

BMJ Open Efficacy of a strategy-based intervention on text-level reading comprehension in persons with aphasia: a study protocol for a repeated measures study

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ABSTRACT

Introduction At least 68% of persons with aphasia (PWA) experience reading difficulties. Even though strategy-based interventions are a promising treatment approach for text level reading comprehension deficits in PWA, empirical evidence for their efficacy remains rare. The primary objective of this study is the analysis of the efficacy of a strategy-based intervention on text-level reading comprehension and on reading activities in PWA. **Methods and analysis** In a repeated measures trial, 24 PWA will first participate in a waiting period and then in a strategy-based intervention (14 face-to-face-sessions, 60 min each). We will apply two combinations of strategies to treat either the microstructure or the macrostructure, respectively. Participants will be randomly allocated to two parallel groups that will receive these combinations in interchanged sequences. Assessments will be implemented before and after each period as well as 3 and 6 months after the intervention. The primary outcome measure is text-level reading comprehension measured with a German version of the Test de Compréhension de Textes (TCT-D) and represented by the score TCT-D Total. A non-blinded and a blinded rater will evaluate the primary outcome measure. Secondary outcome measures will address specific reading functions, reading activities and cognitive functions. The sample size was determined with an a priori power analysis. For statistical analysis, we will use contrast analyses within repeated measures analysis of variance models. We expect significant improvements in primary and secondary outcome measures during the intervention as compared with changes during the waiting period.

Ethics and dissemination This study was approved by the ethics committee of Deutscher Bundesverband für akademische Sprachtherapie und Logopädie (20–10074-KA-MunmErw+Ko). Results and relevant data will be disseminated in peer-reviewed journals, at conferences and on the Open Science Framework.

Trial registration number DRKS00021411 (see Supplementary Table 1).

INTRODUCTION

Background and rationale

Acquired brain injury can impair reading from grapheme or word levels to the comprehension of written texts in the context of

Strengths and limitations of this study

- This study will support clinical decision making in aphasia therapy since it is the first repeated measures group study that evaluates effects of strategy-based interventions on text level reading comprehension.
- Based on theoretical models of text comprehension, the effects of two different combinations of strategy-based interventions on microstructure and on macrostructure will be explored.
- Outcome measures do not only include reading functions and cognitive functions but also reading activities.
- Blinding of speech and language pathologists and patients will not be possible due to the nature of speech and language interventions but we will perform a blind duplication of the evaluation of the primary outcome.
- The effect size of the a priori power analysis was estimated based on more general treatment approaches in persons with aphasia due to the novelty of the specific investigated treatment approach.

cognitive communication disorders or aphasia. At least 68% of persons with aphasia (PWA) experience reading difficulties.¹ With regard to more complex reading functions, prevalence may be even higher.² Text-level reading difficulties constrain activities such as reading medication schedules, text messages, books, job requirement or contracts, which in turn restricts participation in life domains like communication, self-care, family roles, employment as well as domestic and social life.^{3–5} Despite these severe consequences, reading impairments following stroke are often treated insufficiently or remain untreated.⁶ Systematic reviews of Purdy *et al*⁷ and Watter *et al*⁸ indicate that the evidence for the efficacy of text-level reading comprehension treatments in PWA is limited. They suggest further investigation with more rigorous study designs as well as research on

the contribution of cognitive and linguistic factors to text comprehension impairments in PWA.

Current cognitive theories suggest that reading is a constructive process based on an interaction between reader and text.^{9 10} Reading comprehension processes depend on visual processes, the conversion of visual input into a linguistic representation, general knowledge, and a reader's mental lexicon as well as orthographic and linguistic systems.¹¹ When reading a text, readers form three levels of mental representation: The surface level, the textbase and the situational model. While the phrases 'funny girl' and 'the girl is funny' differ in their superficial appearance of exact words and phrases (the surface level), they convey the same semantic content. The semantic content of a text is represented in the textbase in propositional form, thus in an idea-level format.^{9 12} Propositions are 'linguistic units consisting of a relational term (or predicate) and one or more arguments',¹² for example, (FUNNY, GIRL) or (EAT, GIRL, CAKE), and allow to work with the semantic content of a text regardless of the exact wording. In a text, every proposition is linked to at least one other proposition by a relational term or a shared argument, which establishes local coherence.¹³ Following the Construction-Integration-Model by Kintsch,¹² the textbase consists of microstructure (the whole 'network of propositions that represent the meaning of a text',¹² that is, all detailed information of a text) and macrostructure (the most relevant propositions, the gist).¹² Although the process of generation is unclear, the resulting macrostructure indicates that microstructure is reduced according to specific macrorules: selection (selection or deletion of (ir)relevant propositions), generalisation (replacing subordinate by superordinate propositions) and construction (general proposition instead of a sequence of propositions). Due to spreading activation in the propositional network, several plausible meanings may be constructed in the textbase. The activation values of incorrect elements decrease with richer context, and they will be suppressed in the integration phase.¹² At the third level, the information from the textbase, the context and the reader's pre-existing knowledge are integrated continuously taking into account cognitive schemata like scripts (eg, processes) and frames (eg, situations, objects, institutions or character types).⁹ Thus, the meaning of a text is constructed and represented in individual coherent situational models in the episodic memory. Situational models can be considered as a form of inference.¹² Inferences are cognitive processes or results that provide information not explicitly stated in a text.¹⁴ They may involve the automatic or controlled generation of new information, or the retrieval of pre-existing knowledge from long-term memory to bridge gaps.¹²

