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# The effect of augmented speech-language therapy delivered by telerehabilitation on post stroke aphasia – a pilot randomized controlled trial.



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| | |

# Abstract

**Objective:** Pilot a definitive randomized controlled trial of speech-language telerehabilitation in post stroke aphasia in addition to usual care with regard to recruitment, dropouts and language effects.

**Design:** Pilot single blinded randomized controlled trial

**Setting:** Telerehabilitation delivered from tertiary rehabilitation center to participants at their home or admitted to secondary rehabilitation centers**.**

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**Intervention:** Sixty-two participants randomly allocated to five hours of speech and language telerehabilitation by videoconference per week over four consecutive weeks together with usual care or usual care alone. The telerehabilitation targeted functional, expressive language.

**Main measures**: Norwegian Basic Aphasia Assessment: Naming (primary outcome), repetition and auditory comprehension subtests; Verb and Sentence Test sentence production subtest and the Communicative Effectiveness Index at baseline, four weeks, four months post randomization. Data were analyzed by intention to treat.

**Results:** No significant between-group differences were seen in naming or auditory comprehension in the Norwegian Basic Aphasia Assessment at four weeks and four months post randomization. The telerehabilitation group (n=29) achieved a Norwegian Basic Aphasia Assessment repetition score of 8.9 points higher (p=0.026) and a Verb and Sentence Test score 3 points higher (p=0.002) than the control group (n=27) four months post randomization. Communicative Effectiveness Index was not significantly different between groups, but increased significantly within both groups. No adverse events were reported.

**Conclusions:** Augmented telerehabilitation via videoconference may be a viable rehabilitation model for aphasia affecting language outcomes post stroke. A definitive trial with 230 participants is needed to confirm results.

# The effect of augmented speech-language therapy delivered by telerehabilitation on post stroke aphasia – a pilot randomized controlled trial.

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## Introduction

Aphasia is an acquired communication disorder due to brain injury, most commonly seen following stroke with a reported frequency of 30-40 % in acute stroke survivors [1, 2]. Current research on speech-language therapy for aphasia following stroke supports the effectiveness of high intensity - high dose speech-language training on functional and expressive language skills [3, 4, 5].

Although evidence suggests the significance of intensive therapy regimes, it is challenging to provide aphasia rehabilitation described within trial protocols in a local or clinical setting. This is a natural consequence of a healthcare landscape with growing demands, increasing cost, constrained resources and limited speech-language pathologists accessible. Tailored, intensive speech-language therapy may also be difficult to establish, due to geographical barriers, and co-morbidities like decreased motor function and fatigue seen in the stroke population [6].

In this context, telerehabilitation can constitute an unconventional strategy compared to more traditional forms of training as it represents one potential route to augment the dosage of therapy. In addition, telerehabilitation may facilitate equal services when access is limited due to geographical barriers, and utilize available resources in local settings. Hence, delivering speech-language therapy through videoconference gives an opportunity to provide rehabilitation services directly at home, eliminating the need for travel, still allowing “face-to-face” interventions through the screen.

Although there is a growing literature regarding aphasia telerehabilitation, the effect of this new form of aphasia service is however to date still unclear, with low strength of current evidence on efficiency [7, 8]. Especially, there are few trials that explore how telerehabilitation can be used to increase therapy time, and the impact such augmented telerehabilitation might have on aphasia outcomes.

Thus, the main objective of this pilot randomized controlled trial is to contribute to prospective well-designed large-scale trials. We further examine the effectiveness of a speech-language therapy intervention by videoconference in post stroke aphasia in addition to standard speech-language therapy (usual care). We aim to provide information to support the development and delivery of future definitive randomized controlled trials, including calculations for an accurate sample size In addition to language outcomes, our trial reports on features of recruitment and dropouts.

## Methods

Our study was designed as a parallel group, randomized, controlled, pilot trial with blinded assessors. The study received ethical approval from the Norwegian Regional Committee South East for Medical and Health Research Ethics (Approval number 2015/2129). The trial was registered at the Clinical Trials Government website (NCT02768922) and was funded by the South-Eastern Norway Regional Health Authority (project number 2015037), the University of Oslo and Sunnaas Rehabilitation Hospital. The trial and reporting of the trial conforms to the Consolidated Standards of Reporting Trials (CONSORT) guidelines for pragmatic trials [9] and the guideline extensions for randomized pilot and feasibility trials [10]. Our protocol with the choice of outcomes, a description of the intervention and proposed analyses was reported earlier [11]. Recruitment started in May 2016 and ended in May 2018.

Patients were recruited within the Oslo region from stroke units at four different hospitals, from rehabilitation institutions including Sunnaas Rehabilitation Hospital, and from cooperating speech-language pathologists. Staff at recruitment sites screened patients for eligibility, where potential participants received information and an invitation to take part in the trial. The research investigator (HPØ) made an ambulatory visit for further investigations and enrollment. Broad inclusion criteria were selected to ensure a suitable sample size, in line with the timeframe and geographical context. We included a heterogeneous sample of patients with aphasia following stroke, with no limits with regards to time post stroke, previous history of stroke, and handedness. An informed consent form accessible to people with aphasia was used. Written consent was obtained from all participants. The following criteria for inclusion and exclusion were used:



Study inclusion criteria:

- People with aphasia following stroke (any time post stroke).
- Aphasia including naming impairment (percentile score of 70 or lower on the Norwegian Basic Aphasia Assessment subtest naming [12]).
- Norwegian was their main language.

Study exclusion criteria:

- Age below 16 years.
- Patients who were unable to perform five hours of speech-language therapy per week due to medical or cognitive reasons (including moderate to severe hearing or visual impairment).
- Patients who scored > 70 percentile score on the Norwegian Basic Aphasia Assessment subtest naming.
- Patients with traumatic brain injury.

Participants were individually allocated directly after baseline assessment to either the usual care with additional telerehabilitation group (telerehabilitation group) or the usual care group (control group). A web-based random sequence generator without limiting conditions was used by an independent experienced scientist not a member of the project team, to create a list with the randomization sequence. Group allocation for each participant was obtained by phone to a hospital employee otherwise not involved in the study, who securely preserved this list.

All trial participants received usual care during the study period provided by local speech-language pathologists at the community level and/or in a rehabilitation institution. The participants allocated to the telerehabilitation group received augmented language training via videoconference. Participants who were allocated to the control group did not receive any project specific intervention. Due to the nature of the telerehabilitation intervention and the usual care delivered, the speech-language pathologists delivering the intervention and the participants were not blinded to treatment allocation.

