



City Research Online

City, University of London Institutional Repository

Citation: Pearl, G. & Cruice, M. (2017). Facilitating the involvement of people with aphasia in stroke research by developing communicatively accessible research resources. *Topics in Language Disorders*, 37(1), pp. 67-84. doi: 10.1097/tld.0000000000000112

This is the accepted version of the paper.

This version of the publication may differ from the final published version.

Permanent repository link: <https://openaccess.city.ac.uk/id/eprint/16006/>

Link to published version: <https://doi.org/10.1097/tld.0000000000000112>

Copyright: City Research Online aims to make research outputs of City, University of London available to a wider audience. Copyright and Moral Rights remain with the author(s) and/or copyright holders. URLs from City Research Online may be freely distributed and linked to.

Reuse: Copies of full items can be used for personal research or study, educational, or not-for-profit purposes without prior permission or charge. Provided that the authors, title and full bibliographic details are credited, a hyperlink and/or URL is given for the original metadata page and the content is not changed in any way.

City Research Online:

<http://openaccess.city.ac.uk/>

publications@city.ac.uk

Topics in Language Disorders

Title Page: Facilitating the involvement of people with aphasia in stroke research by developing communicatively accessible research resources

Gill Pearl MPhil and Dr Madeline Cruice PhD

Gill Pearl

Chief Executive

Speakeasy, Bury, United Kingdom.

Dr Madeline Cruice

Division of Language and Communication Science

City, The University of London

London, United Kingdom

Corresponding Author: Gill Pearl

1 Market Chambers, Ramsbottom, Bury, Lancashire, BL0 9AJ

gill@buryspeakeasy.org.uk

Acknowledgements:

National Institute for Health Research instigated, supported and funded this project.

ABSTRACT

People with aphasia can be marginalized by a communicatively inaccessible society. Compounding this problem, routinized exclusion from stroke research leads to bias in the evidence base and subsequent inequalities in service provision. Within the United Kingdom (UK), the National Institute of Health Research (NIHR) Stroke Research Network (SRN) identified this problem and funded a 6-month project in 2013-14 that resulted in the creation of practical and freely available resources to equip researchers to engage more people with aphasia in research. Critical elements enabled authentic co-construction of new knowledge regarding accessible research documentation including the process structure, timescale and crucially the fundamental engagement of people with aphasia. Stages in this process included mapping existing resources, engaging with researchers, and with people affected by aphasia, and developing a new set of resources comprising images, accessible text, and templates for research forms. These resulted in high quality outputs, as indicated by preliminary feedback from the research community and people with aphasia.

The voice of people with aphasia is vital to stroke research. Their involvement is key to its relevance, how it is run, and its reach. Simon Denegri, Director for Patients and the Public of the National Institute for Health Research (NIHR) and Chair, INVOLVE. These remarks are drawn from his introduction to the materials whose development is described in this article (see <http://cm.nihr.ac.uk/aphasia>). Denegri's full remarks are provided as Supplemental Digital Content.

BACKGROUND

People who have aphasia are frequently excluded from stroke research (Brady, Frederick & Williams, 2012). As highlighted by Brady and colleagues (2012), in a systematic review of 14 randomized controlled trials of information provision to stroke survivors and caregivers (Smith et al., 2008), only one of 14 studies included participants with aphasia; 10 studies excluded participants with aphasia; and 2 studies did not report their inclusion/ exclusion criteria. Furthermore, the majority of studies (71%) excluded participants with varying degrees of aphasia in a systematic review of depression screening after stroke (Townend, Brady, & McLaughlan, 2007), and some studies (10%) made no mention of the language status of their participants.

Exclusion of people with aphasia from stroke research occurs for a range of reasons, but it is often described as relating to 'poor person-environment fit.' That is, barriers arise due to the aphasic impairment within *the person*, and barriers arise due to the communication skills of the researcher, the (in)-accessibility of written research information, and the general research process, which collectively comprise *the environment*.

Aphasia is a communication disability due to an acquired impairment of language modalities caused by focal brain damage. The label, *aphasia*, is an umbrella term for a disability that affects comprehension and production of both spoken and written language. Speech and language therapists (SLTs¹) are acutely aware of the influence of aphasic language impairment on decision-making (Aldous, Tolmie, Worrall, & Ferguson, 2014). They typically use a range of formal and informal assessments of language and cognition to assist in decision-making capacity assessment requests in the clinical setting. However, SLTs' contributions are not fully recognized and not necessarily valued (Aldous et al., 2014); therefore, SLTs are not routinely involved in stroke research study design and conduct.