Thus, text comprehension depends on a complex interaction of linguistic and cognitive resources. In PWA, on the one hand, cognitive resources such as verbal working memory, episodic memory, monitoring and cognitive flexibility may be impaired.^{15 16} On the other hand, receptive

and productive language skills can be affected to various degrees.^{16 17} Even though general aphasia tests (which often assess phonology, morphology or syntax) may detect only minor or no difficulties, PWA may encounter substantial problems in text comprehension, including a reduced reading speed.^{15 18} Moreover, incomplete lexical and syntactic information may affect the construction of the propositional textbase, especially the microstructure.^{15 19} Furthermore, local and global inferencing skills as well as the construction of macrostructures and of situational models may be impaired.^{15 16} This may be explained by anomalous macrostructural processes or—since knowledge about the world is usually better preserved than linguistic components in PWA—as a consequence of impaired lexical and syntactic processing.¹⁹

To treat reading comprehension in PWA, oral, strategy-based, cognitive and hierarchical reading treatments can be distinguished.⁷ In oral reading treatments, PWA read texts repeatedly aloud, either independently or together with a speech and language pathologist (SLP), to facilitate whole-word recognition and top-down processing (ie, using prior knowledge to enhance understanding).^{7 8} This may be particularly helpful to improve reading comprehension in severe aphasia.²⁰ Hierarchical reading treatments^{21 22} were provided with systematic computerised visual-matching and reading comprehension tasks. Stimuli are available in English language and consisted of symbols, letters, numbers, words, phrases and sentences, whereas text level reading comprehension was neither included in stimuli nor in outcome measures.^{21 22} Cognitive treatments focus on underlying cognitive functions and were conducted with Attention Process Training II/III (computerised exercises to train specific domains of attention)^{23–25} or sequenced exercises addressing working memory (sentence grammaticality judgement and semantic categorisation of words across several sentences).²⁶ They may be particularly beneficial for persons with mild aphasia.⁷ In strategy-based treatments, reading strategies are used to facilitate reading comprehension.⁸ Reading strategies are specific, target-oriented cognitive techniques applied either automatically or consciously and flexibly. They support linguistic and cognitive processes such as the maintenance of text contents and the construction of the textbase and the situational model.^{9 27} Watter *et al*⁸ distinguish visual strategies (eg, underlining, highlighting), content strategies (eg, identification of key words, summarisation, preview of headings) and (meta)cognitive strategies (eg, rereading, recall, self monitoring).

To date, the evidence base is limited: cognitive and strategy-based interventions have been explored in (multiple) case studies, oral and hierarchical reading treatments in randomised controlled trials (RCTs). A gold standard cannot be concluded.^{7 8}

This study focusses on strategy-based treatments in PWA. With regard to PWA, reading strategies may be a suitable option to take into account both linguistic and cognitive processes. Strong evidence exists already

for other populations such as children with reading or learning disorders.^{28, 29} Moreover, strategy-based interventions are cost-effective due to their relatively low dosage.⁸ In contrast to other approaches, reading strategies are not confined to a predefined software or to specific languages, items or text types. They permit the lecture of authentic texts that are age appropriate, relevant and interesting for individuals, which may raise the motivation to engage in therapy. Despite these potentials of strategy-based interventions and despite PWA's ability to apply reading strategies,³⁰ the latest systematic review by Purdy *et al*⁷ identified only four case studies^{31–34} that evaluated strategy-based treatments with a total of six PWA. Four of the patients improved their reading comprehension.⁷ Furthermore, Rogalski and Edmonds³⁵ and Rogalski *et al*³⁶ found that two out of three patients improved in text-related measurements with Attentive Reading and Constrained Summarisation which contains the strategy of summarisation.

The strategies that were applied in the studies listed above are provided in online supplemental table 2. In these studies, mainly content strategies (identifying/writing down key words and key messages, summarising paragraphs and chapters, creating mind-maps and using advance organisers) as well as a few visual strategies (highlighting key words, using cards to block lines above and below focused lines) and the cognitive strategy (re)reading sections aloud and silently were explored. Furthermore, SLPs implemented strategies that can only be applied with a second person, such as discussions to increase motivation, reading/writing aloud to the patient, shared reading and writing, foreshadowing, modelling of reading and writing, providing metaliteracy comments and providing questions about the text.^{31–36}