The dosage of usual care measured by hours from inclusion to follow-up assessment was recorded in a log-form. The log was piloted in cooperation with the participant's family/caregivers. Information on dosage was also retrieved from the speech-language pathologists providing the usual care and through participants' journal during and/or after completion of the trial. Distinctions were made in the therapy log with regards to what type of therapy had been provided; face-to-face speech-language therapy in a single session or by group.

In order to ensure treatment fidelity, transparency and replicability for future studies, the Template for Intervention Description and Replication Checklist and Guide [13], was used to document the telerehabilitation intervention [11, supplementary table 1]. A mixed approach

following best practice was used to design an intervention aiming to enhance functional expressive communication. This included different impairment-based methods like functional-orientated therapy to phonological, semantic, cognitive-linguistic and cognitive-neuropsychological approaches. The therapy was tailored to the individual participant's language impairment, needs and goals in all language modalities (reading, writing, spoken language and auditory comprehension).

The intervention targeted spoken language with tasks including word production, picture naming and discussion about familiar topics. Materials used in the intervention included a Norwegian translation of the Newcastle University Aphasia Therapy Resources [14, 15, 16] and a computer training program targeting all language modalities called Lexia. We also used "Sareptas afasikrukke" [17], a collection of Norwegian tasks comprising individual aphasia exercises training all modalities, e.g. oral and written naming, reading sentences and text. In addition, text, maps and pictures from the Internet were used as resources in therapy sessions.

There were three speech-language pathologists that delivered the telerehabilitation intervention. Training in how to use the therapy material within the telerehabilitation context and in usage of equipment and software was provided through piloting of inpatients at Sunnaas Rehabilitation Hospital (approximately 10 hours). Random fidelity reviews were made by the first author by reviewing therapy records, to ensure that the chosen training material emphasized oral naming and speech production, as well as personalization of therapy with regards to level of impairment and the use of functionally relevant words (for example related to hobbies and family). Reviews were conducted to confirm that the tailored speech-language therapy delivered by videoconference was in keeping with the telerehabilitation intervention as described in trial protocol.

A telerehabilitation intervention of five hours a week in line with current Norwegian national guidelines was chosen [18]. The therapy was delivered via videoconference over four consecutive weeks. Participants were required to complete ≥ 16 sessions of speech-language therapy via videoconference over 32 days in order to secure therapy time as defined per protocol , and account for any expected logistic or technical challenges, as well as medical complications or co-morbidities. As telerehabilitation was given in addition to usual speech-language therapy, the total amount of hours of therapy delivered depended on the rehabilitation resources available in local settings.

The technical setup for the telerehabilitation was built upon the findings of a previous feasibility study [19]. The telerehabilitation was given by a speech-language pathologist using videoconference through internet from Sunnaas Rehabilitation Hospital to a study laptop in the participant's home or in the rehabilitation ward where the participant was admitted. The videoconference software Cisco Jabber/ Acano from the "Norwegian Health Net" was installed in the study laptops given to the participants and in videoconference equipment at Sunnaas Rehabilitation Hospital.

The software LogMeIn was used to remotely control the participant's computer. To ensure adequate confidentiality and meet data safety requirements, the videoconference was provided through encrypted software. The technical setup further included an external speaker to improve sound quality and a wide-angle web camera to enable review of body language and/or gestures. Participants were given training in the use of the computer software usually lasting for 30-60 minutes.

**Assessment of treatment outcomes**

External speech-language pathologists blinded to group allocation performed assessment at the four weeks control and follow-up. Data from baseline testing was collected and recorded

by the research investigator (HPØ) prior to randomization. All participants and/or caregivers were given instructions on how to preserve blinding for the speech-language pathologists who performed the assessments. In two participants, allocation was inadvertently revealed during conversation. Therefore, a second assessor blinded to treatment allocation re-scored these assessments by using video recordings of the test sessions.

The naming subtest from the Norwegian Basic Aphasia Assessment [12] was chosen to measure the effect on naming ability comprising confrontation naming of objects, body parts and actions as well as answering abstract questions. For the evaluation of language functioning beyond naming, the Norwegian Basic Aphasia Assessment subtests auditory comprehension (identification, command following, ideas and relations) and repetition (repetition of words, meaningless syllables and sentences) were also included. We obtained raw scores as well as percentile scores in reference to a general aphasia population (described in [12]). In addition, the Verb and Sentence Test's sentence production subtest [20] was used to evaluate the capability of verb and sentence production beyond words. To investigate functional communication skills, the Communicative Effectiveness Index was also incorporated in the test battery [21].

The Norwegian Basic Aphasia Assessment and the Verb and Sentence Test were assessed at three time points: Baseline, four weeks and four months post randomization. The Communicative Effectiveness Index, which is filled out by family or caregivers, was gathered two times: Following the intervention (four weeks) and the four-month post randomization follow-up.

The effect on naming ability at the four months post randomization follow-up was selected as primary endpoint. Percentile scores more accurately reflect clinically relevant progression than raw scores; thus, the naming percentile score was used with a minimum difference of 8

considered clinically significant. The other language outcomes were chosen as key secondary endpoints.

In addition and also to shed further light on feasibility aspects, quality of life measures, technical log and data regarding the experiences of patients, relatives and therapists with the delivered telerehabilitation, were collected using questionnaires and semi-structured interviews. The latter secondary endpoints will be addressed in other publications.

**Statistical analysis**

Data was analyzed using SPSS version 25.0 (IBM SPSS Inc., Chicago, IL, USA). The analysis of the predetermined primary and secondary outcomes was performed as planned and in adherence with protocol. Descriptive statistics were used to summarize the demographic and clinical presentation of the sample including description of baseline data.

As our study is a phase II exploratory pilot randomized controlled trial, there is a lack of power to fully conclude the effectiveness of our augmented telerehabilitation intervention on language abilities. Statistical analysis was however performed to investigate trends in the data and to make some suggestions on effectivity. The data has furthermore been used to inform accurate sample size estimation for a future definitive randomized controlled trial.

Our analysis was made on intention-to-treat basis, where the level of statistical significance was set at p-value $< 0.05$. To evaluate the immediate and long-term benefit of augmented - telerehabilitation via videoconference on the subtests from the Norwegian Basic Aphasia Assessment and the Verb and Sentence Test, we used linear mixed models analysis. For the Norwegian Basic Aphasia Assessment subtests, percentile score was used for analysis. The fixed effects of the model were time, group allocation and the interaction between group and time to estimate possible differences in development over time between the telerehabilitation

group and the control group. The model was fitted with an unstructured covariance structure. The residuals of each effect variable were visually inspected for normal distribution using histograms and normality plots. Variables with non-normal distribution of the residuals were transformed before subjected to further analysis.