Typically, judgments regarding whether a person meets inclusion criteria in stroke research are determined by a range of aphasia screening or diagnostic tools (see Townend et al., 2007). The identification of participants with aphasia to invite into research studies is crucial, with significant implications. When Jayes and Palmer (2014) investigated research methods used by NIHR stroke research staff, they found that staff used a range of methods to identify participants with communication difficulties for their studies. These included talking to the participant, asking the participant questions to check understanding, consulting relatives and the multidisciplinary team, and reading medical notes, as well as seeking advice from SLTs and using communication or cognitive screening tools (Jayes & Palmer, 2014). Findings suggested further that some participants with communication difficulties were included in studies, possibly inappropriately, via assent when consent could

¹ Note that *speech and language therapist* (SLT) is the term used for speech-language pathologist in the United Kingdom.

(and should) have been sought, and other potentially eligible participants were never approached because of evident communication difficulties.

Overall, this suggests that clear guidelines for conducting research with such individuals are urgently needed to facilitate research staff to identify participants with communication difficulties and to consent them appropriately. It is the purpose of the current paper to contribute information about how to modify the linguistic and communication environment to enhance communication accessibility of research materials, including consent materials, making it possible for more people with aphasia to participate actively in research related to stroke.

Focus on Training Communication Partners

One component of the environment that has a significant impact on the communicative competence of a person with aphasia is the communication skills of others (Simmons-Mackie, Raymer, Armstrong, Holland, & Cherney, 2010). In general, people reveal their communicative competence through giving and receiving information, as well as through interacting with others during conversation (Kagan, 1995). Kagan observed, however, that people with aphasia, due to their reduced ability and opportunity to engage in conversation, may have less opportunity to reveal the competence they do have despite the stroke sequelae. She noted further that this problem may seem more of a barrier than it is when communication partners have difficulty acknowledging the competence of people with aphasia through their own lack of knowledge and skills.

When communicating with people with aphasia, communication partners have a greater responsibility in the partnership to modify their spoken and written communication to accommodate for the aphasic language impairment. This includes researchers. There is a substantial evidence base for communication partner training that demonstrates partners can be effectively trained to modify their communication skills, and this positively impacts on the engagement of the person with aphasia (Simmons-Mackie et al., 2010). In most cases, this training is undertaken in the clinical setting typically in dyads made up of the patient with aphasia and a family member. In this article, we suggest taking a broader systemic focus and thinking of researchers as communicative partners.

Prior research has demonstrated that training of communicative partners can achieve system-wide change when an entire multidisciplinary team receives training in different settings (Simmons-Mackie et al., 2007) or when all healthcare staff receive training within an organization (Jensen et al., 2015). To date, however, we are aware of no research that has focused on researchers' skills as communication partners, and this is arguably an area ready for investigation.

Focus on Modifying Other Resources

It has been established in earlier studies that challenges do still exist in achieving change (Simmons-Mackie et al. 2007), and addressing systems-level practices is key in ensuring any training transfers to everyday practice (Horton, Lane, & Shiggins, 2016). The provision and availability of resources also is known to be a key to successful change (Horton et al. 2016; Jensen et

al. 2015; Simmons-Mackie et al., 2007), which underpins the emphasis of the current project on resource development.

As a further component of modifying the environment to support communicative competence, written information is critical. In all research, written information plays a substantial role in facilitating or hindering access to participating in investigations. Regardless of the severity or type of the aphasic language impairment, people with aphasia frequently have some form of acquired alexia subsequent to stroke, leading them to experience difficulties with reading decoding and comprehension (Brookshire, Wilson, Nadeau, Rothi, & Kendall, 2014), which may manifest at all levels, including letter, word, sentence, and paragraph.

Within the field of health, research shows that printed education materials generally are not written at the level appropriate for people with aphasia (Aleligay, Worrall, & Rose, 2008; Rose, Worrall, Hickson, & Hoffmann, 2011). Using readability analyses conducted on print materials, researchers have found that authors of such materials need to reduce the length of sentences, minimize the use of complex sentences, and use more frequently occurring and highly imageable words (Aleligay et al., 2008). Although not all researchers agree, Aleligay and colleagues identified Flesch-Kincaid readability analysis as the analysis of preference. This technique has the added advantage of being easily available through Microsoft Word, meaning that authors can self-assess their written products.