Elements that require either a second person or text-specific additional material contradict autonomy and may not be useful in authentic reading situations. The strategies explored in PWA to date have predominantly focused on the macrostructure and on the situational model as well as on the integration of background knowledge and (meta)cognitive abilities. They have not been explored in group studies with PWA yet. Considering that the microstructure is particularly prone to impairment in PWA, these strategies could be supplemented by strategies that target the microstructure, that could be used without a second person or additional text-specific material, and that have been suggested for other populations. Strategy-based programmes constructed for other populations include SQ3R (survey, question, read, recite, review), PQRS (preview, question, read, summarise, test) and reciprocal teaching (prediction, clarification, summarisation, question generation).^{10, 37} Based on their meta-analysis, Mayer and Marks²⁸ developed a strategy-based concept for children that includes the activation of prior knowledge, mental imagery, comprehension monitoring, summarising and asking questions. In students with learning disabilities, Souvignier and Antoniou²⁹ found highest effects for the strategies activation of background

knowledge, summarisation, monitoring, asking questions, identification of the topic as well as strategies focusing on the text structure. Schmidt³⁸ suggests the use of referential links as a reading strategy. It is important that strategy combinations are more effective than the use of only one strategy.²⁸ In view of these suggestions, we think that asking questions and using referential links could be implemented in ways that facilitate understanding of the microstructure.

Based on this preliminary evidence and on specific impairments in PWA in linguistic as well as cognitive resources, we will combine specific reading strategies that have been investigated in PWA or that have been suggested for other populations. We will group the strategies in (1) macrostructure and situational model and (2) microstructure and surface structure. To raise motivation and to take advantage of possibly unimpaired schemata, we will embed the strategies in product-oriented goals.³⁹

Objectives and research hypotheses

The primary objective of this study is to determine whether the effects of a systematic strategy-based intervention on text-level reading comprehension and on activities and attitudes related to reading in PWA are superior to spontaneous recovery.

Secondary objectives are (1) to compare the effects of two types of strategy-based interventions on the comprehension of the microstructure and the macrostructure; (2) to investigate the relationship between microstructure, macrostructure and the situational model on the one hand and specific cognitive functions such as working memory, episodic memory, executive functions and selective attention on the other hand.

We expect the superiority of the intervention compared with the waiting period with regard to improvements in text-level reading comprehension and in activities and attitudes related to reading. Furthermore, we anticipate specific effects on the microstructure or the macrostructure depending on the strategies used.

METHODS AND ANALYSIS

The study protocol is based on the Standard Protocol Items: Recommendations for Interventional Trials 2013 statement.⁴⁰

Trial design

The trial is designed as a repeated measures study in a superiority framework with a primary endpoint of text-level reading comprehension. The effects of a strategy-based intervention and of a waiting period will be compared in a single group design. The strategy-based intervention will consist of two elements (Intervention Micro and Intervention Macro). To explore strategy-specific effects and to control for order and sequence effects, participants will be allocated to two parallel groups who will participate in these two elements in counterbalanced order after the waiting period (see figure 1).

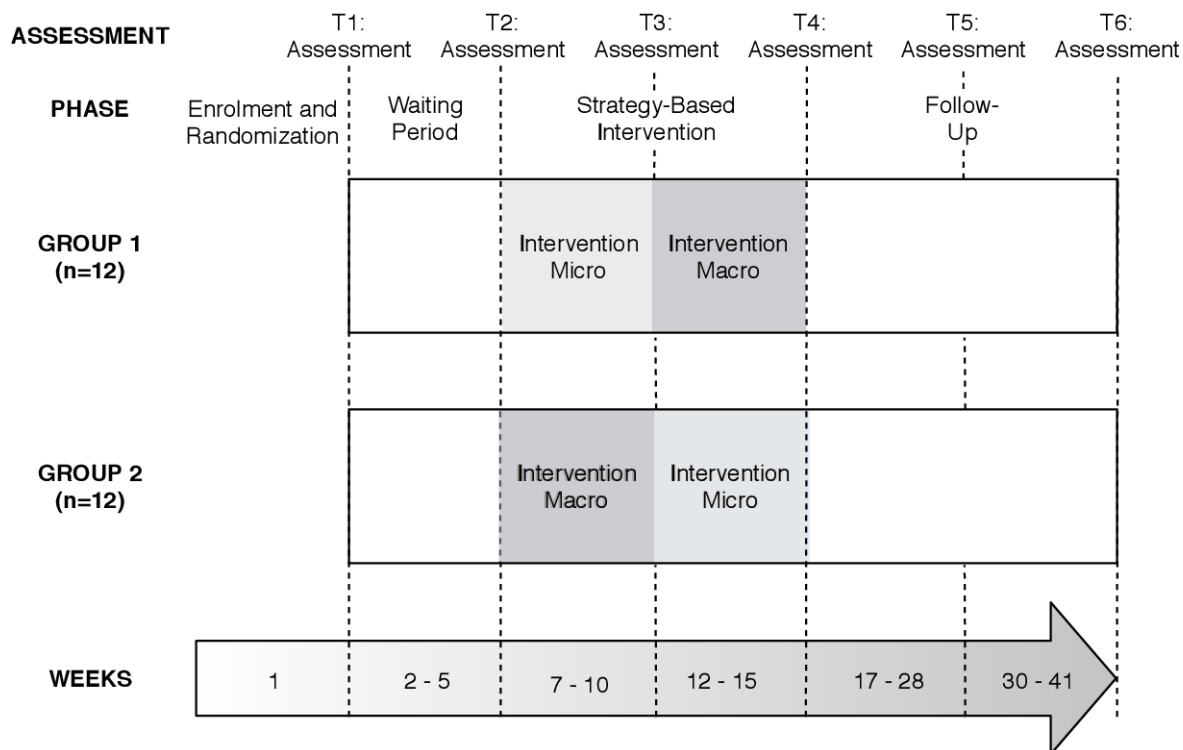


Figure 1 Trial design.