To account for the expected heterogeneity in time post stroke and the dose of usual care speech-language therapy received, the data were also analyzed in separate models including these variables as covariates. As the Communicative Effectiveness Index was assessed at only two time points (four weeks control and at the four months follow-up), it was not incorporated in the linear mixed models analysis, but between and within group comparisons were analyzed using the independent sample t-test and paired sample t-test.

## Results

A total of 86 patients were screened by the research investigator during an ambulatory visit to a stroke unit, a patient's home or a tertiary rehabilitation institution; 62 patients met the study criteria. Details of patient screening, withdrawals, lost to follow up along with reasons for non-completion and adherence are summarized using the CONSORT flow diagram (figure 1). The demographic and clinical characteristics of the groups are shown in table 1.

[Insert Figure 1 here]

[Insert Table 1 here]

Details of the telerehabilitation intervention and usual care delivered during the trial are described in table 2. All therapy (telerehabilitation and usual care) was delivered by speech-language pathologists. The data from the usual care logs revealed that the control group on average received some more hours of usual care than the telerehabilitation group. The

telerehabilitation group received however substantially more hours in total therapy time when adding the telerehabilitation intervention (Table 2).

The majority of therapy by videoconference was given in participants own home, but some participants were located at a rehabilitation ward/institution as they were admitted for rehabilitation following their stroke. Some participants also started their telerehabilitation in a rehabilitation ward and continued their therapy by videoconference at home after discharge.

Participants usually received 60 minutes of speech-language therapy via videoconference per day, five days per week. In some cases, more prolonged therapy time (70-120 minutes) was delivered over fewer days per week, to adjust to the participant's timetable and other planned activities. Prolonged therapy time was only delivered in participants that were able to withstand long sessions. The technical setup for the telerehabilitation was the same regardless of location, with the exception of the internet connection. We used the internet connection available in the local setting, which ranged from mobile and Wi-Fi internet to different types of broadband.

Random fidelity reviews of the therapy reports from the telerehabilitation group found the telerehabilitation intervention to be in adherence with trial protocol. There were no treatment related adverse events or serious harms reported in this trial.

[Insert Table 2 here]

Details of the form return rates, data completeness and time between assessments are described in table 3. The overall data return rates and the data completeness of the Norwegian Basic Aphasia Assessment and the subtest from Verb and Sentence Test, which were administrated by blinded assessors, were good. The return rate of the Communicative Effectiveness Index was somewhat lower as it is a self-reporting questionnaire completed by

family or caregivers. The return rates for all language tests were equally balanced across the two groups.

Time between assessments was somewhat longer in the telerehabilitation group compared to the control group, a result of adherence to the protocol as ≥ 16 sessions of speech-language therapy via videoconference over 32 days was accepted. The overall completion of assessments was however considered to be close to planned time points in the protocol.

[Insert Table 3 here]

**Analysis of language outcomes**

The linear mixed models analysis showed no significant treatment effects for the percentile score of the subtests naming and comprehension from the Norwegian Basic Aphasia Assessment. Regarding the repetition percentile score of the Norwegian Basic Aphasia Assessment and the subtest sentence production of the Verb and Sentence Test however, the mixed models analysis revealed a significant larger improvement over time in the telerehabilitation group (n=29) compared to the control group (n=27). Table 4 shows the language assessment results as well as the results from the linear mixed model analysis including effect estimations.

Figures 2 and 3 illustrate the differences between groups in development over time for the Norwegian Basic Aphasia Assessment repetition and the Verb and Sentence Test. When we added the covariates time post stroke or dose of usual care speech-language therapy to the model, results were very similar with no changes regarding statistical significance (supplementary table 2).

For the Communicative Effectiveness Index, no statistical significance was seen between the groups at the 4 weeks assessment or the 4 months post randomization follow up (table 5). Within group comparisons revealed however significant improvement between assessments in both the telerehabilitation (p=0.001) and the control group (p=0.027).

[Insert Table 4 here]

[Insert figures 2 and 3 here]

[Insert Table 5 here]

**Sample size calculation for a definitive trial**

Data gathered in this pilot trial was used to calculate sample size estimates for a definitive trial on the main effect measure, the percentile score of the Norwegian Basic Aphasia Assessment subtest naming. To adjust for a linear mixed model analysis, the sample size calculations integrated the design effect to correct for the correlation in the data. The minimal clinically meaningful effect was set to a difference in improvement of 8 percentile score in the naming test based on earlier clinical experience. A standard deviation of 20 was chosen from the data collected in this trial. With a 5% significance level and 80% power, we calculate 94 participants in each group, a number of 188 participants in total. With a 20 % drop-out rate, approximately 226 participants are needed for a definitive trial with the Norwegian Basic Aphasia Assessment subtest naming as primary outcome given a parallel group randomized control design.

## Discussion

In this pilot randomized control trial we find that augmented telerehabilitation delivered by videoconference led to a significant increase in the ability to repeat words and to produce

sentences, as measured by the respective subsection of the Norwegian Basic Aphasia Assessment and the Verb and Sentence Test. Furthermore, this increase was significantly larger than in the control group, with the difference between groups considered greater than a minimum clinically meaningful effect. We have not found significant between group differences in the naming and auditory comprehension language outcomes, nor a between group difference in measures of functional language.

A strength of this pilot trial is that the intervention is given and explored within a local and clinical context. Its main weaknesses are a heterogeneous sample and that no detailed information is available about which standard care the participants received. The results must also be seen in the light of the limitations of an underpowered pilot trial, where it is crucial to state that no definitive conclusions can be drawn from our findings. Before evaluating the implications this trial has for future research on speech and language telerehabilitation for aphasia by videoconference, we will further highlight the limitation and weaknesses in our study.

First of all, our language function results should be carefully interpreted given that this is not a full-scale trial. In this pilot, telerehabilitation via videoconference was used strategically to augment dosage of therapy delivered in local settings. We chose to deliver the telerehabilitation in addition to usual care on ethical grounds, as telerehabilitation is relatively new in the field of aphasia research with restricted pre-existing evidence of effect. As the telerehabilitation was additional, this study cannot inform about whether tele-rehabilitation can replace face-to-face speech and language therapy.

The choice to give the telerehabilitation in addition to usual care is therefore an issue of debate, as it represents limitations to determine the single effect of our telerehabilitation intervention. Although we have found a treatment effect with a significantly larger increase in

language outcomes in the telerehabilitation group compared to the control group, no clear conclusion can be made about the cause of this observed effect. Is this due to the effect of the telerehabilitation intervention, the increased therapy time totally received, or both of these factors.

