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Attention control comparisons with SLT for people with aphasia following stroke: methodological concerns raised following a systematic review.

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Abstract

Objective: Attention control comparisons in trials of stroke rehabilitation require care to minimize the risk of comparison choice bias. We compared the similarities and differences in SLT and social support control interventions for people with aphasia.

Data sources: Trial data from the 2016 Cochrane systematic review of SLT for aphasia after stroke **Methods:** Direct and indirect comparisons between SLT, social support and no therapy controls. We double-data extracted intervention details using the template for intervention description and replication. Standardized mean differences and risk ratios (95% confidence intervals (CIs)) were calculated.

Results: Seven trials compared SLT with social support ($n = 447$). Interventions were matched in format, frequency, intensity, duration and dose. Procedures and materials were often shared across interventions. Social support providers received specialist training and support. Targeted language rehabilitation was only described in therapy interventions. Higher drop-out ($P = 0.005$, odds ratio (OR) 0.51, 95% CI 0.32–0.81) and non-adherence to social support interventions ($P < 0.00001$, OR 0.18, 95% CI 0.09–0.37) indicated an imbalance in completion rates increasing the risk of control comparison bias.

Conclusion: Distinctions between social support and therapy interventions were eroded. Theoretically based language rehabilitation was the remaining difference in therapy interventions. Social support is an important adjunct to formal language rehabilitation. Therapists should continue to enable those close to the person with aphasia to provide tailored communication support, functional language stimulation and opportunities to apply rehabilitation gains. Systematic group differences in completion rates is a design related risk of bias in outcomes observed.

Introduction

Rehabilitation of aphasia (the impairment of language after stroke or other neurological disorder) seeks to maximize an individual's return to communication activities and participation. In a recent Cochrane review,[1] SLT (SLT) interventions were found to benefit people with aphasia as evidenced by their performance on measures of functional communication and language impairment (language expression, reading and writing), when compared to people with no access to such therapy.[1] There was no clear evidence in the context of comparisons between SLT and social support attention control interventions.

Rigorous evaluation of rehabilitation interventions should be conducted in the context of a randomized comparison which might include randomization to a usual care group or an attention control group. Suitable control comparator groups ensure that intervention effects can be evaluated in isolation from other factors which might influence outcome, such as natural recovery, increased healthcare professional attention, benefits from trial participation and trial expectations.[2] For example, participants in stroke research have been found to receive better care than non-participating peers.[3] In the context of trials of SLT for aphasia after stroke, social support attention control comparisons have been advocated[4] given that no attention may be questionable on ethical grounds.

People with aphasia are at high risk of social isolation.[5,6] Social support is likely to benefit their well-being and quality of life which in turn could benefit their engagement with rehabilitation and social participation. Clinical psychology and psychotherapy researchers have highlighted the importance of social support, encouragement and a therapeutic relationship as active components of effective therapeutic interventions.[7,8] Regular social support shares some characteristics and benefits with specific therapeutic interventions. SLT, incorporating conversational practice, for people with aphasia is one such intervention. Social support has been found to be an unsuitable control comparator in evaluations of the effectiveness of communication based therapeutic interventions.[7,8]

Regular participation in social situations provides scheduled opportunities for practicing functionally relevant language use, a key outcome for most aphasia rehabilitation interventions. As social support interventions are inherently language based, such attention control interventions are not easily distinguished from more specific SLT interventions. Methodologically, it is important to preserve a clear distinction between trial group

interventions; otherwise, a trial may risk underestimating the effectiveness of an experimental intervention. Trials of other stroke rehabilitation interventions preserve this distinction. For example, in a recent review of physical rehabilitation interventions to improve function and mobility after stroke 12 of 96 trials included an attention control group.[9] The content of those control interventions ranged from upper limb therapy ($n = 6$ trials), cognitive training ($n = 4$ trials), massage ($n = 1$) and a socially based educational group ($n = 1$).[9] None offered an attention control intervention that facilitated the functional application or practice opportunities for the target activity, such as a volunteer-supported walk in the park, participation in a walking group or similar.