Study setting

Participants will be recruited in Germany (regional focus on urban and rural areas of Munich and Erfurt). Assessment and intervention sessions will be implemented in their regular rehabilitation centres, at the University of Erfurt, at the Ludwig Maximilian University of Munich or at participants' homes.

Participants

We will include persons with mild to moderate aphasia. For recruitment, we will advertise the study in newsletters of professional associations, send a flyer to rehabilitation centres, and contact aphasia support groups at meetings, by phone and e-mail. [Table 1](#) shows the eligibility criteria.

Sample size

A priori power analysis using G*Power V.3.1⁴¹ revealed a minimum sample size of $N=21$ to detect an effect size of $d=0.58$ with a power of .80 in a repeated-measures analysis of variance (ANOVA) ($\alpha=0.05$; two measurements: eg, T2, T4; correlation among repeated measures=0.60). The effect size of the power analysis was informed by the effect size of previous research on speech and language interventions for PWA.⁴² We expect a drop-out-rate of 10% ($n=3$). Thus, we will recruit a total sample size of $N=24$.

Assignment of interventions

Participants will be allocated to two groups with the ratio 1:1 by stratified permuted block randomisation. With

Table 1 Inclusion and exclusion criteria

Inclusion criteria	<ul style="list-style-type: none"> ▶ Age of at least 18 years ▶ Aphasia according to Aachen Aphasia Test (AAT)⁴⁵ or no current symptoms/only residual aphasia according to the latest AAT assessment but previously diagnosed aphasia and current language difficulties (subjective or perceived by an SLP) ▶ Anomalous scores in the German version of Test de Compréhension de Textes¹³ (TCT-D) ▶ Native language: German ▶ At least 3 months postonset
Exclusion criteria	<ul style="list-style-type: none"> ▶ Global aphasia and/or severe problems in word level reading (score <12 in AAT subtest 'single word reading comprehension') and/or severe problems in written language (score <22 in category 'written language' in AAT) ▶ Neurological, psychiatric or any other disease that impedes a (repeated) assessment and valid interpretation with the AAT or TCT-D (particularly if the disease can result in decreasing or strongly fluctuating linguistic or cognitive performance) ▶ Premorbid dyslexia

SLP, speech and language pathologist.

regard to prognostic factors,^{17 43 44} we will stratify for age, severity of aphasia (age-adjusted score in the subtest Token Test of Aachen Aphasia Test⁴⁵) and the TCT-D Total score. Randomisation and allocation will be implemented independently by Dr Thomas Lauer, scientific managing director of the ErfurtLab at the University of Erfurt, Germany. SLPs will enter enrolled participants' identification numbers along with their stratification factors into a table that Dr Thomas Lauer will use to generate blocks and to randomly allocate the participants to one of the two groups. The block sizes will not be disclosed, to ensure concealment.

Intervention procedures and material

The interventions will start in the beginning of 2021. They will be implemented by ST and by qualified SLPs who work in a setting licensed by the German health insurance system. Between T1 and T4, the participants will not receive any other aphasia treatment.

Strategy-based intervention. The intervention period consists of two elements, Intervention Micro and Intervention Macro (see [table 2](#)).

To promote transfer, we will only use strategies that participants may apply without a second person, and we will inform participants about the possible use of reading strategies in everyday reading activities. Intervention Micro and Intervention Macro will each consist of seven 60 min sessions, provided twice a week in individual therapy. Additionally, the participants will apply the same strategies as homework for 60 min after each intervention session. Homework will be monitored with a timetable. During the intervention sessions, SLPs write down the answers of the participants.

All external SLPs who deliver the treatment will participate in a preparatory workshop. They will be provided with

- ▶ A manual that contains instructions, examples, structured guidance for facilitation and worksheets.
- ▶ Stimulus material: articles from magazines with increasing difficulty (based on readability index, word count, number of pictures) in a predefined randomised order for each participant.

Procedures of allocated interventions may not be modified. Whenever a participant cannot solve a given task, hierarchical cues will be offered:

1. Authentic situations, for example, 'If you tell your partner later on what that paragraph was about, which key word would you say?'
2. Semantic cues, for example, 'You said 'A hiker marched towards...'. Now we have to replace 'his house'. So, we are looking for another building. Which building does the hiker want to go to?'
3. Phonological cues, for example, 'I am thinking about a building that starts with c.'

Waiting period. The participants will not receive any form of aphasia treatment during 4 weeks prior to the intervention.

Outcomes

The outcome measures (see [table 3](#)) were chosen with regard to the levels functions and activities of The International Classification of Functioning, Disability and Health.⁵ Assessments will take place at six points (T1, T2, T3, T4, T5, T6) with T6 being optional (see [figure 1](#)). Instructions will be standardised without explicit encouragement to use reading strategies postintervention.