Another limitation that needs to be acknowledged is that our choice of design gave limited control over the usual care delivered. As expected, the usual care reflected upon access to therapy in the local context, with a wide range of hours of speech-language therapy received across individual cases. The design of the log for usual care only accounted for hours of therapy by group or single sessions, but lacking data on the actual content of the therapy given. For a definitive trial, we therefore suggest that the therapy approaches used in usual care should be described to a greater extent using the TIDieR checklist [13].

As limited control over usual care delivered represented an important limitation of the trial, we chose to incorporate hours of usual care speech-language therapy as one of the covariates in our statistical models. However, this did not result in any changes regarding statistical significance. One might therefore argue that this strengthens the influence the augmented telerehabilitation intervention may have had on the observed effect. However, these results are underpowered to make any definite conclusions on this statement.

Data from the usual care log showed that the control group on average received more hours of usual care than the telerehabilitation group. This could be a result of the telerehabilitation group not receiving the normal amount of usual care, or that enrolment in the trial increased access to usual care in the control group. The latter was suspected in a few cases, where being a participant in the control group seemed to facilitate more hours of usual care therapy.

In the telerehabilitation group, it may also have been difficult to complete the standard ongoing care, as the telerehabilitation intervention was integrated in an already demanding rehabilitation schedule. Higher drop-out rate has been observed in highly intensive treatment protocols, indicating that high-intensity and high dose interventions may not be acceptable to all [3]. In our trial however, only two patients were lost at baseline in the telerehabilitation group, suggesting that the treatment frequency and duration was acceptable.

Regarding the language outcomes of our pilot, the non-significant results we see in auditory comprehension were to be expected as our intervention did not target auditory comprehension specifically. However, the non-significant results in our primary outcome of naming were interesting, as the ability to produce sentences increased significantly different between groups. The treatment effect on the ability to produce sentences was evident during the intervention and continued to be observed at the four-month follow-up assessment. Thus, our intervention may have influenced participants' spoken language beyond single word production.

One possible reason for this might be that the choice of integrating tasks that enhanced overall functional language, in addition to single naming tasks, promoted greater ability to produce sentences. It is also plausible that tailoring the intervention to each participant's impairment level, might have been a factor that endorsed a greater generalization of conversational skills. Regarding repetition, we also observed a significant increase in this outcome but only evident at the four month follow up assessment. This might indicate that the telerehabilitation intervention has a prolonged influence on repetition, increasing the ability to repeat words over time.

An alternative theory to explain the non-significant results we see in naming is the Norwegian Basic Aphasia Assessment's ability to detect clinical change of our telerehabilitation

intervention. To date, the Norwegian Basic Aphasia Assessment is the most comprehensive, standardized, commonly used test available in Norwegian. The naming subtest might however have too few items from limited semantic areas to fully evaluate naming skills, reaching a ceiling effect in persons with mild aphasia. We used the percentile score instead of raw score to reduce the ceiling effect, but this may not have been sufficient.

For a future trial, it seems – due to the aforementioned reasons – rational to evaluate the choice of the Norwegian Basic Aphasia Assessment as the only instrument for measuring single word naming in a Norwegian study when one specifically wants to target naming as primary outcome.Translation and adaptation of more valid and reliable aphasia assessments into Norwegian is already underway. We also look forward to the application of the consensus international core outcome set for aphasia treatment in future aphasia research [22].

Finally, when it comes to scaling the telerehabilitation intervention up for a larger trial, there are several issues to consider including potential barriers. One issue relates to the recruitment rate, where it took approximately 24 months to recruit 62 participants to this pilot. This recruitment rate of 2.6 patients per month is a respectable number compared to other trials of speech-language telerehabilitation. In our trial, only 28 % of the patients screened were excluded which is lower than reported in other trials [23, 24].

Overall, recruitment for aphasia trials seems to be challenging, also demonstrated in this pilot were we had to make modifications to the protocol to fulfill a suitable sample size. In the original protocol, we wanted to investigate telerehabilitation via videoconference early post stroke, due to few studies on interventions this early and a suspected shortage of services in this period. However, because of an initially slow recruitment rate, our original design was adjusted after the first six months of enrollment. We broadened inclusion criteria to include persons with aphasia in all stages following stroke, which enhanced recruitment substantially.

This created a sample with high ecological validity to the general population of people with aphasia, but resulted in a more heterogeneous mixture of participants.

For a definitive trial, we see that achieving a targeted number of approximately 230 participants as estimated by the power calculation based on this pilot trial, will be difficult with our current geographical setup. A larger future trial should aim to recruit participants from across more centers. A crossover design could also be an alternative to a parallel design, as it requires fewer subjects to achieve power and creates a better balance in confounding covariates Adjustments to the statistical analysis to account for obvious between group confounders, like stage of aphasia and time post stroke, might then be necessary.

In summary, this pragmatic pilot randomized control trial has shown our augmented telerehabilitation intervention to have possible benefits to language outcomes that need to be further investigated beyond this pilot. There have been no reports of treatment related adverse events, serious harms or drop-outs directly related to the telerehabilitation intervention. Further on, the trial supports telerehabilitation as a possible delivery model, to be used to increase dose and of speech-language therapy while reducing barriers like restricted resources, fatigue and mobility problems in post stroke aphasia. A definitive randomized controlled trial will however further shed light on augmented telerehabilitation as a future rehabilitation model for post stroke aphasia.

## Clinical Messages

- In this study, telerehabilitation successfully increased total therapy time of speech-language therapy in post-stroke aphasia.
- Our pilot trial suggests that telerehabilitation in addition to usual care may improve repetition skills and sentence production compared to usual care alone.

- A definitive trial with 230 participants is needed to confirm results.

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## Declaration of conflicting interests:

The Authors declares that there is no conflict of interest.

## Contributors

FB initiated and designed the study and ensured funding. FB, HPØ, MK, and MB planned overall study execution, including the analysis strategy. Local planning at stroke units and patient recruitment was performed by HPØ, RBH, BBJ, and BT. HPØ monitored and ensured progress. HPØ elaborated the manuscript draft; all authors contributed to the manuscript and approved the final version.

