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Fidelity to a motivational interviewing intervention for those with post-stroke aphasia: A small scale feasibility study

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- 1 Fidelity to a motivational interviewing intervention for those with post-
- 2 stroke aphasia: A small scale feasibility study

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- 4 Abstract
- 5 Objective: Depression after stroke is common, and talk-based psychological therapies can be a useful
- 6 intervention. Whilst a third of stroke survivors will experience communication difficulties impeding
- 7 participation in talk-based therapies, little guidance exists to guide delivery for those with aphasia.
- 8 We need to understand how to adapt talk-based therapies in the presence of aphasia. This study
- 9 aimed to explore the feasibility of motivational interviewing (MI) in people with post-stroke aphasia.
- 10 Methods: In a small-scale feasibility study, consecutive patients admitted to an acute stroke ward
- were screened for eligibility. People with moderate to severe aphasia were eligible. Those
- consenting received an intervention consisting of up to eight MI sessions delivered twice per week
- over four weeks. Sessions were modified using aids and adaptations for aphasia. Session quality was
- measured using the Motivational Interviewing Skills Code (MISC) to assess MI fidelity.
- 15 Results: Three consenting patients identified early post-stroke took part; one male and two females
- ages ranging between 40s to 80s. Participants attended between five to eight MI sessions over four
- 17 weeks. Aids and adaptations included visual cues, rating scales and modified reflections
- incorporating verbal and non-verbal behaviours. Sessions were tailored to individual participant
- 19 need. Threshold MISC ratings could be achieved for all participants however, ratings were reduced
- when aids and adaptations were not used.
- 21 Discussion: This small-scale feasibility study suggests that it is feasible to adapt MI for people with
- 22 moderate to severe post-stroke aphasia. These findings merit further exploration of adapted MI as
- 23 an intervention for this patient group.
- 24 Key words: Stroke; Stroke survivors; Aphasia; Motivational interviewing; Feasibility studies.

Introduction

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Stroke recovery requires emotional adjustment, and depression post-stroke is common, with a third of stroke survivors experiencing symptoms [1]. Post-stroke depression is an independent predictor of recovery and quality of life [2], therefore early prevention and treatment is vital. A review of interventions for preventing depression post-stroke found psychotherapeutic interventions to be more effective than pharmacological [3]. However, talk-based therapies may need adjusting for those post-stroke, who can suffer from cognitive or communication difficulties. Whilst a third of stroke survivors will experience communication difficulties [4] impeding participation in talk-based therapies, little guidance exists on delivery in people with aphasia. We need to understand how to adapt talk-based therapies in the presence of aphasia. Motivational interviewing (MI) is a talk-based therapy that has been shown to benefit patient mood post-stroke [5]. MI principles were used to increase awareness of the importance of changing what people make of their situation (adjustment), through amplifying the discrepancy between their current concerns and future goals or personal values and current approaches to addressing them. By reducing ambivalence and strengthening motivation, therapists explore a person's reason for changing what they make of their situation. Confidence to adjust to their current state is reinforced through supporting self-efficacy, enabling the person to develop motivation, and creating readiness to adjust [6]. Specific MI consistent techniques allow delivery of these principles; asking open questions, reflecting statements, providing affirmations and summarising. MI inconsistent techniques include, confronting people or giving advice without permission. Whilst data from this study seemed to indicate a particular benefit for those with mild aphasia [5], it is unclear whether it is possible in those with moderate to severe aphasia. Furthermore, if the delivery of MI needs adjustments, it is not known whether an adapted form of MI can maintain core MI principles. MI has previously been adapted for other populations including learning disabilities [7]. A pilot study of people with learning disabilities and alcohol dependency who experienced communication difficulties, incorporated adaptations including reading aloud materials for those unable to read, and providing regular summaries of topics discussed. Visual analogue scales were used to rate the importance of, or confidence in, a topic; an MI strategy usually discussed verbally. These aids and adaptations improved patients' understanding. While the delivery of MI with people with learning difficulties may differ to those experiencing post-stroke aphasia, some adaptations used may be useful post-stroke.