The primary outcome is text level reading comprehension defined as the score TCT-D Total measured with TCT-D. TCT-D allows to analyse specific text-level reading functions that may be impaired in PWA. TCT-D Total is the sum of microstructure and macrostructure scores across all subtests of TCT-D.

As secondary outcomes, we will collect scores of microstructure, macrostructure, the situational model and reading time with TCT-D. Reading activities as well as attitudes towards reading will be measured with an adapted German version of the Comprehensive Assessment of Reading in Aphasia (CARA) Reading Questionnaire² which was developed specifically for the needs of PWA. At T2 and T4, we will measure inferences and macrostructure using the MAKRO-Screening⁴⁶ and verbal episodic memory using Wechsler Memory Scale IV (WMS IV)⁴⁷ (logical memory 1). Cognitive functions that have been shown to be relevant for reading in PWA will be measured with subtests of the German versions of the WMS-Revised⁴⁸ (digit span forward and backward), Farbe-Wort-Interferenz-Test⁴⁹ and a subtest on attention of Aphasia-Check-Liste.⁵⁰ We will analyse change in individual scores across the whole group and across the subgroups between specific assessment points. We will explore individual effects on functions, activities and participation as well as the potential generalisation of strategy use to everyday reading materials with a semi-structured interview at T4.

Blinding

Participants will be blinded with regard to the specific hypotheses of the study. Due to the nature of behavioural speech and language therapy, neither participants nor SLPs can be blinded with regard to the intervention they receive or provide. Analysis of the main outcome measure TCT-D will be duplicated by blinded assessors for T1, T2 and T4 based on audio recordings and the level of agreement will be reported in the final trial report.^{51 52}

Data collection and participant retention

For all participants, the same data collection methods will be used. Data collection will be performed by ST and by participating SLPs based on manuals and protocol booklets to ensure standardised procedures. We will collect the data described in [table 3](#). Points of assessment are provided in [table 4](#). For additional information on the assessment tools, see online supplemental table 3.

Participants may withdraw from the study at any time. Participants that drop out after enrolment will be asked to participate in the TCT-D and in the CARA questionnaire

**Table 2** Strategies, procedures, rationales and examples; items in italics illustrate answers produced by the participants

Intervention Macro: Macrostructure and situational model

Strategy 1	Use of advance organisers and key words to create a mind map before and while reading
Product	Mind map
Procedures	<ol style="list-style-type: none"> 1. PWA finds out the topic of the text by using advance organisers such as title, pictures or subtitles from the text 2. PWA inserts five associations to that topic into the template of a mind map 3. PWA starts strategy 2 (summarisation). Throughout the course of reading, PWA integrates one to three key words from memory about each paragraph into the mind map
Rationale	The activation of background knowledge is expected to facilitate the integration of the reader's knowledge and the new information from the text (and therefore the construction of the situational model). ²⁸ Advance organisers such as pictures can support paragraph level reading in PWA. ⁵⁶ Inferring a maximum of three key words about each paragraph will require to reduce microstructure to the most relevant information.
Strategy 2	Summarisation and rereading
Product	News in short
Procedures	<ol style="list-style-type: none"> 1. PWA reads paragraph aloud 2. PWA rereads 2–3 sentences of that paragraph aloud 3. PWA rereads the same 2–3 sentences silently 4. Text is covered, PWA summarises these sentences from memory based on macrorules¹² and with specific restrictions (no personal opinion, no unspecific words) similar to Rogalski and Edmonds³⁵ and Rogalski <i>et al</i>³⁶ 5. Same procedure for the next 2–3 sentences from the same paragraph, until paragraph is completed 6. From memory, PWA adds 1–3 key words about the paragraph into the mind map 7. Repeat from step one with the next paragraph
Rationale	We intend to facilitate the comprehension of the macrostructure and the construction of the situational model by actively applying the macrorules. We combine strategies previously described for PWA (use of keywords, writing down key messages, summarisation and rereading text). We will use a modified version of ARCS ^{35 36} in order to integrate the cognitive strategy of rereading text aloud and silently and to target cognitive functions such as attention and maintaining information.
Example	The young guy who wore a suit opened the door. He looked around, sat down and asked for the menu. He ate soup, lasagna and tiramisu, paid, and left. → <i>The guy ate a menu in a restaurant.</i>

Intervention Micro: Microstructure and surface structure

Strategy 1	Asking questions and providing answers
Product	Quiz
Procedures	<ol style="list-style-type: none"> 1. PWA skims a paragraph 2. PWA underlines any part of the first sentence 3. PWA asks for the underlined part of the sentence 4. PWA generates (a) a synonym/paraphrase, (b) a semantically related answer, (c) logically possible but wrong answer according to the text 5. Repeat steps 2–4 until paragraph is completed, then repeat from step 1
Rationale	To date, this reading strategy has not been investigated in PWA apart from providing predetermined questions. ^{7 8} This procedure will allow PWA to ask questions on subordinate propositions, which may facilitate the comprehension of the microstructure. Rearranging sentence structures from statements into questions will only be possible with understanding the links between the clauses. To ensure that participants will not stick to the surface structure but access the semantic content of the answers to the questions, they will generate (a) a synonym/paraphrase and (b) a semantically related answer. To address previously described problems in cognitive flexibility in PWA and to integrate background knowledge, they will generate c) a possible but incorrect answer to the question.