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**Table 1: Participants characteristics**

| Variable | Telerehabilitation group (n=32) | Control group (n=30) |
|---|---|---|
| **Age in years, mean (SD)** | 64.7 (11.7) | 65.0 (12.2) |
| **Gender, n (%)** | | |
| Male | 19 (59.4 %) | 22 (73.3 %) |
| Female | 13 (40.6 %) | 8 (26.7 %) |
| **Stroke type, n (%)** | | |
| Thromboembolic | 24 (75.0 %) | 19 (63.3 %) |
| Haemorrhage | 3 (9.4 %) | 8 (26.7 %) |
| Thromboembolic and Haemorrhage | 5 (15.6 %) | 3 (10.0 %) |
| **Time from stroke onset in months, n (%)** | | |
| <= 3 months | 16 (50.0 %) | 12 (40.0 %) |
| 3-12 months | 5 (15.6 %) | 4 (13.3 %) |
| 12 months → | 11 (34.4 %) | 14 (46.7 %) |
| **Degree of disability, n (%)** | | |
| Modified Rankin Scale at baseline: | | |
| No significant disability | 0 | 0 |
| Slight disability | 15 (46.9 %) | 14 (46.7 %) |
| Moderate disability | 9 (28.1 %) | 9 (30.0 %) |
| Moderately severe disability | 7 (21.9 %) | 7 (23.3 %) |
| Severe disability | 1 (3.1 %) | 0 |
| **Language function at baseline (mean (SD)):** | | |
| Norwegian Basic Aphasia Assessment: | | |
| Naming - percentile | 38.9 (13.7) | 45.0 (17.6) |
| Comprehension - percentile | 47.6 (19.8) | 52.8 (24.0) |
| Repetition - percentile | 41.4 (21.2) | 52.7 (24.4) |
| Verb and Sentence Test, subtest sentence production: | | |
| Total score | 7.5 (6.0) | 9.7 (6.7) |

**Table 2: Features of the telerehabilitation intervention and usual care received during the trial**

| Intervention description | Telerehabilitation group n=30 | Control group n=27 |
|---|---|---|
| **Brief name of intervention** | Augmented therapy by videoconference and usual care therapy | Usual care therapy |
| **Who provided therapy,** n (%): | | |
| Only therapist in municipality | 0 | 16 (59.3 %) |
| Only therapist in rehabilitation institution | 0 | 2 (7.4 %) |
| Only therapist in municipality + therapist in rehabilitation institution | 0 | 9 (33.3 %) |
| Only project therapist at Sunnaas Rehabilitation Hospital | 2 (6.7 %) | 0 |
| Project therapist at Sunnaas Rehabilitation Hospital + therapist in municipality | 22 (73.3 %) | 0 |
| Project therapist at Sunnaas Rehabilitation Hospital, therapist in municipality + therapist in rehabilitation institution | 6 (20.0 %) | 0 |
| **Modes of delivery,** n (%): | | |
| Only Individual therapy face-to-face | 0 | 16 (59.3 %) |
| Only Group therapy face-to face | 0 | 1 (3.7 %) |
| Individual + group therapy face-to face | 0 | 10 (37.0 %) |
| Only therapy by videoconference | 2 (6.7 %) | 0 |
| Therapy by videoconference + individual therapy face-to-face | 20 (66.7 %) | 0 |
| Therapy by videoconference, individual and group therapy face-to-face | 8 (26.7 %) | 0 |
| **Therapy dose and location** | | |
| **Telerehabilitation intervention** | | |
| Location when receiving telerehabilitation intervention, n (%): | | |
| Own home | 20 (66.7 %) | n/a |
| Rehabilitation ward/institution | 5 (16.7 %) | n/a |
| Own home and rehabilitation ward/institution | 5 (16.7 %) | n/a |
| Duration of telerehabilitation intervention in days (mean, SD) | 27.6, 2.4 | 0 |
| Hours of therapy by videoconference (mean, SD) | 18.6, 1.5 | 0 |
| **Usual care** | | |
| Location during usual care therapy, n (%): | | |
| No usual care delivered | 2 (6.7 %) | 0 |
| Own home | 3 (10.0 %) | 3 (11.1 %) |
| Rehabilitation ward/institution | 1 (3.3 %) | 2 (7.4 %) |
| The therapist's office | 18 (60.0 %) | 14 (51.9 %) |
| The therapist's office and rehabilitation institution | 6 (20.0 %) | 8 (29.6 %) |
| **Hours of Usual care therapy :** | | |
| Usual care therapy individually (mean, SD) | 17.9, 11.4 | 19.0, 10.1 |
| Usual care therapy by group (mean, SD) | 2.6, 5.3 | 6.0, 9.6 |
| Usual care therapy in total (mean, SD) | 20.4, 12.0 | 25.0, 13.8 |
| **Total hours of therapy received** | | |
| Telerehabilitation Intervention + Usual care therapy (mean, SD) | 39.0, 12.2 | 25.0, 13.8 |

**n/a= not applicable**

**Table 3: Form return rates, data completeness and time between assessments**

| | Telerehabilitation group | Control group |
|---|---|---|
| **Norwegian Basic Aphasia Assessment, n (%)** | | |
| Baseline | 32 (100 %) | 30 (100 %) |
| 4 weeks assessment | 30 (94 %) | 27 (90 %) |
| 4 months assessment | 29 (91 %) | 27 (90 %) |
| **Verb and Sentence Test, subtest sentence production, n (%)** | | |
| Baseline | 32 (100 %) | 30 (100 %) |
| 4 weeks assessment | 30 (94 %) | 27 (90 %) |
| 4 months assessment | 28 (88 %) | 27 (90 %) |
| **Communicative Effectiveness Index, n (%)** | | |
| 4 weeks assessment | 28 (88 %) | 25 (83 %) |
| 4 months assessment | 24 (75 %) | 22 (73 %) |
| **Time between assessments (mean, SD)** | | |
| From baseline to 4 weeks assessment (days) | 36.2, 5.9 | 31.2, 3.6 |
| From baseline to 4 months assessment (weeks) | 17.3, 1.6 | 16.8, 0.95 |