A substantial body of evidence regarding written information, readability and aphasia exists in the work of Australian researchers Rose and colleagues,

which is summarized here. Although the focus of the research conducted by Rose and colleagues was on printed materials for educating people about stroke and aphasia, we submit that the principles and findings are transferable to research documentation.

First, in a small scale (N=12) experimental study manipulating text presentation using aphasia-friendly principles, Rose and colleagues (2003) found that people with mild to moderately severe aphasia comprehended 11.2% more information from aphasia-friendly formatted written information. A subsequent qualitative study (semi-structured interviews undertaken by a SLT) with 40 people with aphasia explored their perspectives of facilitators and barriers to reading educational print materials regarding stroke and aphasia (Rose et al., 2011). The researchers identified facilitators and barriers in both *content* characteristics (amount of text, amount of information, language, relevance) and *design* characteristics (typography, layout, emphasis, document type, color, graphics) preferred by the research participants who had aphasia. As examples, participants preferred sans serif font, bolding and italicizing of words to highlight key information, bulleting of key points, use of color, and language conveyed with short words, phrases, sentences and paragraphs (see Rose et al., 2011 for detail on facilitators). The same people with aphasia agreed to respond to a survey of their design preferences for comparison with existing recommendations for other clinical populations. Results revealed preferences for numbers expressed as numerals (not words), 14-point font, Verdana font, and 1.5 line spacing (Rose, Worrall, Hickson, & Hoffmann, 2012). Finally, a small-scale study (N=22 aphasia, N=15 significant others) showed that graphic illustrations provided no

statistical advantage in reading comprehension or reading time; however, people with aphasia reported needing the illustrations to aid understanding and that they preferred color photographs to black and white line drawings (Rose et al., 2011).

Similar findings have been noted by researchers from the Netherlands (Dalemans, Wade, van den Heuvel, & Witte, 2009), wherein people with aphasia reported the following strategies facilitated their participation: using large font, bolding the key concepts in questions, using pictograms, reducing the length of questions, placing one question per page, and presenting visual images of the answer/ possibilities in words and in pictures. The findings from these multiple studies demonstrate how written information can be adjusted to increase communication accessibility.

The Need for Accessible Information

In addition to the above-mentioned research evidence, there is substantial current emphasis on accessible information in England, including legislative emphasis culminating in the recent agreement and approval (in July 2015) of the Accessible Information Standard (<https://www.england.nhs.uk/ourwork/patients/accessibleinfo/>). The standard focuses on organizations in health and social care outlining how patients with disabilities need to receive information in formats appropriate to their needs, and have access to communication support. The standard involves identification of needs, documenting and communicating such needs and how they can be met, and ensuring people receive accessible information and communication support if needed. Detailed information about the standard is

available online, and illustrates a strong organizational and cultural move recognizing that good and effective communication is needed for good care. It is also needed for good research.

Difficulties understanding, reading and speaking, poorly skilled communication partners, and inaccessible written information clearly make engaging in research challenging for people with aphasia. Informed consent has many components, some of which are straightforward (e.g., right to refuse to consent without penalty) versus components that are extremely complex (e.g., the concept of clinical equipoise; Penn, Frankel, Watermeyer, & Mueller, 2009, which involves the ethics of assigning people to different arms of an intervention study when the researcher has reason to believe that one arm is likely to be more effective). Informed consent procedures are not consistently reported in published journal articles, and when they are, frequently the process is not presented in enough detail to judge its adequacy (Penn et al., 2009). When Penn and colleagues took a micro-lens perspective to the interaction between researcher and participant with aphasia being enrolled in a randomized controlled trial, they found that, despite good intentions, the process of gaining informed consent was fraught with difficulty. They also found that researcher strategies of pausing and verifying comprehension were the most effective (Penn et al., 2009). Based on their work, Penn et al. produced a conceptual model of the staged process of gaining informed consent. The model places considerable emphasis on the set-up/ pre-enrollment phase and highlights the role of a language specialist on the research team for process and informed consent. The model also includes the design of tailored informed consent materials. It is our contention that such a

model deserves broader discussion amongst clinical researchers, and we have used it to guide the project reported here.

Prior to describing our project, we emphasize that the condition of aphasia does not mean the individual is lacking in mental capacity to make decisions. Aphasia does not affect one's intelligence; however, if unsupported, aphasia can limit the extent to which an individual appears competent in daily life. In order to be judged as able to make a decision, an individual needs to be able to understand the information relevant to the decision, retain that information, use that information in the process of making a decision, and communicate that decision.

