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Tablet-Assisted Speech and Language Therapy for Acute Post-Stroke Aphasia: A Randomized Clinical Trial (LEXI Study)

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ABSTRACT

Background: Aphasia after acute stroke is a frequent and disabling condition, impairing communication and quality of life. We investigated whether tablet-assisted Speech and Language Therapy (SLT) using the Neolexon application is superior to standard SLT in acute stroke patients.

Methods: In this prospective, open-label, randomized, controlled clinical trial, patients with acute post-stroke aphasia were recruited from one stroke center and two neurorehabilitation clinics in Germany. Participants were stratified by aphasia severity and randomized to tablet-assisted SLT ($n = 53$) or standard SLT ($n = 51$), initiated during inpatient care and continued in rehabilitation (30 min/Day). The primary outcome was the change in the Bielefelder Aphasia Screening (BIAS) percentile rank from baseline to 90 days. Secondary outcomes included frequency and duration of self-training.

Results: From 07/2021 to 09/2024, 4097 patients were screened and 104 randomized (mean age 74.4 ± 11.2 years; 51.9% female). No significant difference in BIAS change was found at 90 days (18 vs. 14). The trial was stopped early for futility. The intervention group engaged in self-directed training more frequently (37.7% vs. 21.6%) and trained longer (10 vs. 4 h). Subgroup analyses showed benefits of tablet-assisted SLT in patients with mild ($\beta = 15.51$; 95% CI -1.67 to 32.69) and moderate aphasia ($\beta = 23.58$; 95% CI -4.48 to 51.65), and those with a National Institutes of Health Stroke Scale of less than 5 ($\beta = 21.69$; 95% CI 5.54 – 37.84).

Conclusions: Although underpowered to demonstrate overall superiority, tablet-assisted SLT showed potential benefits in patients with mild to moderate aphasia and less severe strokes in the acute setting.

Trial Registration: ClinicalTrials.gov Identifier: NCT04080817

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1 | Introduction

Aphasia affects up to one-third of patients following acute stroke and is associated with poor long-term outcomes, including depression, reduced quality of life (QoL), social isolation, and a reduced likelihood of returning home or to work [1–4]. Speech and language therapy (SLT) is the standard of care for post-stroke aphasia and has demonstrated efficacy in rehabilitating chronic post-stroke aphasia. Current stroke management guidelines emphasize early assessment and prompt initiation of SLT [5, 6]. However, the optimal therapeutic modality, intensity, frequency, timing, and patient selection criteria for SLT in the acute stroke setting remain controversial [5, 7, 8].

In recent years, digital technologies have emerged as promising tools to augment standard SLT [9, 10]. Computer- and tablet-assisted therapies enable adaptive and individualized training, promote autonomy, and may enhance motivation and therapy adherence [11], all of which are crucial factors in promoting neuroplasticity and recovery [12]. Moreover, they can also address systemic limitations in SLT delivery, including insufficient therapy intensity and declining availability during rehabilitation [11, 13]. Studies suggest that such technology-supported therapy is generally feasible, well-accepted by patients and caregivers and may offer additional cost-effectiveness [14–16]. Although existing evidence supports the efficacy of technology-assisted interventions in improving various language functions and indicates that they may be as effective as face-to-face therapy in individuals with chronic aphasia, robust data for patients with acute or hyperacute stroke remain scarce. Whether digital therapies can complement conventional SLT during the critical early phase after stroke is largely unexplored.

In this investigator-initiated randomized clinical study, we evaluated whether tablet-assisted SLT using the Neolexon application improves language outcomes compared to standard SLT in patients with acute post-stroke aphasia.

2 | Methods

2.1 | Study Design and Population

This investigator-initiated, prospective, open-label, randomized controlled trial was conducted at one comprehensive stroke center (LMU University Hospital Munich) and two residential neurorehabilitation clinics (Clinic for Neurology, Medical Park, Reithof Park, Bad Feilnbach and Rehabilitation center, Passauer Wolf, Bad Griesbach) in Germany.

All patients admitted to the stroke center due to acute stroke were screened within 24 h of admission and enrolled based on the following eligibility criteria: (1) age ≥ 18 years, (2) aphasia due to acute ischemic or hemorrhagic stroke, with a corresponding Language Screening Test Score (LAST) of ≤ 13 points [17] (3) German as their native language, (4) no known preexisting dementia or aphasia due to other neurological disorders, (5) life expectancy > 1 year, and (6) provision of written informed consent. If the patient lacked decision-making capacity at screening, written consent was obtained from their proxies.

2.2 | Randomization

Participants were randomized (1:1) to receive either tablet-assisted SLT with the Neolexon application or standard SLT using a web-based system (Randomizer Version 2.2.0, Institute for Medical Informatics, Statistics, and Documentation, Medical University of Graz) with a permuted block approach. Stratification was based on aphasia severity at baseline, as assessed by the Language Screening Test: mild aphasia (LAST 11–13 points), moderate aphasia (LAST 6–10 points), and severe aphasia (LAST 0–5 points).

2.3 | Intervention

The Neolexon application (Limedix GmbH, Munich, Germany) is a tablet-based software designed for use either under the supervision of a speech therapist (therapist app version) or independently by the patient (self-training app). It offers personalized training exercises focused on oral and written naming, reading comprehension, and auditory language comprehension. These exercises are based on a database containing over 8400 nouns, verbs, and adjectives, more than 2400 sentences, and approximately 116 texts of varying syntactic complexity and length. Speech therapists create individualized patient profiles and can customize training parameters, such as the number of syllables, syllable structure, word stress, and word frequency. During self-training, patients can continue practicing with their personalized profile. The application automatically tracks therapy progress and therapists can continuously adjust training exercises accordingly. Additionally, it systematically records the duration of all training sessions. The Neolexon application is certified as a Digital Health Application in Germany (Pharmazentralnummer [PZN]: 18017082).