Our recent systematic review of SLT interventions for people with aphasia identified 57 randomized controlled trials that compared a speech and language intervention with another SLT intervention (36 trials; $n = 1242$) with no access to therapy (22 trials; $n = 1620$) or with social support (7 trials; $n = 447$) described by the trialists as an attention control.[1] In this article, we aim to (a) examine the similarities and differences in the SLT and social support attention control interventions compared within these randomized controlled trials; (b) present the evidence on the comparative effectiveness of SLT and social support interventions on language outcomes, intervention adherence and trial drop-outs using meta-analyses and indirect comparisons; (c) consider the relative acceptability and potential risk of bias in the use of social support interventions in trials of the clinical effectiveness of SLT for aphasia after stroke.

Methods

This analysis starts from a systematic review and meta-analysis of randomized controlled trials that evaluated SLT interventions designed to improve language or communication among adults with aphasia as a result of stroke and which were compared to social support interventions. Our review was conducted to agreed methodological and reporting standards[10,11] and is reported in detail elsewhere.[1] Briefly, we systematically searched several electronic databases including Central Register of Controlled Trials, MEDLINE, EMBASE, Cumulative Index to Nursing and Allied Health Literature, Allied and Complementary Medicine Database.

SLT interventions were defined as any form of targeted practice, tasks or methodologies which had the aim of improving language or communication abilities of people with aphasia, regardless of the individual delivering the intervention. Social support interventions were

defined as stimulating functionally relevant social language use in a naturalistic setting following an intervention regimen or schedule detailed within the trial protocol and often informed by a speech and language therapist's assessment or intervention manual but which did not include components that targeted specific aspects of language rehabilitation. Descriptions of complex non-pharmacological interventions are known to be insufficient.[12]

For this analysis, we extracted available information on the interventions from published papers, and we contacted the primary research teams to supplement data extraction. We used the Template for Intervention Description and Replication (TIDieR) to support systematic data extraction.[12] We then profiled the interventions using these headings to consider the similarity and differences between SLT and social support interventions. Data extraction was conducted independently by two review authors with a third resolving any disputes.

We conducted direct and indirect comparisons between SLT interventions with social support comparators and with no therapy controls. Outcomes of relevance included functional communication, receptive language, expressive language or aphasia severity. We also considered the number of participants that dropped out from the trials (during the interventions or at the outcome assessment time points and for any reason) and the extent of non-adherence to allocated interventions.[10] Where suitable statistical summary data were available, we combined the selected outcome data in pooled meta-analyses and indirect comparisons. Where a single outcome measure was assessed across trials which used different measurement tools (thus producing indirectly comparable data), we were unable to assume a common treatment effect and combined the data using standardized mean differences. For binary outcomes (attrition data), we combined the data using relative risk ratios.

Pooled effect sizes for SLT versus no SLT and SLT versus social support were calculated from random effects meta-analyses using the DerSimonian and Laird[13] method. Effect sizes for social support versus no SLT were then estimated based on Bucher et al'.s[14] method for adjusted indirect comparisons. In these analyses, standardized mean differences (with Hedge's adjusted g to correct small sample bias[15]) were used for aphasia outcomes. Risk ratios were used to compare drop-out and non-adherence rates. Where randomized participants were at risk of being included twice in a single meta-analysis, we split the number of participants in the shared group across the two trials.[10] For continuous data, the mean and standard deviation values remained the same. For dichotomous data, we split both the number of events and total number of patients. We assessed heterogeneity using the I^2 statistic, where values of greater

than 50% indicated substantial heterogeneity. To address potential heterogeneity, we used random effects models to pool the data and the source of any substantial heterogeneity was investigated.