More widely, methods to facilitate the participation of people with communication difficulties in research has involved using words and/or pictures to visualise information [8], incorporating non-verbal behaviour, simplifying questions, supporting comprehension and expression, checking that participants have been understood correctly [9] and training communication partners [10]. Aids and adaptations can facilitate communication for people who may struggle verbally, making it possible for people with aphasia to participate in a talk-based therapy. To date, despite data suggesting a potential benefit of MI to people with aphasia post-stroke [5], no study has explored the feasibility of how to adapt MI for this group.

A systematic review of interventions to prevent and treat depression in those with post-stroke aphasia [11] found various interventions that could be considered for those with sub-threshold to mild depression. However, the review highlighted a need to strengthen the evidence base and adapt preventative and treatment interventions. In order to do this, trials must be reported in a way that allows study replication and comparisons [11, 12]. However when adapting talk-based therapies, it is important that the adapted intervention maintains fidelity to the core principles of the therapy. Treatment fidelity builds confidence that changes to the dependent variable are attributable to the independent variable, in this case the talk-based therapy. This can be measured using various factors (design, training, delivery, receipt and enactment) [12].

This small-scale study aimed to explore the feasibility of delivering MI to people with moderate to severe post-stroke aphasia. This was achieved through two objectives, i) documenting the aids and

adaptations utilised, and ii) observing how the utilisation of aids and adaptations affects MI fidelity.

The study did not explore the impact of MI on mood outcomes.

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Methods

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Ethical approval was granted (August 2012) from National Research Ethics Service: North-West – Preston. The feasibility study was nested within a larger study, performed on an acute stroke unit (ASU). The larger study explored delivering MI in patients with no or mild communication difficulties post-stroke and not those with moderate to severe aphasia. Consecutive people with suspected stroke admitted to the ASU May-December 2013 were screened for eligibility. People were eligible if: aged 18 or over; diagnosis of stroke; medically stable; moderate to severe aphasia based on the Communication Observational Assessment Tool, (COAT) [13], capable of consent; and living within the hospital catchment. Patients were ineligible if they were receiving psychological input (receiving treatment from a psychology professional) or had no verbal expression. Patients with mild communication difficulties were excluded but would have been eligible for the larger study. Formal screening for communication ability was not standard practice on the ASU. To screen for the study, an observational tool was required which was i) non-invasive to the patient, ii) for clinical team use, and iii) able to categorise communication ability through routine observations. The COAT was used (See Appendix 1), based on Speech and Language Therapist (SLT) guidance allowing clinical staff (therapy or nursing) to screen to rate communication using five levels (none/ mild/ moderate/ moderately severe/ severe communication difficulties). Purposive sampling was utilised to recruit patients with a range of communication abilities. We aimed to select 6-12 people across the three communication levels (Severe/ Moderately severe/ Moderate), with equal numbers from each. People meeting eligibility criteria were approached by the stroke research nurse or research assistant. Aphasia-friendly study information and consent

forms (Appendices 2 and 3) were provided, based on guidance [14,15]. Consent was taken by the stroke research nurse, with written informed consent provided, or witnessed consent for those unable to write.

Participant demographic and stroke details were recorded. Baseline measures of functional dependence (Barthel, [16]),communication and mood were completed. Communication was assessed using the Frenchay Aphasia Screening Test (FAST, [17]) and the Comprehensive Aphasia Test (CAT, [18]), the results of which guided the choice of aids and adaptations to tailor communication and MI delivery. Mood was measured using two participant self-report tools, the DISCS [19] and Yale [20] with a score of 2 or more and 1 respectively indicating low mood. Where possible, carer-rated mood measures were administered using the Stroke Aphasic Depression Questionnaire-10 [21] and Signs of Depression Scale [22], with cut-points of 14 and 2 respectively indicating low mood.