Table 4: Results of language outcomes using the linear mixed models analysis

| Outcome variable | Baseline, mean (SD) | 4 weeks assessment, mean (SD) | 4 months FU, mean (SD) | Telerehab group 4 weeks Effect estimate (95% CI) | Telerehab group FU Effect estimate (95% CI) | Time*group 4 weeks Effect estimate (95% CI) | Time*group FU Effect estimate (95% CI) | P value Time*group |
|---|---|---|---|---|---|---|---|---|
| **NGA subtest naming** | | | | | | | | |
| Telerehabilitation group | 38.9 (13.7) | 47.3 (18.9) | 50.4 (22.4) | 8.7 (5.4 – 12.1) | 11.7 (7.4 – 16.1) | - 2.9 (-7.8 – 1.9) | -1.9 (-8.2 – 4.3) | 0.489 |
| Control group | 45.0 (17.6) | 50.2 (23.3) | 54.1 (24.9) | | | | | |
| **NGA subtest repetition** | | | | | | | | |
| Telerehabilitation group | 41.4 (21.2) | 47.2 (22.6) | 53.0 (25.8) | 7.3 (3.9 – 10.6) | 13.5 (8.6 – 18.4) | -2.6 (-7.5 – 2.3) | -8.9 (-16.1 – 1.8) | **0.026** |
| Control group | 52.7 (24.4) | 58.6 (25.2) | 58.4 (23.4) | | | | | |
| **NGA subtest comprehension** | | | | | | | | |
| Telerehabilitation group | 47.6 (19.8) | 59.3 (23.3) | 61.0 (24.0) | 11.5 (7.6 – 15.3) | 13.5 (7.9 – 19.1) | -4.2 (-9.8 – 1.4) | -4.0 (-12.1 – 4.1) | 0.332 |
| Control group | 52.8 (24.0) | 59.2 (28.5) | 61.5 (29.5) | | | | | |
| **VAST intransitive verbs** | | | | | | | | |
| Telerehabilitation group | 4.2 (3.2) | 6.0 (3.5) | 6.8 (3.2) | 1.8 (1.1 – 2.6) | 2.5 (1.7 – 3.3) | -1.8 (-2.9 – -0.8) | -1.8 (-2.9 – -0.6) | **0.004** |
| Control group | 5.3 (3.2) | 5.3 (3.4) | 6.1 (3.4) | | | | | |
| **VAST transitive verbs** | | | | | | | | |
| Telerehabilitation group | 3.4 (3.0) | 4.8 (3.7) | 5.8 (3.4) | 1.3 (0.7 – 1.9) | 2.2 (1.5 – 2.9) | -1.2 (-2.1 – -0.3) | -1.2 (2.2 – -0.3) | **0.017** |
| Control group | 4.4 (3.7) | 4.6 (3.9) | 5.4 (3.8) | | | | | |
| **VAST total score** | | | | | | | | |
| Telerehabilitation group | 7.5 (6.0) | 10.7 (6.9) | 12.5 (6.4) | 3.1 (2.0 – 4.3) | 4.6 (3.3 – 6.0) | -3.0 (-4.7 – -1.4) | -3.0 (-4.8 – -1.1) | **0.002** |
| Control group | 9.7 (6.7) | 9.9 (7.2) | 11.5 (7.0) | | | | | |

NGA = Norwegian Basic Aphasia Assessment

VAST= Verb and Sentence Test, subtest sentence production

FU= Follow-up assessment

Table 5: Results of language outcomes Communicative Effectiveness Index by the independent t-test.

| Outcome variable | 4 weeks assessment, mean, SD (n) | 4 months assessment, mean, SD (n) | 4 weeks Mean difference (95% CI) | 4 months Mean difference (95% CI) | P value 4 weeks assessment | P value 4 months assessment |
|---|---|---|---|---|---|---|
| **Communicative Effectiveness Index** | | | | | | |
| Telerehabilitation group | 53.9, 19.4 (28) | 61.3, 19.0 (24) | 3.2 (-8.8 – 15.3) | -0.03 (-12.2 – 12.1) | 0.592 | 0.996 |
| Control group | 57.2, 24.2 (25) | 61.3, 21.9 (22) | | | | |