Results

Intervention description – SLT versus social support

We included seven trials ($n = 447$ randomized participants) that compared SLT with a social support intervention.[16–22] Two were three armed trials[16,22]; thus, there were nine randomized comparisons. (Table 1). One was a cross-over trial where we extracted data up to the point of intervention crossover.[18] We found no evidence of a difference between the groups as measured on functional (activity and participation) or language outcome measures. However, more participants dropped out ($n = 65$ for any reason) or failed to adhere ($n = 45$) to the social support interventions than those that were allocated to SLT ($n = 40$ drop-outs, $P = 0.005$; $n = 11$ non-adherence, $P < 0.00001$). Thus, social support interventions may have been less acceptable to the participants than targeted language intervention.[23] Below we consider the two interventions on the data items from the TIDieR checklist[12] (Table 2 and Supplementary Table 1).

Why. Social support interventions were almost exclusively described by trialists as an intervention to control for the effects of social contact, encouragement to communicate and attention within the trial ('attention control',[16,21] control for 'attention effect'[17] or 'control the effects of social contact',[19] 'control sessions'[20]) (See Supplementary Table 1). One described active ingredients within the intervention which was 'stimulation-orientated, designed to provide psychological support and work on communication in unstructured settings'.[22] In contrast, where described, the SLT interventions sought to facilitate language recovery (Supplementary Table 1).16,18–22

What. Most social support interventions aimed to encourage and stimulate conversation facilitated by the intervention provider. One trial specifically encouraged a participant-led social interaction[21] where participants regularly took part in a local class or group activity of their choice which was not detailed in the trial report.[19] Three described providing psychological support or building a rapport with participants.[21,22] Those providing social support had access to a manual of suitable conversation topics,[18,21] a conversational support strategy handbook,[16] information on participants' aphasia,[17,22] assessment scores and support

requirements.[17] One trial employed a formal narrative re-telling task[20] while social support participation in other trials involved the creative arts,[19,21] listening to music, watching television, reading, playing approved board games or gardening.[21] The specific materials were rarely reported (Supplementary Table 1).

In contrast, SLT interventions were usually defined and detailed in the protocol.[16,19–22] Where described, the therapy included targeted stimulation of specific language structures and skills[21] including comprehension[18,19,22] and expressive skills[16,18–20,22] including reading and writing.[18,22] Two SLT interventions were left to the therapists' discretion (Supplementary Table 1).[17,18] Intervention fidelity monitoring was described in six trials[21,22] where three monitored a percentage of the overall sessions.16,17

Who. Where reported, social support was provided by volunteers, psychologists, nurses, researchers, community-based facilitators or SLT students (Table 2). In six trials, the social support providers were trained in the delivery of the intervention,[16–18,20–22] had information on the participants' aphasia,[17,22] their formal aphasia assessment scores and communication support needs,[17] a manual supporting the intervention.[16–21] Participants across groups were similar except for one trial[17] where those that received SLT were significantly older than those that received social support (Table 1). SLT was typically provided by professionally qualified speech and language therapists except for in two trials, one where it was delivered by a trained researcher,[20] and one where therapy delivered by the therapist was augmented by additional input from a family member (Table 1).[19]

How. The model of intervention delivery was similar. Most social support and therapy interventions were provided on a one-to-one and faceto-face basis. In two cases, both interventions were provided at group level[19] or via a computer interface (Table 2).[16]

Where. Social support and formal therapy interventions were, where reported, usually provided in similar settings. One trial provided social support in 'unstructured settings'[22] while the location of the comparison therapy group was unreported. Another provided social support at home while formal therapy was provided in clinic with home practice (Table 2).[16]