2.4 | Study Procedures

The intervention commenced immediately at the stroke unit and continued through residential neurorehabilitation. The duration of neurorehabilitation was determined at the discretion of the treating physicians, and participants continued receiving their allocated SLT throughout their residential rehabilitation period. Participants received up to 30 min of supervised SLT daily. Participants allocated to the control group received SLT according to local clinical standards. In both groups, therapy was provided by qualified speech and language therapists, and patients could be treated by different therapists during their hospital stay. Both groups were instructed in self-training by their treating speech and language therapists. Patients in the Neolexon group received individualized digital exercises via the app, while those in the control group were offered analog materials (e.g., printouts or workbooks), based on patient preference and capabilities. The frequency and duration of analog self-training were documented by the treating speech and language therapists. SLT in groups during residential neurorehabilitation was allowed in both groups (sessions of up to 30–60 min per day). Digital media were not used in the control group or in any group sessions. Patients and therapists could not be blinded to treatment allocation.

Logopedic and neurological assessments were conducted at baseline after randomization, after 7 days (± 2 days) or upon discharge (whichever came first), after 30 days (± 7 days) at the residential neurorehabilitation facility, and after 90 days (± 14 days) during a face-to-face study visit at either the outpatient clinic, the residential facility, or the participant's home.

Neuroimaging (CT or MRI) was performed upon admission to characterize stroke type and lesion location. Handedness was determined using the Edinburgh Handedness Inventory [18]. The study schedule is detailed in Table S1.

2.5 | Primary Outcome

The primary outcome was the change in percentile rank on the Bielefelder Aphasia Screening Rehabilitation Version (BIAS-R) from baseline to the 90-day follow-up. The BIAS is a comprehensive language assessment that evaluates eight language modalities: spontaneous speech, auditory comprehension, automated speech, elicited oral language production, word fluency, repetition, reading comprehension, and reading and writing. It consists of 205 items and has demonstrated excellent objectivity, validity, and reliability [19]. The BIAS-R extends the BIAS Acute Version (BIAS-A) by including all of its subdomains and adding further items to assess language performance in the post-acute phases following stroke [19]. The BIAS-A was administered at baseline, while the BIAS-R was conducted at the 30-day and 90-day follow-up visits.

2.6 | Secondary Outcomes

Secondary outcomes included self-training frequency, self-training duration throughout the study period, changes in the Aphasia Check List (ACL) [20], the Aachen Aphasia Bedside Test (AABT) [21], the LAST, the National Institutes of Health Stroke Scale (NIHSS), the Barthel Index (BI) and the modified Rankin Scale (mRS). Health-related QoL measures included changes in the Beck's Depression Inventory (BDI), the EuroQol Visual Analog Scale (VAS) and the EuroQol EQ-5D-5L Level Sum Score (LSS) [22–24]. In cases where quality-of-life measures could not be reliably assessed due to severe aphasia, assessments were conducted with the support of the participant's caregivers, if available. Secondary outcomes were assessed at both the 30-day and 90-day follow-up visit.

2.7 | Statistics

Language performance at 90 days was assessed by comparing the percentile rank in the BIAS-R at 90 days to the BIAS-A percentile rank at baseline. Based on consensus within our study team, a 10% median difference in the BIAS-R at 90-day follow-up between both groups was considered a minimal and clinically notable difference. In the study protocol, the initial planned sample size was 180 patients (90 per group), calculated based on an assumption of superiority and a clinically meaningful difference between treatment groups [25]. However, due to a slow recruitment rate, the study team decided to conduct an interim analysis after the inclusion of approximately 100 patients. This sample size calculation, which resulted in the premature

termination of the trial for futility, was made accordingly and was based on the assumption of superiority. It indicated that 1764 patients were required, with 899 patients in the intervention group and 865 patients in the control group (see Methods S1) [26]. The primary and secondary analysis was conducted in the modified intention-to-treat (mITT) population, incorporating patients who gave both informed consent and had an available 90-day follow-up. This resulted in a total of 104 patients ($n = 53$ receiving tablet-assisted SLT and $n = 51$ receiving standard SLT) included in the final analysis. Descriptive statistics are presented as means (standard deviation [SD]), medians (interquartile range [IQR]), or counts (n) and percentages (%) as appropriate. Univariate comparisons between the intervention and control groups were performed using the Mann–Whitney U test, χ^2 test, or Fisher's exact test, as appropriate. Normality was assessed using the Shapiro–Wilk test. The association between the intervention and each outcome parameter was assessed using unadjusted and adjusted multilinear or binary regression analyses depending on the outcome measure. Effect estimates are reported as adjusted and unadjusted effect estimates with 95% confidence intervals (95% CI). For the primary outcome adjustments were made for age, NIHSS at baseline and baseline LAST score. Effect sizes for group comparisons were estimated using Cohen's d , calculated as the mean difference between groups divided by the pooled SD. Effect sizes were interpreted based on Cohen's conventional thresholds: small ($d = 0.2$), medium ($d = 0.5$), and large ($d = 0.8$) [27]. A $p < 0.05$ was considered statistically significant. Statistical analyses were conducted using SPSS version 26 for Windows (IBM Corp., Armonk, NY, USA). Sample size calculation was carried out using Python version 3.12.0. Figures were generated using GraphPad Prism version 10 (GraphPad Software, Boston, MA, USA).

2.8 | Standard Protocol Approvals, Registrations, and Patient Consents

Written informed consent was obtained from each participant. In cases where the patient lacked the capacity to provide informed consent, consent was obtained from their proxy. If the patient later regained decision-making capacity, they were informed retrospectively and provided consent accordingly. This study was approved by the ethics committee of LMU Munich (protocol: 10-068). This trial was registered at [ClinicalTrials.gov](https://clinicaltrials.gov) (Identifier: NCT04080817; date of registration: September 4, 2019). The study conforms with the World Medical Association Declaration of Helsinki. The first enrollment was on July 13, 2021. The final follow-up occurred on September 7, 2024. The study protocol and statistical analysis plan were published as open access [25]. We used the CONSORT checklist when writing our report [28].