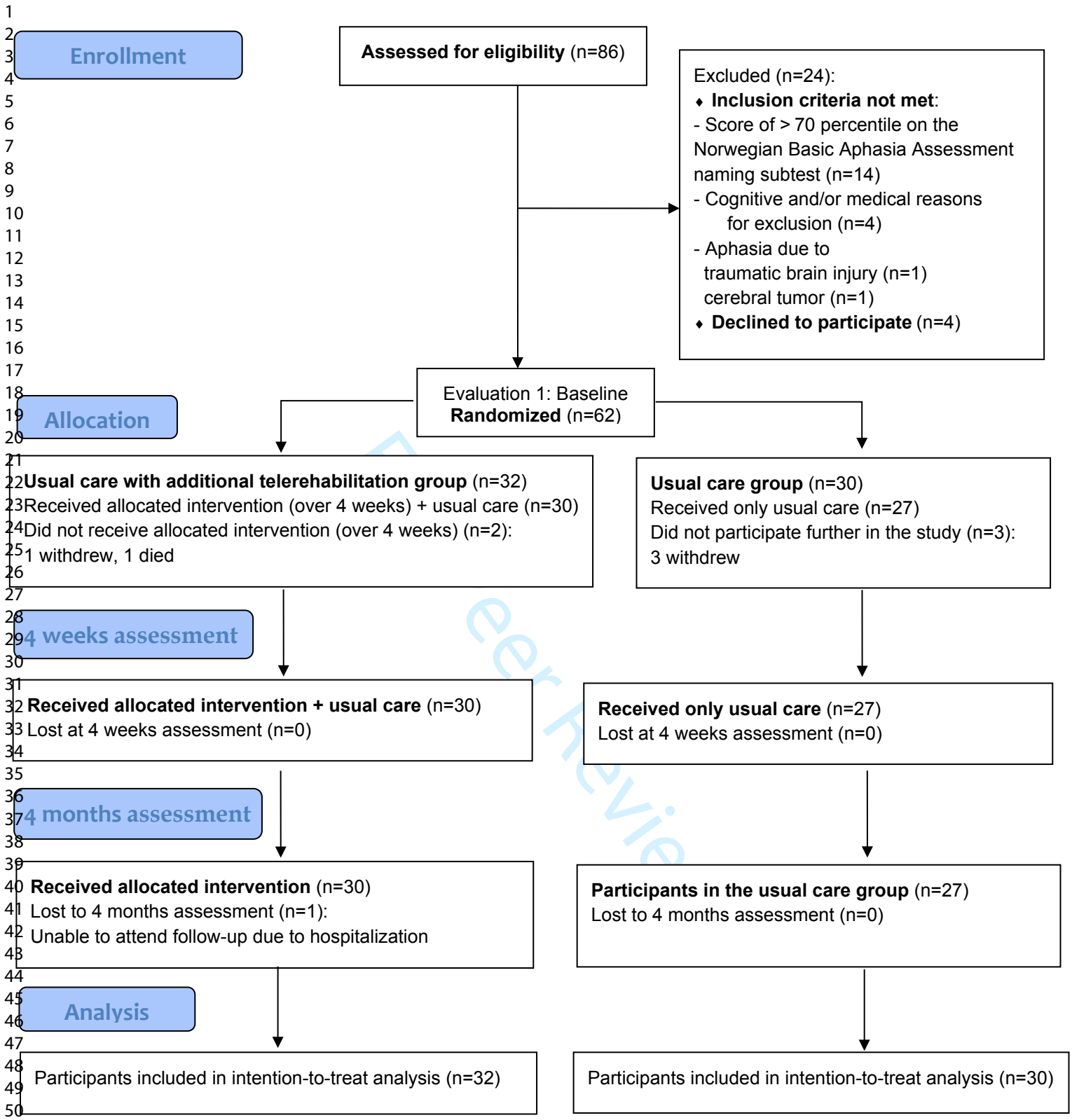


Figure 1: The CONSORT Flow Diagram

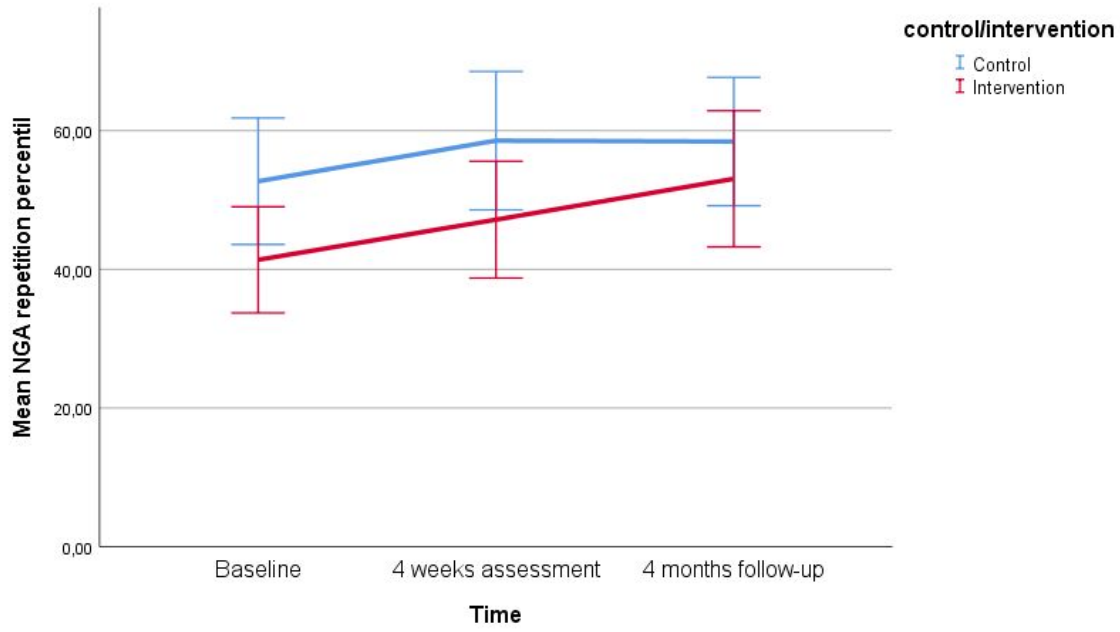


**Figure 2:** Multiple Line Mean of NGA repetition percentile by Time by control/intervention

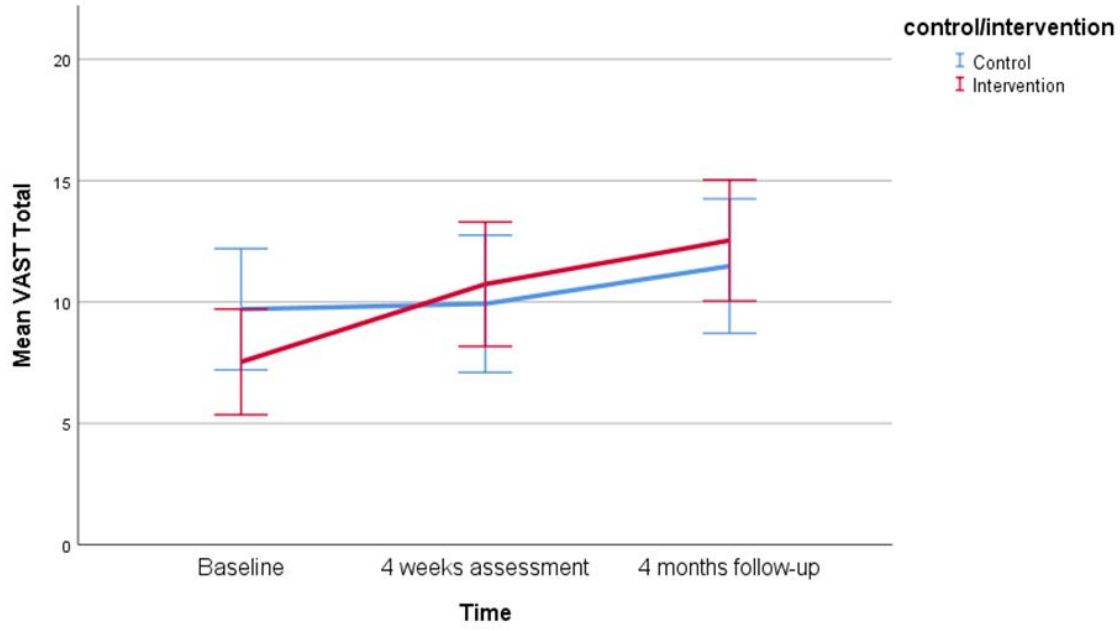


**Figure 3:** Multiple Line Mean of VAST Total by Time by control/intervention

# CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

| Section/Topic | Item No | Checklist item | Reported on page No |
|---|---|---|---|
| **Title and abstract** | | | |
| | 1a | Identification as a pilot or feasibility randomised trial in the title | 1 |
| | 1b | Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials) | 2 |
| **Introduction** | | | |
| Background and objectives | 2a | Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial | 3-4 |
| | 2b | Specific objectives or research questions for pilot trial | 4 |
| **Methods** | | | |
| Trial design | 3a | Description of pilot trial design (such as parallel, factorial) including allocation ratio | 4 |
| | 3b | Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons | 18 |
| Participants | 4a | Eligibility criteria for participants | 5 |
| | 4b | Settings and locations where the data were collected | 4-5 |
| | 4c | How participants were identified and consented | 5 |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | 6-8 |
| Outcomes | 6a | Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed | 8-10 |
| | 6b | Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons | NA |
| | 6c | If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial | NA |
| Sample size | 7a | Rationale for numbers in the pilot trial | 5, In protocol article. |
| | 7b | When applicable, explanation of any interim analyses and stopping guidelines | NA |
| Randomisation: | | | |
| Sequence generation | 8a | Method used to generate the random allocation sequence | 6 |
| | 8b | Type of randomisation(s); details of any restriction (such as blocking and block size) | 6 |
| Allocation concealment mechanism | 9 | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned | 6 |