Intervention design

Participants received up to eight sessions of MI, two half-hour sessions per week for four weeks.

Session duration and frequency were adapted from the four one-hour sessions in the original trial of MI in stroke [5] to lessen the cognitive demand and fatigue from engaging in MI. Sessions were video and audio-recorded, allowing therapists to later reflect on the session, prepare for the next session, and monitor consistency of technique. MI sessions were delivered by the same therapist, in hospital or at home according to participant choice post-discharge. Post-intervention, participants received usual care.

MI therapists

Three Therapy Assistants (TAs) from the ASU multi-disciplinary team received training covering: stroke foundations, core research principles, theoretical background to MI and the psychological mechanisms that effect change, and practical MI training, delivered by MI therapists from the original MI post-stroke trial [5], who also provided supervision. The training lasted one day per week for nine weeks, including independent learning sessions. This was followed by a minimum of ten

practice MI sessions with volunteers. Therapists delivered MI with patients with no or mild communication difficulties post-stroke, until confidence and threshold competency were achieved, assessed with the MI Treatment Integrity (MITI) Code [23]. Therapists were provided with an intervention manual, allowing them to monitor their delivery and increase the likelihood that the intervention was delivered as intended.

Aids and adaptations

Aids were physical prompts used to facilitate conversation, whilst adaptations were alterations to the delivery of spoken information. The aids utilised included a communication framework Talking Mats® [24] a simple low-tech method of facilitating communication; a set of cards each with a written word and a corresponding picture. Nine category cards provide a starter topic of conversation (domestic life, relationships, work and education, leisure, learning and thinking, ways of coping, communication, mobility, and self-care). For each category, an accompanying set of cards allows further exploration of each topic. Cards are used (thumbs up, thumbs down, unsure) to indicate response. People may include their own cards (e.g. picture of an activity or relative). The "ways of coping" cards reflecting different emotions, were used to respond to other category cards. Cards are moved around the mat to express thoughts on a topic. While Talking Mats® may not be suitable for all participants; it has previously been used successfully in people with post-stroke aphasia [25], and was a useful resource to initiate conversations. Ahead of MI sessions, a single Talking Mats® training session was provided by the researcher; however tailoring this to patient needs was guided by the SLT.

A second aid utilised was the visual rating scale (VRS); a vertical scale where participants rated a response from 0-10. This was used to establish the level of importance or confidence around an issue. Finally, a photo-book was used as a conversation starter, and pen and paper were available for participants or therapists to use as necessary.

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Data analysis

Video and audio footage were uploaded and synchronised in NVivo 10. Data were analysed to document the use of aids and adaptations, incorporating verbal and non-verbal information. Video footage was annotated and audio data was transcribed and coded. The MI Skills Code (MISC, Version 2.1, [26]) was used instead of the MITI to evaluate therapist MI competence and fidelity (MI consistency), participant behaviours (patient engagement), and the interaction between the two (therapist and patient collaboration), thus offering a more detailed analysis than the MITI as the latter two are not included in the MITI. The MISC was developed to analyse specific therapist behaviours, evaluating therapist adherence to MI principles (fidelity). Two aspects of MI delivery are assessed: Global ratings and individual utterances. Global ratings take a holistic view of MI sessions, establishing more broadly whether there is adherence to the 'spirit' of MI. MISC global ratings reflect MI spirit, empathy, acceptance, egalitarianism, genuineness and warmth. Scores range from 0-7 (higher scores indicating greater adherence) and provide an overview of MI principles demonstrated in each session. Global ratings allow evaluation of i) the therapist's performance, ii) the person's involvement, and iii) the collaboration between therapist and person. This indicates the therapeutic alliance established. Therapist's individual utterances are used to calculate the proportion of MI consistent responses. A second researcher independently coded half of the sessions for global MISC ratings to validate interpretation. To calculate the overall proportion of MI consistent utterances per session, each therapist utterance was coded as MI consistent (MICO) or MI inconsistent (MIIN). Therapist competence is established following MISC guidelines [26] which recommends minimum therapist proficiency levels to achieve 'expert' or 'threshold' scores (for experienced or novice therapists respectively). To reach threshold competency, therapists must achieve over five in global ratings and