3 | Results

3.1 | Baseline and Treatment Characteristics

The LEXI trial was terminated prematurely in September 2024 after a prespecified interim analysis suggested futility based on revised sample size calculations using available 90-day outcome data (see Methods S1). Between June 2021 and September 2024,

a total of 4097 patients were screened, of whom 104 (2.5%) were enrolled and randomized (Figure 1). Of these, 53 patients (51.0%) received tabled-assisted SLT using the Neolexon app, and 51 patients (49.0%) standard SLT. The median time from last known well to randomization was 3.3 days (IQR: 2–4).

Eleven participants (10.6%) died before completion of the 90-day follow-up, 28 (26.9%) withdrew consent, 4 (3.8%) were not able to participate in study visits due to medical reasons and 2 (1.9%) were lost to follow-up. The most common reason for withdrawal of consent was unwillingness to complete the logopedic assessments (78.6%). Ultimately, 30 patients (56.6%) in the intervention group and 26 (51.0%) in the control group were included in the mITT-analysis. An overview of reasons for study discontinuation is presented in Table S2.

Baseline characteristics (mean age, sex distribution, stroke type, aphasia severity) are reported for all randomized patients ($n = 104$) and were well balanced between groups (Table 1). The mean age was 74.4 years (SD 11.2), and 54 patients (51.9%) were female. The most common cause of aphasia was acute ischemic stroke in the left middle cerebral artery territory, occurring in 85 patients (81.7%). At the time of randomization, the median NIHSS score was 7 vs. 4 in the intervention and control groups, respectively. Participants in the standard SLT group received more often acute stroke treatment

(52.8 vs. 72.5%; $p = 0.045$), including intravenous thrombolysis, endovascular treatment, or both. The median baseline BIAS percentile rank was 16 (IQR 0–48) in the intervention group and 24 (IQR 4–48) in the control group ($p = 0.252$). Regarding aphasia severity at randomization, 30 patients (28.8%) had mild aphasia (LAST 11–13 points), 23 (22.1%) had moderate aphasia (LAST 6–10 points), and 51 (49.1%) had severe aphasia (LAST 0–5 points). The results of the univariate analysis are presented in Table 1.

The amount of supervised SLT was comparable between groups, median 18 vs. 17 min per day in the stroke center ($p = 0.433$) and 21 vs. 18 min in the neurorehabilitation facility ($p = 0.612$), respectively. The median length of stay was similar between groups, both at the stroke center (13 vs. 13 days; $p = 0.371$) and in the residential neurorehabilitation facility (43 vs. 35 days; $p = 0.173$). Detailed treatment characteristics are presented in Table 2.

3.2 | Primary Outcome

Analyses were performed on the mITT population, including all randomized patients with available 90-day follow-up data ($n = 56$). At a median follow-up of 98 days (IQR: 94–105), there was no difference in the change of BIAS percentile ranks between the two