Continued

Table 2 Continued

Example	Original sentence: The boy waited in front of his house. <i>Where did the boy wait?</i> a. <i>in front of his residence building</i> (synonym) b. <i>in front of his apartment</i> (semantically related) c. <i>behind a cow</i> (logically possible but wrong according to text)																				
Strategy 2	Using referential links and elaboration																				
Product	Fake news																				
Procedures	1. PWA identifies topic of the text 2. PWA substitutes topic by topic that is similar to the original topic and that PWA is interested in 3. PWA substitutes word by word as many words as possible and produces a semantically coherent text based on the structure of the original one																				
Rationale	The participants will produce a coherent text based on the surface structure of the original text by substituting as many words as possible. Similar techniques have been used in second/foreign language teaching. ^{57–59} Valency theory ⁶⁰ suggests that this task will require participants to understand thematic roles of all elements in a sentence. To maintain the surface structure, participants will have to apply the strategy of using referential links between the elements. Furthermore, participants will continually have to switch between the situational models of the original and the new text which may address potential difficulties in cognitive flexibility.																				
Example	<table border="0" style="width: 100%; text-align: center;"> <tr> <td></td> <td>The boy</td> <td>waited</td> <td>in front of</td> <td>his house</td> </tr> <tr> <td></td> <td>↓</td> <td>↓</td> <td>↓</td> <td>↓</td> </tr> <tr> <td>eg, 1</td> <td><i>The skier</i></td> <td><i>cued up</i></td> <td><i>behind</i></td> <td><i>the line.</i></td> </tr> <tr> <td>eg, 2</td> <td><i>A hiker</i></td> <td><i>marched</i></td> <td><i>towards</i></td> <td><i>a cottage.</i></td> </tr> </table>		The boy	waited	in front of	his house		↓	↓	↓	↓	eg, 1	<i>The skier</i>	<i>cued up</i>	<i>behind</i>	<i>the line.</i>	eg, 2	<i>A hiker</i>	<i>marched</i>	<i>towards</i>	<i>a cottage.</i>
	The boy	waited	in front of	his house																	
	↓	↓	↓	↓																	
eg, 1	<i>The skier</i>	<i>cued up</i>	<i>behind</i>	<i>the line.</i>																	
eg, 2	<i>A hiker</i>	<i>marched</i>	<i>towards</i>	<i>a cottage.</i>																	

ARCS, Attentive Reading and Constrained Summarisation; PWA, persons with aphasia.

for a final assessment. They will be reported in the final trial protocol with reasons for drop out. Temporal deviations of up to 3 weeks, for example, in the case of illness of participants or SLPs, will not result in drop out and planned intervention or assessment sessions will be continued. At least 75% of the assigned homework must be completed until the last therapy session of each intervention period for participants to be included in the per protocol analysis. We will undertake all reasonable efforts for participant retention during the study period:

- ▶ Treatment locations close to participants' homes.
- ▶ Option to perform interventions at participants' homes.
- ▶ A worksheet for structuring homework.
- ▶ SLPs will support the participants in integrating the homework into their daily routines (eg, setting an alarm, asking family members to remind the participants, preparing memos) and call participants prior to follow up appointments, if requested.

Data management

A data management plan will be provided on Open Science Framework (OSF)⁵³ on the publication of the final trial report. Subsequent to informed consent, the data described above will be recorded with an audiorecording device, transcribed and entered in SPSS.⁵⁴ Collected data will be described by metadata and will be pseudonymised by assigning a number to each participant. The list that links personal data to other data will be destroyed for the sake of anonymisation after the data analysis. Data will

be stored on a laptop, on an external hard-drive and on a decentral server of the university of Erfurt and will be archived for at least ten years on millennial discs. Backups will be implemented regularly.

Statistical methods

Primary and secondary analyses will be conducted using contrast analyses within repeated measures ANOVA models. We will apply a two-step approach to address the primary objective. First, changes in the primary outcome (TCT-D Total) will be analysed over time. Three contrasts (T2–T4; T2–T5; T2–T6) will be used to analyse whether the intervention led to any short-term and/or long-term benefits. Second, we will investigate superiority to spontaneous recovery by comparing the change scores from step one (T2–T4; T2–T5; T2–T6) with the change score from the waiting period (T1–T2). To address the secondary objectives, we will conduct the same analysis with the outcomes of the German version of CARA Reading Questionnaire to investigate superiority of the intervention with regard to reading activities. Furthermore, we will compare contrasts (T2–T3; T2–T4) between groups to explore strategy-specific effects on macrostructure and microstructure as well as on reading activities. Potential moderator effects will be explored using severity of aphasia, gender, age and education as moderators. We will use a 0.05 significance level for all models. We expect dropouts to be minimal. In case of missing data points, we will use listwise deletion and conduct analyses on just the

Table 3 Assessment tools and descriptions of assessment categories and procedures

