settings in China [33]. A 10-minute conversation is used to measure participants' communication efficiency in the in-patient setting pre- and post- intervention. The participants are asked to talk about their daily lives and their medical services with the SLP. The conversation will be video recorded and analyzed by an SLP who is not involved in the intervention sessions. The SLP will evaluate the conversation based on four qualitative domains: adequacy, appropriateness, promptness, and communication sharing, using the 5-point scale of qualitative dimensions of communication in the FACS [36].

The SADQH-10 is used to evaluate depressive symptoms in PWA [38]. The SS-QOL is used to evaluate stroke-specific health-related quality of life [39]. A satisfaction questionnaire designed by the research team is used to evaluate the satisfaction of the interventions. The participants will complete the SADQH-10, the SS-QOL, and the satisfaction questionnaire. The participants' caregivers will also complete the satisfaction questionnaire.

Table 2

Measurement instruments

- | |
|------------------------------------------|
| 1. CBN sub-test on the ASHA FACS [36,37] |
| 2. ABC test [33] |
| 3. 10-minute conversation |
| 4. SADQH-10 [38] |
| 5. SS-QOL [39] |
| 6. Satisfaction questionnaire |

Fig 2 shows the schedule of each outcome measure. The primary outcome measure: the CBN sub-test on the ASHA FACS, is completed baseline and post-intervention. The secondary outcome measures: the ABC, a 10-minute conversation, and the SADQH-10 are also completed baseline and post-intervention. The satisfaction questionnaire is completed after the intervention. The SS-QOL is completed after a 2-week follow-up for evaluating the quality of life after participants are discharged by the in-patient rehabilitation program. The additional file 1 is an overview of the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist.

Sample size

No large RCTs have been carried out within the field of Aphasia AACT in in-patient rehabilitation settings. Previous AAC studies used interventions not applicable to the current protocol and used small sample sizes. We are, therefore, unable to calculate prior accurate sample size. Thus, the sample size is calculated based on the primary hypothesis to detect a minimal but clinically significant difference between the experimental and the control groups on functional communication and language performance. In a previous RCT study [37], the participants were people with severe aphasia compared to people with aphasia in the overall sample. The FACS mean scores were 3.48 (SD = 0.90) and 5.78 (SD = 0.89) for the severe aphasia group and the overall sample, respectively. The differences were significant for the overall mean, $t(92)=8.29$, ($p \leq 0.001$). This trial uses the two scores as the assumptions of the results of the two groups. This study uses a comparison between two means of the two-sample with the two-sided equality formulas to calculate the sample size and achieve a statistical power of 80% and a significance level of 5%. The trial must include a total of eight participants. Each group needs four participants to detect this difference. Since the power calculation only relates to the primary endpoint of pragmatic communication skills, and the target group has a high level of heterogeneity, the trial aims for a larger sample size than 8 participants. Based on the retrospective analysis of patients with aphasia in the YY Hospital, a sample of 24 participants can potentially be recruited over this period. After considering a drop out rate of 20%, the study aims to recruit 30 participants in total.

Data analysis

Outcomes of interest will be analyzed on an intention-to-treat basis. Potential differences of baseline outcomes between the groups are tested using independent t-tests for continuous variables, the Mann-Whitney U test for ordinal variables, and chi-square tests for categorical variables. Outcomes of the measures over time are compared for the experimental condition versus the control condition using repeated measurement analysis. This analysis considers the correlation of repeated measurements within the same patients and handles missing data, assuming that the data are missing randomly. The dependent variables are the outcome measures, and the independent variables are time and group assignments and the interaction between these variables. In these analyses, adjustments are made for potentially confounding variables that can be unequally distributed over the groups despite the randomization procedure. All statistical analyses are performed using the Stata statistical software. An alpha level of 0.05 is accepted as significant. The results of the statistical models are presented in the

form of regression coefficients, their 95% confidence intervals, and effect sizes. The statistician who completed the data analyses is blinded to group allocation until the analysis is completed.

Discussion

The present protocol describes a pragmatic randomized controlled trial that should make a valuable contribution to the field of AAC applied for people with post-stroke moderate to severe aphasia in in-patient rehabilitation settings. The trial's primary objective is to investigate the effectiveness of AACT combined with traditional SLT in communication/language abilities, depressive symptoms, and quality of life. To our knowledge, no RCTs have explored the combination of two treatment approaches for PWA in in-patient rehabilitation settings.