175 80% MICO utterances. Expert level should achieve over six for global ratings and 90% MICO 176 utterances. 177 Results 178 179 Between May-December 2013, 201 patients with suspected stroke were screened for eligibility. 180 Eleven were eligible and three consented to participate. A summary of screening and recruitment 181 data is presented in Figure 1. 182 >>>Insert Figure 1 here<<< 183 Due to staff attrition, one therapist was the sole provider of MI to the study. The therapist divided 184 her time between her role as MI therapist and therapy assistant supporting SLT and dietetics stroke teams. The therapist had experience of working with people with aphasia utilising aspects of 185 186 supported conversation, however formal communication training was not provided. 187 188 Demographic information and baseline measures 189 190 191 Demographic information for the three participants is presented in Table 1. At baseline, participants 192 varied in level of aphasia, with participant 1 scoring considerably lower than other participants 2 on 193 all communication measures. Participants differed in functional ability, level of social support 194 (separated/married/widow), and post-stroke role change (working/social/family). No participant 195 screened as having low mood, as seen in Table 2. 196 >>Insert Table 1 here<< 197 Insert Table 2 here

Details of the MI intervention received are shown in Table 3. Participants began MI within 2-12 weeks post-stroke, attending between 5-7 sessions.

200 Insert Table 3 here

Aids and adaptations utilised in MI sessions

Aids and adaptations used to facilitate communication, incorporating both verbal and non-verbal information were identified. Talking Mats® was particularly useful for enabling open questions and, through moving the appropriate card on to the mat, the participant was able to respond without relying on verbal or written communication alone. Talking Mats® was introduced to all participants, however only the participant with severe aphasia utilised this aid frequently. Talking Mats® cards were supplemented with pictures relevant to the participant in order to illustrate an idea, for example, using a picture of a care home the participant had recently visited.

The VRS, although initially intended for use in establishing the participant's level of importance or confidence of an issue was also employed by participants to respond to open questions. For example, to demonstrate how they felt about staying in hospital (low for dislike, higher indicating positivity).

Each participants' photo-book showed key aspects of their life, including family, pets, or holidays.

The photo-book acted as a conversation starter for participant 1 in particular (severe aphasia),

prompting discussion of home life and family. The participant with moderately severe aphasia used
an aid of pen and paper, providing her with multiple routes to communicate.

SLT guidance included supportive conversation techniques, such as employing a slow pace of conversation, and allowing adequate time for participants' responses. The therapist also used aids to enhance the patient's understanding, including pointing to pictures or words that were being discussed to reinforce the message such as writing key words as they are discussed. Gesture was

used by both therapist and participants, providing multiple methods to convey the same information. MI adaptations involved using increased reflections, including reflections of non-verbal information e.g. information conveyed through gesture. Summaries allowed participants to maintain focus on the conversation whilst simultaneously providing an opportunity for the therapist to ensure they had understood the participant. Table 4 highlights the MI strategies used.

>>Insert Table 4 here<<

The impact of adaptations on MI fidelity

A second researcher independently coded half of the sessions for global MISC ratings to validate interpretation. Full agreement of ratings or a one-point difference was achieved for 93%. A two-point difference occurred in 7% of ratings, and each was discussed until a consensus was reached.

Therapist levels of MI fidelity varied across sessions from sub-threshold to expert level. This variation in MI fidelity was most prominent in sessions delivered with participant 1, who had severe aphasia.

A higher level of MI fidelity was applied with participants 2 and 3; with most sessions reaching expert level.

The MI ratings are displayed in Table 5. It was expected that the therapist should reach a minimum of threshold level (over five in global ratings / 80% MICO utterances) however for participant 1 (severe aphasia), therapist MI ratings varied from below threshold to expert level.