Category	Assessment Tools	Description
General information	Participant Profile	<ul style="list-style-type: none"> ▶ Name, age, gender, education ▶ Aphasia history: Date of Onset, aetiology, lesions ▶ Information on inclusion and exclusion criteria <p>The Aachener Aphasia Test (AAT)⁴⁵ diagnoses and classifies aphasia and defines its severity. It consists of the Token Test, an analysis of the spontaneous speech, and four subtests on word and sentence level in repetition, reading, writing, naming and understanding.⁴⁵</p> <p>Montreal Cognitive Assessment (MoCA)⁶¹ is a cognitive screening tool that assesses short-term memory, visuospatial abilities, executive functions, attention, concentration and working memory, language and orientation to time and place.⁶² The maximum total score is 30.⁶¹</p>
Text level reading comprehension	TCT-D <ul style="list-style-type: none"> ▶ Macrostructure ▶ Microstructure ▶ situational model ▶ TCT-D Total ▶ reading time 	<p>The TCT-D is the German version of Test de Compréhension de Textes.¹³ It consists of three parallel versions with narrative texts. In each assessment session, participants will read three texts that vary systematically in the amount of propositions and in the need for updating the situational model. To assess macrostructure, participants summarise each text. For microstructure, they answer questions about detailed information from the text. Rating is based on a standardised protocol. The scores in <i>microstructure</i> and <i>macrostructure</i> from the three texts are then added up to the primary outcome measure TCT-D <i>Total</i>. The situational model is classified as successfully updated if two specific events presented in the text can be integrated.</p>
Additional tools to measure discourse comprehension	<p>MAKRO⁴⁶</p> <ul style="list-style-type: none"> ▶ text reception ▶ inferences <p>WMS-IV⁴⁷</p> <ul style="list-style-type: none"> ▶ Logical memory 1 	<p>The MAKRO screening⁴⁶ provides two parallel versions. In text reception, the participants read a narrative text and answer ten single-choice questions in written form. Correct answers are rated with three points, compared with 0 points for wrong answers. In <i>inferences</i>, a brief written sequence of events has to be completed with a missing causal inference. According to an evaluation protocol, 0–3 points can be given, resulting in a maximum score of 30 points.</p> <p>Logical memory 1 measures verbal episodic memory and the ability to remember information that was presented only once, such as information in coherent stories or conversations. In logical memory 1, participants listen to two short stories that are read out to them and reproduce the stories verbally immediately afterwards. The reproduction is then compared with a standardised protocol and each detail that is recalled is rated with one point adding up to a total score.^{47 63}</p>
Activities and attitudes related to reading	German version of CAPA Reading Questionnaire ²	<p>The German version of the Reading Questionnaire of the Comprehensive Assessment of Reading in Aphasia (CARA) consists of three sections in which participants are asked to rate activities and attitudes on visualised Likert scales with a range from 1 to 9: Section A refers to current reading and is introduced by the phrase 'At the moment, how difficult do you find reading and understanding' followed by eight items 'single words/short sentences/paragraphs/a book/reading aloud/ concentrating on reading/remembering what you have read/having a conversation about what you have read'. Section B focuses on thoughts and feelings and section C investigates different reading activities such as reading labels, signs, letters or newspaper articles. For each section, a sum score is calculated based on the ratings.²</p>

Continued









Table 3 Continued

Category	Assessment Tools	Description
Cognitive functions	WMS-R ⁴⁸ ▶ digit span forward ▶ digit span backward ACL ⁵⁰ ▶ Aufmerksamkeitsstest	<p>We will use WMS-R⁴⁸ to assess the verbal maintenance of information with the subtest <i>digit span forward</i>, and the maintenance and processing of information with the subtest <i>digit span backward</i>. In both subtests, the participants reproduce verbally presented digit sequences with increasing length in the same or in reversed order, respectively. Each correctly reproduced sequence is rated with one point, resulting in a maximum of 12 points for each subtest.^{48,63}</p> <p>Selective attention will be measured with the subtest <i>Aufmerksamkeitsstest</i> of Aphasie-Check-Liste (ACL)⁵⁰. Within a given time period, the participant is expected to cross out two predefined signs in six columns with 144 targets and distractors. The numbers of processed items, omissions, incorrectly selected items, mistakes in total, differences between processed items and mistakes as well as the percentage of mistakes are calculated and can then be compared with cut-off scores for three different age groups. The number of processed symbols is supposed to give information about the aspect of speed, whereas the accuracy reflects qualitative aspects of selective attention.⁵⁰</p> <p>Inhibition and divided attention will be measured with <i>Farbe-Wort-Interferenz-Test</i> (FWIT)⁴⁹, which is a colour-word-interference-test based on Stroop⁶⁴. In three rounds each, the participant is asked to read out colour words, to name the colour of lines and to identify the colour of incongruent colour words. Median time and mistakes are recorded. Based on these median times, we will use the adjusted specific inference variable SEL and its t-value for further analysis.⁴⁹</p>
Generalisation	Semistructured interview	<p>We developed an interview guideline with open-ended main questions and follow-up questions to explore effects on functions, activities and participation (1) across domains, (2) in language-related domains, (3) in text comprehension and (4) in language activities. Generalisation of strategy use will be explored by asking about changes in the way participants approach texts.</p>

WMS-IV, Wechsler Memory Scale IV; WMS-R, Wechsler Memory Scale-Revised.