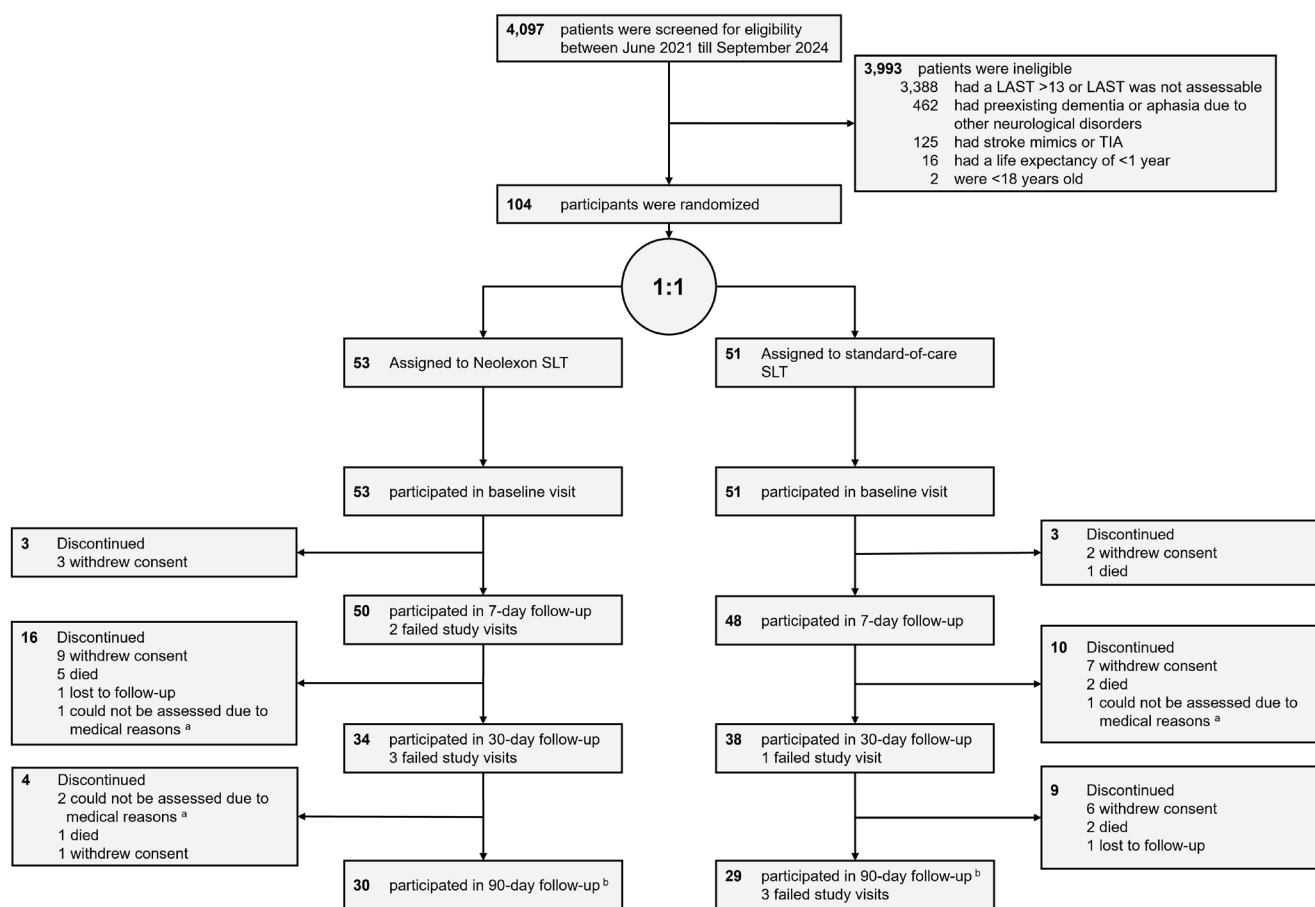


FIGURE 1 | CONSORT flow diagram of the trial. ^aMedical reasons included COVID-19 infection, acute delirium, severe systemic infection and newly diagnosed brain tumor requiring surgery (one participant each). ^bIncluded in the intention-to-treat analysis. LAST Language Screening Test; SLT speech and language therapy; TIA transient ischemic attack.

TABLE 1 | Baseline characteristics.

	Tablet-assisted SLT, N = 53 patients	Standard SLT, N = 51 patients	p
Age at randomization (years), mean (SD)	73.1 (12.3)	75.7 (9.98)	0.225
Female sex, <i>n</i> (%)	27 (50.9)	27 (52.9)	0.847
Last known well to randomization (days), median (IQR)	3.2 (1.8–5.2)	3.5 (2.3–8.7)	0.938
Type of stroke, <i>n</i> (%)			0.320
Ischemic	46 (86.8)	48 (94.1)	
Hemorrhagic	7 (13.2)	3 (5.9)	
Vessel territory (in case of ischemic stroke)			0.356
Anterior cerebral artery	0 (0.0)	0 (0.0)	
Middle cerebral artery	42 (91.3)	47 (97.9)	
Posterior cerebral artery	2 (4.3)	0 (0.0)	
Stroke in > 1 vessel territory	2 (4.4)	1 (2.1)	
Hemorrhage localization, <i>n</i> (%)			0.518
Frontal	1 (14.3)	0 (0.0)	
Fronto-parietal	1 (14.3)	0 (0.0)	
Temporal	3 (42.8)	2 (66.6)	
Temporo-parietal	0 (0.0)	1 (33.3)	
Parietal	1 (14.3)	0 (0.0)	
Parieto-occipital	1 (14.3)	0 (0.0)	
Hemisphere lesioned, <i>n</i> (%)			0.615
Left	49 (92.5)	48 (94.1)	
Right	3 (5.7)	3 (5.9)	
Both	1 (1.9)	0 (0.0)	
Acute stroke treatment, <i>n</i> (%)			0.045
IVT only	3 (5.7)	8 (15.7)	
ET only	13 (24.5)	22 (43.1)	
IVT and ET	12 (22.6)	7 (13.7)	
School education (years), median (IQR)	10 (8–13)	10 (8–13)	0.973
Handedness, <i>n</i> (%)			0.610
Right	38 (90.5)	38 (92.7)	
Left	3 (7.1)	3 (7.3)	
Both	1 (2.4)	0 (0.0)	
NIHSS, median (IQR)	7 (4–14)	4 (2–10)	0.072
pmRS, median (IQR)	0 (0–1)	0 (0–0)	0.256
mRS, median (IQR)	3 (4–5)	4 (3–4)	0.170
BI, median (IQR)	43 (20–73)	55 (25–80)	0.394
LAST, median (IQR)	0 (5–10)	7 (1–12)	0.165

(Continues)

TABLE 1 | (Continued)

	Tablet-assisted SLT, N = 53 patients	Standard SLT, N = 51 patients	<i>p</i>
LAST 0–5, <i>n</i> (%)	29 (54.8)	22 (43.1)	
LAST 6–10, <i>n</i> (%)	12 (22.6)	11 (21.6)	
LAST 11–13, <i>n</i> (%)	12 (22.6)	18 (35.3)	
BIAS-A percentile rank, median (IQR)	16 (0–48)	24 (4–48)	0.252
ACL, median (IQR)	32 (0–89)	68 (13–93)	0.155
Mean AABT percentile rank ^a , median (IQR)	43 (13–67)	46 (24–72)	0.225
EuroQol VAS, median (IQR)	50 (43–70)	68 (50–85)	0.138
BDI, median (IQR)	8 (6–17)	7 (2–15)	0.190
EuroQol EQ-5D-5L LSS, median (IQR)	11 (7–17)	11 (7–16)	0.641

Note: Significant differences are marked bold.

Abbreviations: (p)mRS, (pre)modified Rankin Scale; AABT, Aachen Aphasia Bedside Test; ACL, Aphasia Check List; BDI, Beck's Depression Inventory; BI, Barthel Index; BIAS-A, Bielefelder Aphasia Screening Acute; ET, endovascular treatment; IVT, intravenous thrombolysis; LAST, Language Screening Test; LSS, Level Sum Scale; NIHSS, National Institutes of Health Stroke Scale; SLT, speech and language therapy; VAS, Visual Analog Scale.

^aPercentile rank averages across the categories of singing, sequential speech and phrases, object identification, and naming.

TABLE 2 | Treatment characteristics.