Participant 2 (moderately severe aphasia) therapist MISC ratings were good, with all sessions reaching threshold level and many sessions reaching expert level (over six for global ratings / 90% MICO utterances). Participant MISC ratings reached expert level for all sessions except one session which achieved threshold level indicating strong engagement.

Participant 3 (moderate aphasia) therapist MISC ratings for participant were also good, with the therapist reaching threshold level in all sessions, and some sessions reaching expert levels. All

patient MISC ratings reached expert level, indicating both therapist and participant were positively engaged with a strong therapeutic alliance.

248 >>Insert Table 5 here<<

To draw attention to the potential impact of aids and adaptations on the MI content, a summary of sessions with participant 1 (severe aphasia) is shown in Table 6.

>>Insert Table 6 here<<

Discussion

MI has previously been used to prevent depression post-stroke [5]; however, this is the first study to provide support for the feasibility of delivering MI adapted for those with moderate to severe post-stroke aphasia. While involving only a small number of participants, this study has demonstrated that when MI sessions were adapted to meet the needs of those with aphasia, MI principles and fidelity can be achieved. The MI therapist was able to reach threshold levels of MI fidelity, which was demonstrated through both MI consistent utterances and global ratings. Expert levels were achieved in some sessions, as is highlighted in Tables 4 and 5.

The therapist was able to maintain high levels of MI fidelity with participants with less severe aphasia (participants 2 and 3), however, struggled to maintain this level across sessions with participant 1 (severe aphasia). This is evident when comparing individual sessions for participant 1 (Table 5). Session 3 is the highest rated for MI consistency and spirit. The visual rating scale (VRS) was used 14 times, which may have facilitated 17 open questions. Closed questions were used 49 times; however, these are often required for people unable to provide more in-depth verbal responses. Therapist and participant MISC global ratings and overall MI fidelity both reached expert level, and MI inconsistent responses are low (n=3) indicating a successful session. In contrast, session 5 has a sub-threshold level of MI. The VRS was used five times, with only 2 open questions

facilitated, and 131 closed questions used. Ratings for participant engagement and collaboration are low, with a higher number of MI inconsistent responses (n=17). Aids and adaptations may have facilitated MI techniques, such as open questions and reflections, and consequently the delivery of MI. When aids and adaptations were not used, participants were limited in the information they could communicate. The therapist's ability to tailor sessions for participant 1 (severe aphasia) appeared to impact on MI fidelity as well as participant engagement. However, it may not be that the use of aids and adaptations were responsible for the change in the ability to maintain MI principles. Other factors, including changes in circumstance experienced may have impacted on sessions. The participants experienced varying degrees of life changes post-stroke, including level of physical disability, social support, role change, and consequently had different issues to adjust to. Participant 1, who had multiple significant changes following the stroke, may have been more challenging for the therapist to engage with, than those with fewer or less significant issues to adjust to. Previous MI trials were often limited by their lack of documentation to explain what intervention was delivered [27], reducing validity and replicability. In order to adequately demonstrate treatment fidelity [12, 27, 28] in this study, a range of issues were considered and documented, including: session number, duration and content; therapist background, training and support; MI delivery and adherence to MI principles. The accurate reporting of delivering adapted MI may be particularly important to ensure transparency of what intervention has truly been delivered. Failure to do so, particularly in MI trials, has been highlighted as problematic [29].