When and how much. Most intervention comparisons were matched for frequency (sessions weekly), intensity (hours of intervention weekly), duration (overall length of intervention) and dose (total hours of intervention delivered) (Table 2). Interventions were provided during two

to four sessions, for 2–3 hours weekly, over 1–12 months. Intervention dose ranged from 8 to 156 hours. In one trial, the social support weekly (minimum of 3 hours) and total dose (52 hours) of intervention was less than the SLT comparison (5 hours and up to 160 hours)[19] (Table 2). In another, it was difficult to compare weekly frequency and intensity but the average dose and total duration of social support (15 hours over 16 weeks) was similar to SLT provision (18 hours over 16 weeks).[21]

Effects of interventions

Statistical data which permitted inclusion within speech and language versus social support meta-analyses were available for five trials[16–18,20,21] (Table 3). Suitable outcome data were unavailable for the remaining trials.[19,22] In three instances where data permitted pooled meta-analysis, there was no evidence of a difference between the groups' performance on functional communication or auditory comprehension. One small trial ($n = 18$)[18] reported that the participants that received social support gained significant benefit on measures of general receptive language, expressive language, writing, word fluency and aphasia severity (Table 3).

Based on data from five trials significantly more participants receiving social support dropped out of the trials during or at post-intervention assessments compared to the number lost to SLT interventions ($P = 0.012$, risk ratio 0.65, 95% confidence interval 0.46–0.91) (Table 4). None of the five trials employed an intention to treat analysis approach. An additional 13 people were excluded from the primary trials for failing to complete intervention protocols but their allocation was unclear and so they were not included in our analysis.[18] When we considered voluntary withdrawal (non-adherence to the intervention), the difference became more pronounced[17,19,21,22] ($P < 0.001$, risk ratio 0.24, 95% confidence interval 0.12–0.47) (Table 4). Four additional participants voluntary withdrew from the social support group because of 'volunteer problems'.[17]

Using the group summary data from the recently updated Cochrane review of SLT for aphasia after stroke,[1] we conducted direct and (for the first time) indirect comparisons using the language outcome data (functional communication, receptive and expressive speech and severity of aphasia). Our previous meta-analyses found that SLT was significantly more effective than no SLT.[1] We found some very weak evidence (based on one small trial $n = 18$) that participants receiving social support performed significantly better on some language

outcomes (writing, general receptive, expressive language and severity) than participants that received SLT (Table 3).

The novel indirect comparisons presented within this article found limited evidence to suggest that participants receiving social support interventions performed better on measures of writing, general expressive language and severity of aphasia compared to participants that received no therapy (Table 3). Heterogeneity was low. Similarly, we found no evidence of a difference in drop-out and non-adherence rates between social support groups and no therapy control groups. However, this may be due to the small sample sizes of included studies (Table 4).

Discussion

While SLT benefits people with aphasia compared to no intervention, our meta-analysis found no evidence of an impact on participant outcomes when direct SLT intervention was compared in a small number of trials (involving few participants) to a social support attention control. The significantly higher drop-out (differential drop-out) and non-adherence rates among participants randomly allocated to social support interventions compared to SLT is a potential source of bias which threatens the validity of the results and is a recognized source of concern.[24,25] Those participants that remained in the trial and completed the outcome assessments may have differed from those that dropped out. Evidence of such differences between the interventions raises questions about the acceptability and suitability of social support as a control comparison in randomized controlled trials of aphasia therapy.23,24

We found that the format, location, frequency and intensity (weekly) and overall duration and dose of social support and SLT interventions were matched across comparisons. Only one of seven trials ensured a differential dose between the comparisons.[19] Social support providers received training by a speech and language therapist prior to providing that support. Therapists also provided information on the patient's abilities and difficulties following assessment, training, support and materials to the providers of social support. Interventional procedures and materials developed and supplied by the therapy research team were also shared across interventions in some trials.

In contrast, targeted rehabilitation of specific language structures (informed by patient preference or assessment findings) and a clear language recovery goal were only described in speech and language interventions. The extent of the similarities observed between the SLT and social support interventions however have diluted any distinction between targeted rehabilitation activities and a planned attention control intervention. Indirect comparisons highlighted some significant differences in outcome measures between participants in social support activities and those that received no SLT, but the data were generally based on small sample sizes and a small number of trials.