Treatment characteristics			
	Tablet-assisted SLT, N = 53 patients	Standard SLT, N = 51 patients	<i>p</i>
Supervised SLT (min/day), median (IQR)			
Stroke center			
Individual training	18 (15–21)	17 (12–22)	0.433
Neurorehabilitation			
Individual training	21 (16–22)	18 (16–32)	0.612
Group training	15 (11–21)	10 (6–17)	0.188
Number of supervised SLT sessions, median (IQR)			
Stroke center			
Individual training	7 (5–9)	7 (5–11)	0.287
Neurorehabilitation			
Individual training	18 (10–28)	17 (9–26)	0.839
Group training	15 (9–23)	11 (7–18)	0.171
Length of stay in stroke center (days), median (IQR)	13 (8–15)	13 (9–17)	0.371
Length of stay in residential neuro rehabilitation (days), median (IQR)	43 (28–67)	35 (24–48)	0.173

Note: Treatment characteristics of the mITT population are summarized at each participants' latest follow-up. The average daily duration of supervised speech and language therapy (SLT) was calculated by dividing the total cumulative SLT time received at both the stroke center and the neurorehabilitation facility by each participant's length of stay. SLT speech and language therapy.

groups (18 vs. 14; $p=0.266$; Table 3, Figure 2). Similar results were observed at the 7- and 30-day follow-ups (Table S2).

Tablet-assisted SLT with Neolexon was not associated with a change in the BIAS percentile rank in unadjusted multilinear

regression (unadjusted $\beta=8.81$; 95% CI -2.44 to 20.05 ; $p=0.122$; Table 3). However, after adjustment for age, baseline NIHSS and LAST, tablet-assisted SLT with Neolexon was associated with an improvement in BIAS-R percentile ranks (adjusted $\beta=11.74$; 95% CI 0.33 – 23.15 ; $p=0.044$; Table 3).

TABLE 3 | Uni- and multivariate outcome analysis at 90-day follow-up.

	Univariate analysis			Multivariate analysis	
	Tablet-assisted SLT	Standard SLT	<i>p</i>	Effect estimates (95% CI)	<i>p</i>
<i>Primary outcome</i>					
Change in BIAS-R percentile rank	18 (7–39)	14 (4–28)	0.266	8.81 (–2.44 to 20.05) 11.74 (0.33 to 23.15) ^a	0.122 0.044
<i>Secondary outcomes</i>					
Self-training frequency	20 (37.7)	11 (21.6)	0.088	2.20 (0.94 to 5.39)	0.121
Cumulative self-training duration	10 (6–15)	4 (2–6)	0.001	5.96 (2.03 to 9.88)	0.004
Aphasia Check List (ACL)	31 (21–54)	34 (23–49)	0.848	0.62 (–13.37 to 14.50)	0.930
Aachen Aphasia Bedside Test (AABT) percentile rank ^b	15 (3–28)	12 (–2 to 25)	0.475	4.26 (–6.07 to 14.59)	0.412
Language Screening Test (LAST)	4 (2–6)	2 (1–7)	0.126	0.87 (–0.93 to 2.67)	0.338
National Institutes of Health Stroke Scale (NIHSS)	–3 (–6 to –2)	–2 (–5 to –1)	0.136	–1.73 (–3.90 to 0.43)	0.114
Modified Ranking Scale (mRS)	–1 (–2 to 0)	–1 (–2 to 0)	0.372	0.32 (–0.46 to 1.09)	0.419
Barthel Index (BI)	33 (0–55)	20 (5–45)	0.635	4.57 (–11.52 to 20.66)	0.572
Beck's Depression Inventory (BDI)	–2 (–8 to 2)	–4 (–8 to 2)	0.642	–1.07 (–8.69 to 6.54)	0.775
EuroQol EQ-5D-5L Level Sum Score (LSS)	–2 (–6 to 0)	–4 (–7 to –1)	0.313	0.60 (–3.74 to 4.94)	0.780
EuroQol Visual Analog Scale (VAS)	13 (0–35)	10 (–1 to 30)	0.714	1.26 (–17.61 to 20.13)	0.892

Note: Significant differences are marked bold. Outcomes at 90-day follow-up are presented as median (interquartile range), or counts (*n*) and percentiles (%) where applicable in univariate analysis. Values for all outcome measures represent the change from baseline to the 90-day follow-up. Multivariate analyses were performed using primary and secondary outcome measures at 90-day follow-up as dependent variables. Unadjusted and adjusted effect estimates are presented as β coefficients or Odds Ratios depending on the selected dependent variable with 95% confidence intervals.

^aAdjusted for age, baseline NIHSS and baseline LAST.

^bPercentile rank averages across the categories of singing, sequential speech and phrases, object identification, and naming. BIAS-R Bielefelder Aphasia Screening Rehabilitation Version.

3.3 | Secondary Outcomes

At 90-day follow-up, a numerically higher number of participants in the tablet-assisted SLT group conducted self-training compared to the control group (20 [37.7%] vs. 10 [21.6%]; $p=0.088$; OR 2.20; 95% CI 0.94–5.39; $p=0.121$). Among those who performed self-training, participants using the Neolexon app trained for longer total durations than those using analog training materials (10 h vs. 4 h; $p=0.001$; $\beta=5.96$; 95% CI 2.03 to 9.88; $p=0.001$). All other secondary outcome measures were comparable between both groups in uni- and multivariate analyses at 90-day follow-up (Table 3, Figure 2). Absolute values of all outcome measures at 7-, 30- and 90-day follow-up are presented in Table S3.