SLT approaches aim to recover verbal communication skills by behavior modification, cognitive therapy, and pragmatic therapies regardless of time post-stroke. While AAC may provide a means of communicating through devices and techniques when spoken communication skills do not work in SLT [25]. In fact, AAC and traditional restorative approaches are not mutually exclusive, and AAC can be viewed as a dual-purpose tool that can simultaneously drive inter-systemic reorganization with the potential to support language function while providing compensatory strategies during communication breakdowns. Furthermore, AAC intervention may help to reduce PWA's level of impairment by increasing the use of alternative options for communication and improving participation in daily life with increased independence [24].

Our trial is looking at the feasibility of scaling the intervention up for clinical implementation. Evidence suggests that PWA has decreased quality of life, poorer health outcomes, and limited participation in medical encounters due to their communication and language disabilities [9, 29]. People with moderate to severe aphasia are more likely to experience adverse medical events (e.g., medication errors) than those without a communication disability [9, 29, 40]. AACT can help PWA reduce frustration from communication difficulties and participate in various communication situations in in-patient rehabilitation settings [9]. A paper-based (low-technology) communication board, like the board in this study, is to be used to communicate with caregivers and health care providers in in-patient rehabilitation settings. It is also easy to access, carry, and modified [9]. As an in-patient stay is often the first step on a long-term care continuum, AAC can maximize PWA's communication skills within desired life roles and prepare them and their families for life after the in-patient stay [9, 29]. We are expecting to develop a greater understanding of AACT for PWA in in-patient rehabilitation settings. If the trial is shown to be feasible, not harmful, and explore clinically meaningful improvement beyond this pilot, AACT can be applied within an in-patient setting in future practice.

In our previous experience, AAC is often not prescribed in the early stages of recovery and is more likely to be recommended to people with severe aphasia who cannot produce functional natural language. However, recent evidence suggests that early AACT in in-patient settings may increase the acceptance of AAC and decrease the risk of not using language during the early recovery stage. Early AACT may also

increase PWA's motivation to communicate in various situations and have better long-term participation outcomes. Therefore, they were more active when making their healthcare decisions, experiencing increased participation in life events, and discovering new social roles [17]. This evidence supports the purpose of the trial's intention to investigate early AACT's effectiveness in in-patient settings. The results of the trial will also contribute to the research evidence of AACT in Chinese-speaking PWA.

A limitation of this study is that this protocol is not double-blind. However, the participants and the SLP will be blinded to treatment allocation. The study also cannot eliminate the confounding effects from the early-stage spontaneous recovery after stroke. When the trial is completed, the results will strengthen the evidence of early AACT's effectiveness for PWA in in-patient rehabilitation settings. Furthermore, to implement AACT to support functional communication, facilitate language recovery, reduce depressive symptoms, and ultimately improve PWA's quality of life.

Trial status

The recruitment of the trial started in January 2020, and 9 participants have been recruited and randomized into the trial. The research team expects to complete the inclusion and the follow-up measures in December 2021.

Abbreviations

AAC: Augmentative and alternative communication; ABC: Aphasia Battery of Chinese; ASHA: American Speech and Hearing Association; CBN: Communication of Basic Needs; CONSORT: Consolidated Standards of Reporting Trials; FACS: Functional Assessment of Communication Skills for Adult; MEC: Medical Ethics Committee; PWA: People with aphasia; RCT: Randomized controlled trial; SADQH-10: 10-item Hospital version of the Stroke Aphasic Depression Questionnaire; SLP: Speech and language pathologist; SLT: Speech-language therapy; SPIRIT: Standard Protocol Items, Recommendations for Interventional Trials; SS-QOL: Stroke-Specific quality of life Scale. YY hospital: Yueyang Hospital of Integrated Traditional Chinese and Western Medicine Affiliated to Shanghai University of traditional Chinese medicine.

Declarations

Ethics approval and consent to participate

The study has received ethical approval by the ethics committee of Yueyang Hospital of Integrated Traditional Chinese and Western Medicine, Shanghai University of traditional Chinese medicine. A Consent Form for participation in the trial has been developed and approved by the Ethics Committee. Informed consent will be obtained from all participants in the trial.

Consent for publication

Not applicable.

Availability of data and materials

Not applicable

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

LH, S-HKC contributed to the protocol design and the writing of this manuscript. LH is responsible for the daily operational aspects of the study. STX is the statistician in this project. S-HKC and CLS are the corresponding authors and supervisors in this project. YLW, XJ, PW,JKS, JMT, SCZ, and GHZ all contributed to the design and drafted the manuscript. All authors read and approved the final manuscript..