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The small number of participants limited the study, restricting our understanding of the impact of

adaptations and a more informative analysis may have been possible with participants with a

broader range of communication difficulties. A larger scale study may wish to investigate this

292	further, and may consider using multiple therapists to deliver MI to further our knowledge of the
293	impact of the therapist in this complex relationship.
294	The feasibility study indicates that the delivery of MI to those with post-stroke aphasia has potentia
295	for future development. This study has implications for talk-based therapies post-stroke, in
296	particular for those who may struggle to engage in standard talk-based therapies. Adapted MI could
297	offer a form of psychological support that is not currently delivered.
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299	Conflict of interest

None declared

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Table 1. Demographic information and baseline scores of communication, cognition and functional dependence

	Participant 1	Participant 2	Participant 3
Sex	Male	Female	Female
Age	44	65	87
Screening measure			
Level of communication difficulty (COAT)	Severe	Moderately	Moderate
		Severe	
Communication: FAST (max. 30)	1	23	16
CAT expression: Repetition	0/50, 0/74	27/50, 54/74	20/50, 38/74
Naming	0/29, 0/58	16/29, 29/58	13/29, 24/58
Reading	0/35, 0/70	26/35, 56/70	27/35, 54/70
Written Language	0/76	54/76	49/76
CAT Comprehension of written language	10/62	52/62	46/62
Comprehension of spoken language	15/66	52/66	56/66
CAT Cognitive screen	9/38	37/38	30/38
Functional dependence: Barthel (max 20)	4	20	19

^{*}COAT= Communication Observational Assessment Tool, FAST=Frenchay Aphasia Screening Test,

CAT=Comprehensive Aphasia Test,

Table 2. Baseline mood scores

Mood tool	Participant 1	Participant 2	Participant 3
Yale single-item	0	0	0
DISCs (max. 5)	0	1	1
SODS	Not available	1	1
SADQ-10	Not available	8	12

Yale single-item (cut-off 1), DISCs=Depression Intensity Scale Circles (cut-off 2), SODS=Signs Of Depression Scale (cut-off 2)), SADQ-10=Stroke Aphasic Depression Questionnaire-10 (cut-off 14).

Table 3. Details of Motivational Interviewing intervention received

	Participant 1	Participant 2	Participant 3
Number of MI sessions received	5	8	7
Time from stroke to first MI session (weeks)	12	2.5	4
Duration of intervention (weeks)	7	5	5
Length of sessions in minutes Mean (range)	21 (16-30)	23 (18-29)	29 (13-40)

Table 4. Session communication strategy and MISC code ratings

of	Median (range)						
	iviculari (range)	Median (range)	questions:	Median (range)	Median (range)	Median (range)	consistency**
sessions			Median (range)				(%)
							range
5	5 (2-14)	8 (2-17)	72 (49-131)	1 (0-7)	19 (10-28)	6 (2-12)	71-95
8	1.5 (0-6)	4.5 (3-12)	26 (18-78)	2 (0-7)	21 (10-26)	2 (0-8)	93-100
7	1 (0-4)	2.5 (0-8)	21.5 (6-28)	2.5 (1-9)	10 (3-14)	2.5 (0-8)	88-100
	5	5 5 (2-14) 8 1.5 (0-6)	5 5 (2-14) 8 (2-17) 8 1.5 (0-6) 4.5 (3-12)	5 5 (2-14) 8 (2-17) 72 (49-131) 8 1.5 (0-6) 4.5 (3-12) 26 (18-78)	5 5 (2-14) 8 (2-17) 72 (49-131) 1 (0-7) 8 1.5 (0-6) 4.5 (3-12) 26 (18-78) 2 (0-7)	5 5 (2-14) 8 (2-17) 72 (49-131) 1 (0-7) 19 (10-28) 8 1.5 (0-6) 4.5 (3-12) 26 (18-78) 2 (0-7) 21 (10-26)	5 5 (2-14) 8 (2-17) 72 (49-131) 1 (0-7) 19 (10-28) 6 (2-12) 8 1.5 (0-6) 4.5 (3-12) 26 (18-78) 2 (0-7) 21 (10-26) 2 (0-8)

^{**}MI consistent utterances scored 0-100%, with over 80% reaching threshold level and over 90% for expert level.