3.4 | Subgroup Analysis

In the mITT population, a prespecified subgroup analysis stratified by baseline LAST scores showed no improvement in BIAS-R percentile ranks at 90-day follow-up in patients with severe aphasia (LAST 0–5 points: $\beta=-5.75$; 95% CI –28.70 to 19.20; $p=0.682$; Figure 3). In patients with mild (LAST 11–13 points: $\beta=15.51$; 95% CI –1.67 to 32.69; $p=0.074$) and moderate aphasia (LAST 6–10 points: $\beta=23.58$; 95% CI –4.48 to 51.65;

$p=0.092$), effect estimates pointed towards an improvement, but they did not reach statistical significance. An exploratory analysis by NIHSS score (≤ 5 vs. > 5 points) showed an improvement in BIAS-R percentile ranks at 90-day follow-up in patients with an NIHSS of 1–5 ($\beta=21.69$; 95% CI 5.54–37.84; $p=0.01$).

3.5 | Effect Sizes

In the mITT population, the intervention demonstrated a minimal effect size at the final follow-up (Cohen's $d=0.03$). Similarly, among patients with severe aphasia (LAST 0–5), the effect size remained small (Cohen's $d=0.21$). However, in patients with mild (LAST 11–13) and moderate aphasia (LAST 6–10), the intervention showed large effect sizes (Cohen's $d=0.89$ and 1.1, respectively).

4 | Discussion

The LEXI trial did not demonstrate the efficacy of tablet-assisted SLT in the early rehabilitation of aphasia following acute stroke due to its limited sample size and most likely influenced by the inclusion of participants with very severe aphasia. Consequently,

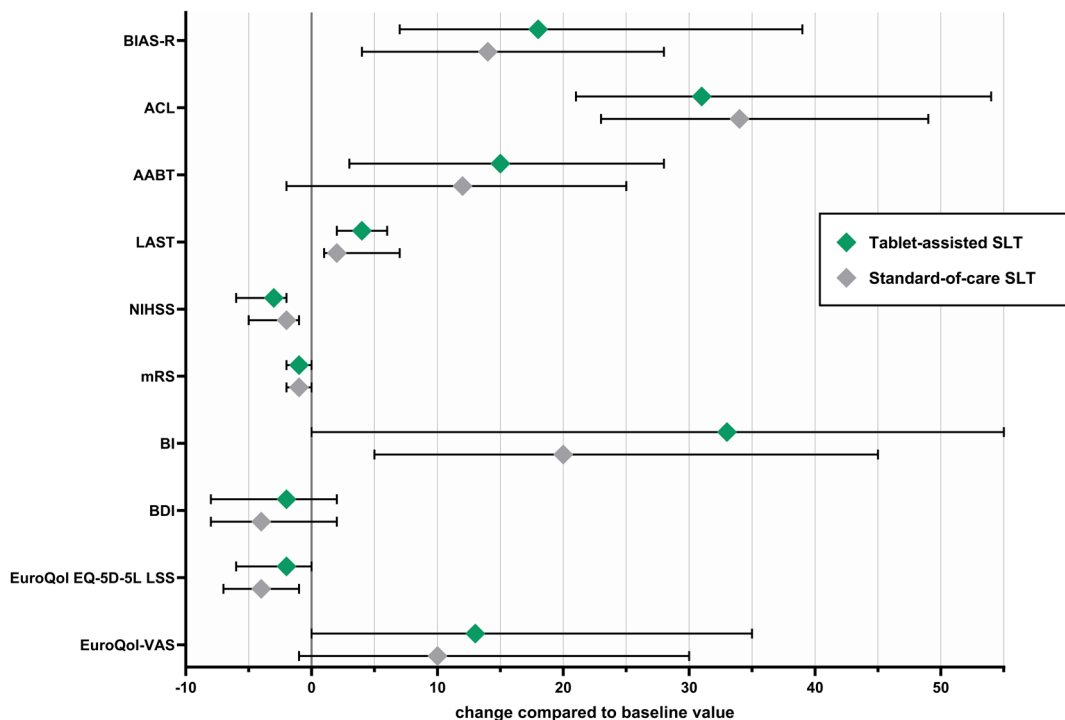


FIGURE 2 | Primary and secondary outcomes. Changes from baseline (X-axis) in primary and secondary outcome measures are presented as medians (symbols) with interquartile ranges (bars) for both the tablet-assisted SLT and standard SLT groups. The values on the X-axis indicate percentile ranks or points depending on the outcome measure. AABT Aachen Aphasia Bedside Test; ACL Aphasia Check List; BDI Beck's Depression Inventory; BI Barthel Index; BIAS-R Bielefelder Aphasia Screening Rehabilitation Version; LAST Language Screening Test; LSS Level Sum Score; mRS modified Rankin Scale; NIHSS National Institutes of Health Stroke Scale; VAS Visual Analog Scale.