| | | | |
|---|---|---|---|
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | 5,6 |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | 6,8, |
| | 11b | If relevant, description of the similarity of interventions | NA |
| Statistical methods | 12 | Methods used to address each pilot trial objective whether qualitative or quantitative | 10-11 |
| **Results** | | | |
| Participant flow (a diagram is strongly recommended) | 13a | For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective | 11, CONSORT flow diagram |
| | 13b | For each group, losses and exclusions after randomisation, together with reasons | CONSORT flow diagram |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up | 4 |
| | 14b | Why the pilot trial ended or was stopped | NA |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group | Table 1 |
| Numbers analysed | 16 | For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group | CONSORT flow diagram |
| Outcomes and estimation | 17 | For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group | Table 4, Table 5 |
| Ancillary analyses | 18 | Results of any other analyses performed that could be used to inform the future definitive trial | Table 2 and 3, 14 |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | 12 |
| | 19a | If relevant, other important unintended consequences | NA |
| **Discussion** | | | |
| Limitations | 20 | Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility | 15-16 |
| Generalisability | 21 | Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies | 16-18 |
| Interpretation | 22 | Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence | 15-19 |
| | 22a | Implications for progression from pilot to future definitive trial, including any proposed amendments | 19 |
| **Other information** | | | |
| Registration | 23 | Registration number for pilot trial and name of trial registry | 4 |
| Protocol | 24 | Where the pilot trial protocol can be accessed, if available | Published in Trials. |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders | 20 |
| | 26 | Ethical approval or approval by research review committee, confirmed with reference number | 4 |

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.
*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

**Supplementary table 1**: Main features of the intervention

**Table 1** The intervention illustrated by main features from the Template for intervention Description and Replication (TIDieR) Checklist and Guide

| |
|---|
| *Brief name:* Intensive speech and language therapy by videoconference |
| *Why:* To improve expressive language function in patients with aphasia after stroke |
| *What:* Intensive speech and language therapy with an emphasis on naming. The therapy will be tailored to the participant's language impairment level and focus on expressive language and everyday communication. Material used in the training will include the Newcastle University Aphasia Therapy Resources (NUMA), a collection of SLP-made tasks for aphasia compiled as *Sareptas afasikrukke* and Lexia (computer-based training program). In addition, text and pictures from the Internet may also be used |
| *Who provided:* Speech and language pathologists sited at Sunnaas Rehabilitation Hospital. Speech-language pathologists (SLPs) will receive training in how to give intervention by videoconference within the context of a clinical trial |
| *How:* Using videoconference and remote control software to a laptop at the patient's location |
| *Where:* From Sunnaas Rehabilitation Hospital to the patient's home or institution, e.g., rehabilitation ward or nursing home |
| *When/How much:* The experimental intervention consists of 5 h of speech and language therapy a week, over 4 weeks (total dose of 20 h of therapy). Participants with ≥ 16 sessions over 32 days will be considered to be per protocol |

Reproduced from: Øra et al. Trials (2018) 19:208
https://doi.org/10.1186/s13063-018-2588-5

Supplementary table 2: Results of language outcomes using linear mixed models analysis with covariates

| Outcome variable | Baseline, mean (SD) | 4 weeks assessment, mean (SD) | 4 months FU, mean (SD) | Telerehab group 4 weeks Effect estimate (95% CI) | Telerehab group FU Effect estimate (95% CI) | Time*group 4 weeks Effect estimate (95% CI) | Time*group FU Effect estimate (95% CI) | P value Time*group covariates |
|---|---|---|---|---|---|---|---|---|
| **NGA subtest naming** | | | | | | | | |
| Telerehabilitation group | 38.9 (13.7) | 47.3 (18.9) | 50.4 (22.4) | 8.7 (5.3 – 12.1) | 11.7 (7.3 – 16.0) | - 3.0 (-7.9 – 1.9) | -2.0 (-8.3 – 4.3) | 0.479 |
| Control group | 45.0 (17.6) | 50.2 (23.3) | 54.1 (24.9) | | | | | |
| **NGA subtest repetition** | | | | | | | | |
| Telerehabilitation group | 41.4 (21.2) | 47.2 (22.6) | 53.0 (25.8) | 7.3 (3.9 – 10.6) | 13.6 (8.7 – 18.5) | -2.6 (-7.5 – 2.3) | -9.1 (-16.2 – 1.9) | **0.023** |
| Control group | 52.7 (24.4) | 58.6 (25.2) | 58.4 (23.4) | | | | | |
| **NGA subtest comprehension** | | | | | | | | |
| Telerehabilitation group | 47.6 (19.8) | 59.3 (23.3) | 61.0 (24.0) | 11.5 (7.6 – 15.3) | 13.5 (7.9 – 19.1) | -4.2 (-9.8 – 1.4) | -4.0 (-12.0 – 4.1) | 0.324 |
| Control group | 52.8 (24.0) | 59.2 (28.5) | 61.5 (29.5) | | | | | |
| **VAST intransitive verbs** | | | | | | | | |
| Telerehabilitation group | 4.2 (3.2) | 6.0 (3.5) | 6.8 (3.2) | 1.8 (1.1 – 2.6) | 2.5 (1.7 – 3.3) | -1.8 (-2.9 – -0.8) | -1.8 (-2.9 – -0.6) | **0.004** |
| Control group | 5.3 (3.2) | 5.3 (3.4) | 6.1 (3.4) | | | | | |
| **VAST transitive verbs** | | | | | | | | |
| Telerehabilitation group | 3.4 (3.0) | 4.8 (3.7) | 5.8 (3.4) | 1.3 (0.7 – 1.9) | 2.2 (1.5 – 2.9) | -1.2 (-2.1 – -0.3) | -1.3 (2.2 – -0.3) | **0.017** |
| Control group | 4.4 (3.7) | 4.6 (3.9) | 5.4 (3.8) | | | | | |
| **VAST total score** | | | | | | | | |
| Telerehabilitation group | 7.5 (6.0) | 10.7 (6.9) | 12.5 (6.4) | 3.1 (2.0 – 4.3) | 4.6 (3.3 – 6.0) | -3.0 (-4.7 – -1.4) | -3.0 (-4.9 – -1.1) | **0.002** |
| Control group | 9.7 (6.7) | 9.9 (7.2) | 11.5 (7.0) | | | | | |

NGA = Norwegian Basic Aphasia Assessment

VAST= Verb and Sentence Test, subtest sentence production

FU= Follow-up assessment