Previous systematic reviews in this field have tended to focus on the effectiveness of therapy interventions with limited attention given to the processes followed in the comparator groups.[26–29] Our systematic consideration of both the experimental therapy intervention and the social support attention control comparisons highlighted important clinical and methodological issues.

The important contribution a therapeutic relationship makes to supporting, encouraging and motivating patients within the rehabilitation context is generally accepted.[30] Regular social support may well include some of the active elements of this therapeutic dynamic. Psychological support, naturalistic feedback on success or failure of communication, self-monitoring of communication performance, engagement in social activity and networks, demonstration of good conversational models and conversational practice[11] are also present in social support interventions. Regular provision of such support is likely to increase well-being, benefit mood, provide motivation and encourage continued effort among a patient group known to be socially isolated as a consequence of their aphasia.[5,6]

Regular use of language within a social situation also has the potential to improve functional communication skills through regular conversational practice and naturalistic feedback. Given these benefits, speech and language therapists should ensure that their rehabilitation intervention programme proactively engages and builds the capacity of others in the patient's social circle (volunteers, family members and friends) to provide enhanced social support after stroke related aphasia. This in turn augments the provision of social support beyond what can be provided directly by the therapist. When social support is delivered alongside targeted language rehabilitation it may address the differential drop-out and non-adherence rates observed within trials (which suggest that social support interventions offered as an alternative

to therapy maybe unacceptable to people with aphasia). Social support has a role within the rehabilitation and recovery of people with aphasia[4] providing functionally relevant opportunities to put into practice gains made during targeted language rehabilitation activities.

From a methodological perspective, the distinction between SLT and social support interventions within these trials has been eroded particularly given that the components of social support are seen as essential elements in SLT. The distinctions between the interventions were few making it more difficult to establish the effectiveness of those isolated intervention components and increasing the risk of comparison choice bias. Protecting trials from such biases which introduce a consistent tendency for the estimate of effect to differ from the true value is essential to high-quality trial design and is particularly challenging when focusing on improving communication. In the context of SLT trials, comparison with an active concurrent control of usual care or another experimental SLT approach would be more acceptable (and is more typical of stroke rehabilitation effectiveness trials in other fields).[9]

Active controls in the context of aphasia rehabilitation may differ in the delivery model (professional therapist vs. volunteer)[31] or theoretical approach (semantic vs. phonological).[32] Concurrent regimen-controlled interventions might include those that vary in terms of intensity, duration or dose of therapy delivered.[33,34] Control group interventions may be specifically designed to complement a specific rehabilitation intervention, for example, self-directed computerized SLT therapy compared to self-directed computer-based non-language cognitive tasks.[35,36] Such comparisons would ensure that participants across both arms share exposure to the trial processes (i.e. receive the same attention from the trial staff in assessments, follow-ups, information) but interventions should remain clearly differentiated.

Conclusion

Interventions that provide social support were used as attention control comparisons in trials of SLT for aphasia after stroke. The interventions shared numerous similarities and were matched in frequency, intensity, duration, dose and delivery. In several cases social support provider training, support, information, intervention materials and manuals were informed by speech and language therapists. Social support interventions may have been unacceptable to participants with aphasia within trials of therapy effectiveness; however, as part of a comprehensive language rehabilitation programme, social support is an important adjunct.

Therapists are well placed to enable others in the individual's social circle to provide tailored, support and functional language stimulation opportunities for the person with aphasia.

Clinical Messages

- Social support and SLT interventions shared many characteristics.
- Social support is integral to SLT for aphasia. Therapists work with others to optimize social support approaches, thus extending therapy.
- More people stopped participating in social support interventions than SLT making it a poor comparator in evaluations of therapy effectiveness

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