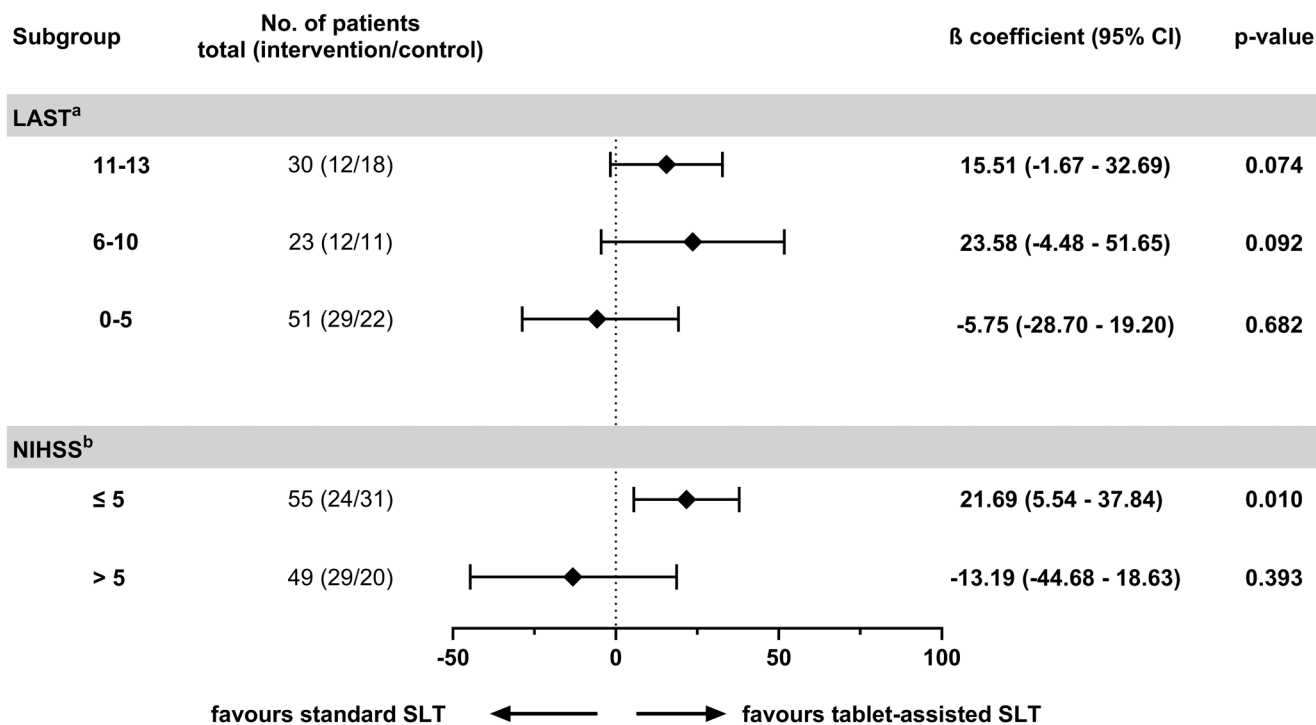


FIGURE 3 | Subgroup analysis. β coefficients and 95% confidence intervals (CIs) represent unadjusted effect estimates for each subgroup, obtained through multilinear regression analysis indicating an improvement in the BIAS-R percentile rank at 90-day follow-up. ^aPrespecified subgroups analysis. ^bPost hoc subgroup analysis. LAST, Language Screening Test; NIHSS, National Institutes of Health Stroke Scale.

the trial was terminated prematurely owing to the low probability of achieving superiority. However, this study yields several important findings, summarized as follows.

First, our prespecified subgroup analysis revealed trends suggesting the efficacy of tablet-assisted SLT with Neolexon in patients with mild to moderate aphasia, as supported by our effect size estimates. A post hoc subgroup analysis further aligned with this finding, indicating a potential benefit in patients with mild strokes. Moreover, the primary outcome analysis—after adjusting for baseline aphasia and stroke severity—demonstrated a positive effect of the intervention on BIAS-R percentile rank improvement at the 90-day follow-up, although patients in the standard SLT group also improved on the BIAS-R percentile rank, and the absolute change did not differ significantly between groups in univariate analysis. However, these findings support the conclusion that tablet-assisted SLT may be effective in less severely affected acute stroke patients and highlight the relevance of stratification by baseline stroke and aphasia severity in future trials.

Second, we observed a numerically higher frequency of self-training in patients randomized to tablet-assisted SLT. Furthermore, those patients who conducted self-training using the Neolexon app trained for a longer duration compared to patients, who received analog training material which may have important implications for early aphasia rehabilitation. Third, our trial provides valuable insights into the challenges associated with eligibility criteria selection and study visit design for future trials investigating computer-supported SLT for stroke patients in the acute setting.

The lacking effect of tablet-assisted SLT in severe aphasia likely reflects the association between low LAST scores and severe stroke-related disabilities, such as hemiparesis, disorders of consciousness and neglect, limiting the benefits of computerized therapy even when applied in tandem with a speech therapist [29, 30]. In fact, patients with LAST scores of 0–5 had a median NIHSS of 12, compared to 4 in moderate and 3 in mild aphasia. Moreover, only seven patients with LAST scores of 0–5 performed self-training during the study, potentially attenuating the intervention's effect. Additionally, patients assigned to the tablet-assisted SLT group had more severe strokes, and a higher proportion of patients with severe aphasia (LAST 0–5) were allocated to the tablet-assisted SLT group compared to those receiving standard SLT. Although this difference was not statistically significant, it may have mitigated the potential benefits of SLT in this cohort, particularly given the small sample size. This is further supported by the fact that the effect estimate showed a significant association between tablet-assisted SLT and greater changes in BIAS-R, after adjusting for baseline LAST and NIHSS scores.

Despite strong evidence for computerized SLT in chronic post-stroke aphasia, notably from the Big CACTUS trial, data on its efficacy in the acute phase is rare [16, 31]. To date, only one study ($n = 22$) has demonstrated non-inferiority of computerized SLT versus face-to-face SLT, alongside a feasibility study ($n = 24$) and a small pilot study ($n = 9$) [32–34]. This trial contributes to the current literature by evaluating computerized SLT in the acute phase using a randomized controlled design and incorporating a broad range of speech-language assessments across multiple rehabilitation time points.