4 Table 5. Patient MISC and overall MI consistency ratings

Participant	Total no. of	Therapist MI spirit rating*:	Patient	Therapist & Patient	Overall MI consistency** (%)
	sessions	Median (range)	engagement rating*:	collaboration rating*:	(range)
			Median (range)	Median (range)	
1	5	4 (4-6)	6 (4-6)	5 (3-5)	71-95
2	8	6 (5-6)	6 (5-6)	5 (5-6)	93-100
3	7	5.5 (5-6)	6 (6-7)	5.5 (5-6)	88-100

^{5 *}Global ratings scored from 0-7, with scores over 5 reaching threshold level and over 6 for expert level

^{6 **}MI consistent utterances scored 0-100%, with over 80% reaching threshold level and over 90% for expert level.

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Table 6. Summary of aids and adaptations used and MI content of sessions with a person with severe aphasia

Sess.	Use of VRS	Use	Open	Closed	Reflections	Summaries	Therapist	Patient	Therapist &	MI	MI	Overall MI
		questions	questions			MI spirit rating*	engagement rating*	patient collaboration rating*	inconsistent responses ** %	consistent responses ** %	consistency ** %	
1	3	8	72	19	7	4	5	4	5	38	88	
2	7	13	59	18	0	4	6	5	5	44	90	
3	14	17	49	25	1	6	6	5	3	52	95	
4	2	5	99	10	0	4	6	5	15	37	71	
5	5	2	131	28	4	4	4	3	17	44	72	

⁹ Sess.= Sessions, VRS=Visual rating scale. * Global ratings scored from 0-7, with scores over 5 reaching threshold level and over 6 for expert level.**MI consistent utterances scored 0-100%, with over 80% reaching threshold level and over 90% for expert level.

13 Communication Observation Checklist (Please Tick One)

WS2	Please Tick		Please Tick
Level 1: No Observed Difficulties		Level 2: Mild Communication Problems -reduced verbal expression and fluency -speaks in sentences -may have occasional word finding difficulties -able to have a conversation -engages in turn taking	
WS3			
-may speak in phrases -may be able to use longer sentences -may have occasional word finding difficulties -sound substitution errors may occur		Level 4: Moderately Severe Aphasia -poor expression using only short phrases or single words	
Level 5: Severe Aphasia -unable to speak in phrases -severe word finding difficulties -reduced expression due to dysarthria only -someone who relies purely on gesture or a communication chart to communicate			

^{*}It should be noted that only categories 3-5 were relevant to the nested feasibility study, and levels 1 and 2

pertained to the larger scale study.

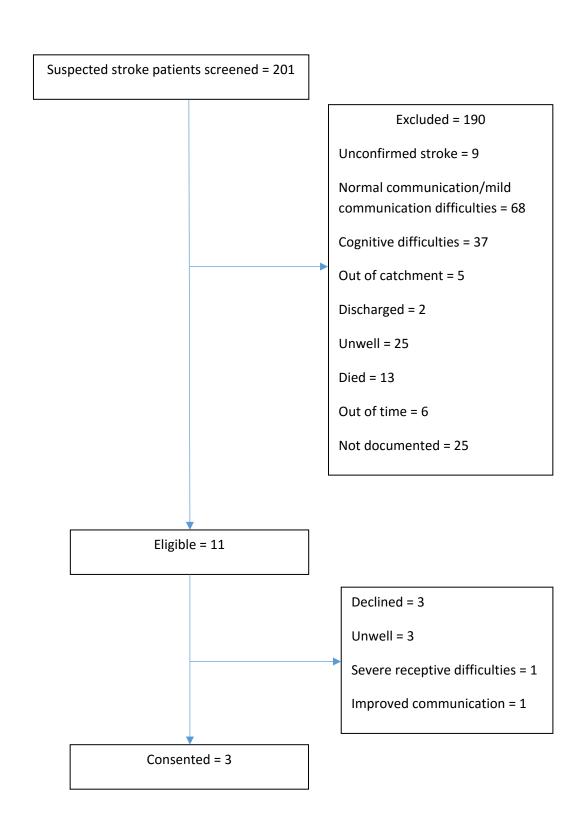


Figure 1: Screening and recruitment to the feasibility study