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Figures

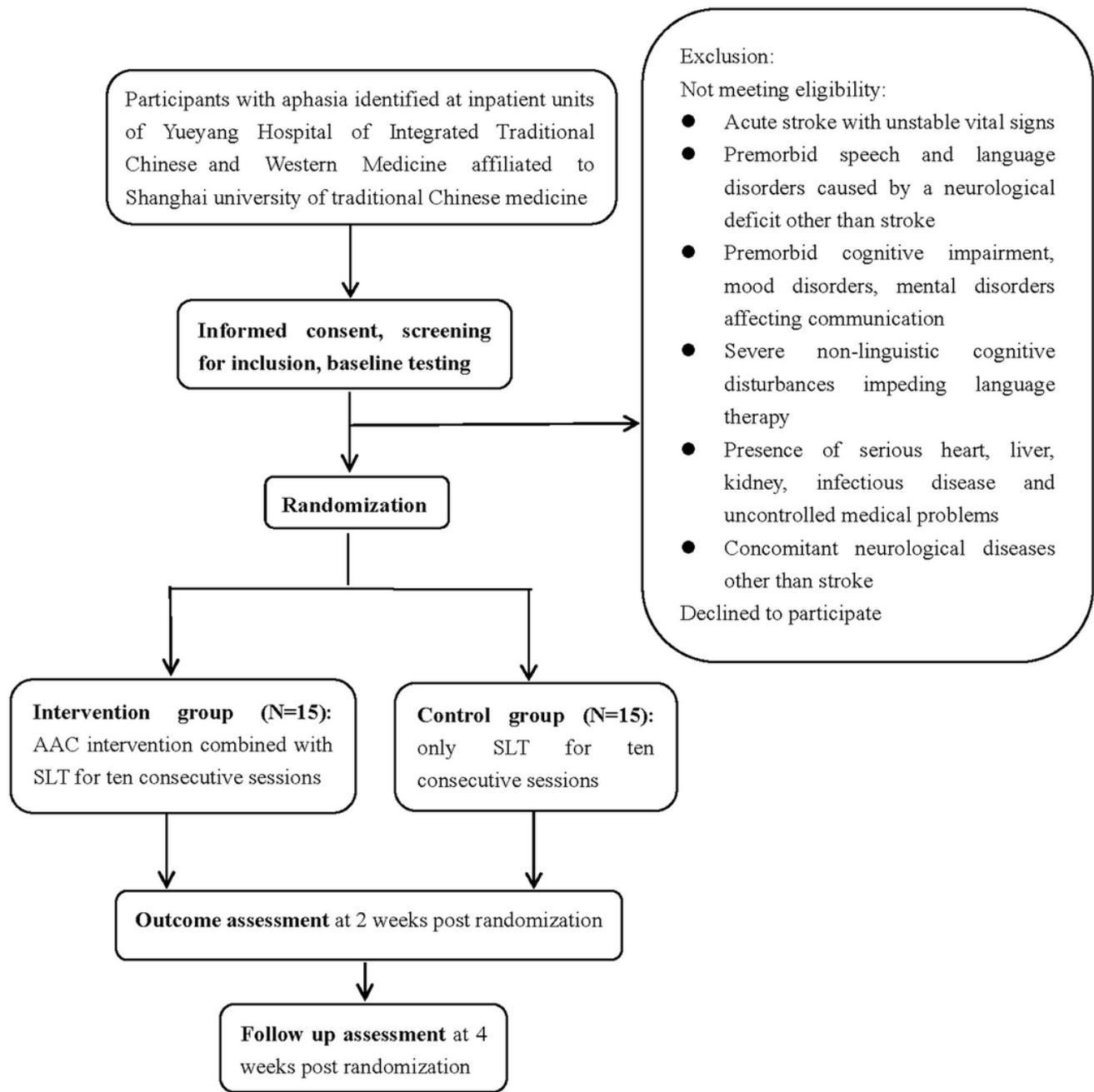


Figure 1

Flow diagram trial design

	Enrolment	Baseline assessment	Allocation	Intervention	Post intervention assessment	Follow-up assessment
Timepoint	Before baseline assessment	Day 0	After baseline assessment	Day 1 through day 10	Day 11	2 weeks post therapy
Enrolment:						
Eligibility screen	×					
Informed consent	×					
Allocation			×			
Interventions:						
Control group(SLT only)				→		
Experimental group (AACT + SLT)				→		
Assessments:						
ABC test	×				×	
SADQH-10		×			×	
CBN sub-test on the ASHA FACS		×			×	
10-minute conversation		×			×	
Satisfaction questionnaire					×	
SS-QOL						×
Demographic data	×					
Medical data	×					

Figure 2

Trial schedule of enrollment intervention and assessment

Supplementary Files

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