Limitations include the trial's limited sample size, its open-label design and lack of blinded outcome assessments, which introduce potential bias. Furthermore, 28 patients withdrew consent, with most citing reluctance to complete speech-language assessments, leading to a notable proportion of missing 90-day follow-up data. The cognitive demands of comprehensive assessments, particularly for individuals with aphasia, underscore the need to simplify outcome measures, which should be considered when designing future trials. As no effects on QoL were observed, consistent with previous computerized speech-language therapy studies [35], reducing QoL-related measures may improve adherence and reduce dropout rates. Furthermore, two BIAS versions (BIAS-A at baseline and BIAS-R at follow-up) were used to assess language performance, which may introduce bias in outcome evaluation; however, as the BIAS-R fully includes all subdomains of the BIAS-A and was specifically developed for longitudinal assessment, the resulting bias is considered minimal [19]. An additional limitation of this study is that the time required for patients to learn to use the tablet was not systematically recorded. Consequently, potential differences in learning time, particularly among patients with severe aphasia or cognitive deficits, could not be assessed. Furthermore, family members and caregivers were not routinely instructed in tablet use, and although prompting by family or caregivers was permitted, it was not systematically monitored or quantified. These factors may have influenced the consistency, adherence, and overall effectiveness of self-directed training outside supervised sessions. We encountered challenges in recruitment, with only 2.5% of screened patients meeting eligibility criteria. The acute setting posed two key challenges, which together accounted for nearly 85% of the ineligible patients: [1] rapid spontaneous or treatment-induced recovery in mild to moderate aphasia, leading to undetectable deficits on the LAST, consistent with early aphasia recovery patterns [36, 37] and [2] severe stroke cases frequently presenting with complications such as impaired consciousness, delirium or infection-related encephalopathy, precluding LAST assessment within 24 h. The LAST's limited sensitivity to subtle deficits may have further influenced recruitment [17, 38]. Future studies may benefit from more sensitive screening tools, such as the BIAS-A, though its longer administration time (up to 1 h vs. 5 min for LAST) may limit feasibility in acute care [17, 19]. In this study, patients were enrolled very early after stroke onset given the acute setting and trial design (median of approximately 3 days from last known well to randomization in both groups). Therefore, we do not believe that faster inclusion alone would mitigate the impact of rapid spontaneous improvement. Furthermore, our results suggest that device-assisted SLT may not be effective in patients with severe aphasia and/or severe stroke. Consequently, future trials should focus on patients with mild to moderate aphasia and consider introducing an NIHSS cutoff, for example at 5 points, to optimize treatment responsiveness in the acute setting.

5 | Conclusion

This trial comparing tablet-assisted SLT using the Neolexon application to standard SLT in acute post-stroke aphasia was underpowered to demonstrate superiority, possibly due to the inclusion of patients with severe aphasia. However, tablet-assisted

SLT with Neolexon showed potential benefits in patients with mild to moderate aphasia and less severe strokes, and it may enhance self-training in the acute stroke setting. Further large-scale studies are needed to evaluate the efficacy of device-supported SLT in acute post-stroke aphasia.

Author Contributions

Johannes Wischmann: conceptualization; methodology; software; data curation; investigation; validation; formal analysis; supervision; visualization; project administration; resources; writing – original draft; writing – review and editing. Leanna Brasch: data curation; investigation; writing – review and editing. Julia Franzen: data curation; investigation; writing – review and editing. Jennifer Schwierz: data curation; investigation; writing – review and editing. Oksana Kovalenko: data curation; investigation; writing – review and editing. Andrea Gutmann: methodology; validation; formal analysis; data curation; writing – review and editing. Franziska Erbert: conceptualization; software; data curation; investigation; supervision; project administration; resources; writing – review and editing. Luisa Bußmann: data curation; investigation; writing – review and editing. Julia Lauer: data curation; investigation; writing – review and editing. Claudia Dumberger: data curation; investigation; writing – review and editing. Alexander Mandl: Data curation; Investigation; Writing – review and editing. Marie Mehringer: data curation; investigation; writing – review and editing. Annette Münsterer: data curation; investigation; writing – review and editing. Julia Spitzer: data curation; investigation; writing – review and editing. Lena Winterhalter: data curation; investigation; writing – review and editing. Vanessa Frank: data curation; investigation; writing – review and editing. Marika Rheinwald: data curation; investigation; writing – review and editing. Katharina Lehner: conceptualization; methodology; software; data curation; supervision; resources; writing – review and editing. Franziska Ammer: data curation; investigation; writing – review and editing. Angelika Pfahler: data curation; investigation; writing – review and editing. Stefanie Lampart: data curation; investigation; writing – review and editing. Charlotte Young: data curation; investigation; supervision; writing – review and editing. Peter Young: data curation; investigation; supervision; resources; writing – review and editing. Barbara Goettert: data curation; investigation; writing – review and editing. Marcella Bitzan: data curation; investigation; writing – review and editing. Stephanie Rinder: data curation; investigation; writing – review and editing. Oliver Meier: Data curation; investigation; supervision; project administration; resources; writing – review and editing. Katharina Feil: conceptualization; methodology; software; data curation; validation; formal analysis; supervision; funding acquisition; visualization; project administration; resources; writing – original draft; writing – review and editing. Lars Kellert: conceptualization; methodology; software; data curation; validation; formal analysis; supervision; funding acquisition; visualization; project administration; resources; writing – original draft; writing – review and editing.

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Conflicts of Interest

The authors declare no conflicts of interest. K.L. was employed as a project lead at Limedix GmbH during part of the study period. Limedix is the manufacturer of the Neolexon application evaluated in this study. This relationship had no influence on the study design, data collection, data analysis, or interpretation of the results. P.Y. received funding for travel or speaker honoraria from Idorsia, Sanofi, Amicus, Löwenstein Medical, Bioprojet and Mementor outside of this study. P.Y. is supported by the Dr. Werner und Raphael Müller Narcolepsy Foundation. C.Y. is supported by the Dr. Werner und Raphael Müller Narcolepsy Foundation. K.F. received grants from the University of Tübingen (AKF and Sigrid-Örgel Stiftung) and speakers' honoraria/consulting fees from AstraZeneca and BMS/Pfizer, all not related to this work. L.K. received funding for travel or speaker honoraria from Alexion, AstraZeneca, Bayer Vital, Boehringer Ingelheim, Bristol-Myers Squibb, Daiichi Sankyo, Lilly and Pfizer outside of this study.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section. **Data S1:** ene70443-sup-0001-Supinfo1.docx.