Table 4 Schedule of enrolment, interventions and assessments. Separate colours indicate different schedules for group 1 and group 2

Study period	Time point						
	0	T ₁	T ₂	T ₃	T ₄	T ₅	T ₆
Enrolment							
Eligibility screening (apart from TCT-D)	X						
Informed consent	X						
Allocation		X					
Interventions							
Waiting period							
Intervention Micro							
Intervention Macro							
Assessments							
General information: age, date of onset, characteristics of aphasia according to AAT, MoCA	X						
Text level reading comprehension: TCT-D: macrostructure, microstructure, situational model, reading time		X	X	X	X	X	X
Additional tools to measure discourse comprehension: MAKRO subtests, WMS-IV subtests			X		X		
Activities and attitudes related to reading: German version of CARA questionnaire		X	X	X	X	X	X
Cognitive functions: FWIT, WMS-R subtests, ACL subtests			X				
Generalisation: semistructured interview							X

T6 is voluntary.

AAT, Aachener Aphasie Test; ACL, Aphasie-Check-Liste; CARA, Comprehensive Assessment of Reading in Aphasia; FWIT, Farbe-Wort-Interferenz-Test; MoCA, Montreal Cognitive Assessment; TCT-D, Test de Compréhension de Textes; WMS-IV, Wechsler Memory Scale IV; WMS-R, Wechsler Memory Scale-Revised.

metrics that have both pretreatment and post-treatment data points available.

Monitoring

ST or the Deutscher Bundesverband für akademische Sprachtherapie und Logopädie (dbs) ethics committee may withdraw particular participants if any new information indicates that continuing participation is not in their best interests. Adverse events or unintended effects reported by participants will be described in the final trial report. Adherence to the therapy manual will be monitored by ST through a standardised therapy documentation form and weekly supervision for participating SLPs. There will be neither independent auditing procedures, nor an official data monitoring committee or an interim analysis because the study is pure behavioural, non-invasive speech and language therapy and therefore, we expect no risks or harms.

Patient and public involvement

Patients and/or the public were not involved in the design, conduct, assessment of the burden, reporting or dissemination plans. Support groups with PWA will be involved in the recruitment of participants.

Ethics and dissemination

The study has been approved by the ethics committee of dbs (reference number: 20-10074-KA-MunmErw+Ko). Participants may be informed about their individual results after the final assessment on request. They will be advised on how to proceed in case of unexpected findings. There are no publication restrictions. Results will be disseminated as soon as possible regardless of the magnitude or the direction of effect in journals that focus on speech and language therapy or related subjects. Anonymised participant-level datasets and statistical codes will be provided on OSF repository after journal publication according to findable, accessible, interoperable and reusable principles with a digital object identifier and a CC-BY Creative Commons Licence. Authorship in the final trial report will be granted according to standards presented in McNutt *et al.*⁵⁵. Professional writers and editorial services will not contribute to the study.

Protocol amendments

Important protocol modifications will be registered on Deutsches Register Klinischer Studien (see online supplemental table 1) and communicated to the ethics committee.

Consent to participate

SLPs will obtain informed consent from participants or their representatives with forms approved by the ethics committee (see online supplemental file 1 for English language example). Signed forms will be collected by ST.

Consent for publication

Not applicable. No details relating to individual persons have been included.

Confidentiality

Personal data will be collected on paper and on electronic data storage devices. Sensitive data will be stored in password-protected digital files or in a locked cabinet. Pseudonymised data may solely be shared according to specific regulations approved by the dbs ethics committee.

DISCUSSION

To date, evidence for text-level reading comprehension treatments in PWA remains rare and precludes sound clinical reasoning. In this study, we will investigate the effects of a strategy-based intervention on text level reading comprehension in a repeated measures study. The results will contribute to a better understanding of the role of cognitive functions and of reading strategies as well as to decision-making in text level reading comprehension treatments in PWA. Effects on specific reading functions and activities may allow SLPs to combine strategies according to individual reading profiles.

Due to the lack of a German-language tool to measure text level reading comprehension in PWA, we will use the translated version of the TCT¹³ for which no German normative data exists yet. We will address this issue by collecting data from a parallelised healthy reference group. Furthermore, we will use additional tools that have been validated and normalised with German samples in the assessment sessions T2 and T4 before and after the strategy-based intervention (see table 4).

Three parallel versions of the TCT-D exist, whereas at least five assessment sessions will take place. To estimate the possible impact of retest effects, each participant of the healthy parallelised reference group will be tested twice with the same version of the TCT-D in the same interval as participants of the intervention groups.

If we find positive effects of the strategy-based intervention, future research should compare strategy-based interventions with other treatment options in RCTs.

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Contributors S-MT conceived the study and led the protocol development. S-MT, PS, SC and FD developed the study design. FD helped with implementation. SC supported the translation and adaptation process of TCT (13). S-MT is responsible for data acquisition and data management. PS provided statistical expertise in clinical trial design. All authors contributed to refinement of the study protocol and

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