Thus, it is important that information is explained and presented in a way that is easy to understand (using simple language and visual aids), that different methods of communication have been explored (e.g., non-verbal), and that others who may help with communication have been involved, including a SLT (Mental Capacity Act Code of Practice, 2007, see p. 29). Whilst the Code of Practice does have general guidance on communication and specific guidance for individuals with communication and/or cognitive impairments (sections 3.10 and 3.11), there remains no provision of knowledge, skills, or tools needed by others, which includes researchers, to make information (spoken or written) accessible to facilitate this process (Jayes & Palmer, 2014). A clear implication of the study's findings is the need for ethically approved communication accessible resources (and training) to support stroke researchers (Jayes & Palmer, 2014).

Regarding implications for researchers, there is a marked risk that people with aphasia who agree to participate in research studies, do so without a full understanding (Penn et al., 2009). Researchers report a lack of skills or resources to assist with the process of including people with aphasia in their work (Jayes & Palmer, 2014). This is understandable as without knowledge, skills, and resources, it can be hard to engage people with communication difficulties in research conversations, whether these involve spoken or written language. This is challenging for researchers who need to have conversations with people as participants; or as part of the research process as a source of ideas, as consultants, steering group members, user groups or co-researchers. However, it is important that researchers distinguish between people who lack the capacity to consent or to be involved, and those whose competence is masked by the use of traditional methods of engaging or obtaining consent that do not accommodate their language skills. We agree with other researchers that more can be done to facilitate involvement of people with aphasia (Kagan & Kimelman, 1995; Penn et al., 2009; Rose et al., 2011), whilst recognising that some with more marked (severe) aphasia may still be unable to participate.

METHODS

Rationale and Goals for project

In designing this project, we had an intention to develop new resources and also share information about existing resources, which would equip researchers to involve more people with aphasia in research as participants and engage them fully as part of the research process. This included

resources for researchers with no pre-existing knowledge of aphasia. The impetus for this work arose not from the research literature but from staff working at the time within the NIHR Stroke Research Network (SRN, now part of the NIHR Clinical Research Network). At the time, stroke research in England was supported by the NIHR SRN in multiple ways. For example, staff at the NIHR collated information, supported clinical research study development, assisted studies through recruitment challenges, and provided support for patient and public involvement. During this process, staff observed that many stroke research studies did not include people with aphasia. This often happened as part of the research study exclusion criteria with aphasia as a named disability., It also happened by default through excluding people with 'communication problems' that would prevent them from engaging, or through exclusion at the consent stage of people who were unable to engage with the standard consent process.

The NIHR staff had concerns that this exclusion could damage the research, could affect recruitment into trials, and could affect the generalizability of results. Their discussions with researchers as part of their general NIHR duties and with aphasia specialists led to their conclusions that a significant number of researchers lacked the knowledge or easy access to appropriate resources to address these problems.

In response, the NIHR, Stroke Research Network's national coordinating centre agreed funding for a 6-month project to employ an experienced aphasia specialist with knowledge of the research process who could combine this experience and knowledge to oversee a project to completion. This provided an opportunity to reflect on where the challenges lay, and had

potential for the development of good quality aphasia specific resources to assist researchers in involving people with aphasia in their investigations.

Procedures

Consistent with its goals, this project invested heavily in involvement of people with aphasia to ensure that the resources produced were appropriate from their perspective as end users. The research literature on accessibility served as a starting point for the user group discussions. New resources were developed through a process of facilitated discussion for each aspect in fine detail. The final resources were evaluated by a small group of people with aphasia who differed from those involved in the initial user group.. The project method was constrained by the need to deliver the outputs within budget and within the relatively short timescale of six months. Aims of the project were to develop new resources, and in particular stroke and aphasia graphics specifically designed for this population.

Funding allowed for a full time project manager (first author). Additionally, the budget supported authentic engagement of people with aphasia and the employment of a graphics artist and computer technician. To ensure completion within the 6-month timeline, the project was conducted in the following six stages, which are detailed in the paragraphs below:

1. Identifying and mapping existing aphasia resources (months 1 and 2)
2. Engaging with stroke and aphasia researchers (months 1 and 2)
3. Establishing a user group (month 2)
4. Identifying preferences for resources (months 2 and 3)
5. Developing new images and associated text (month 3 – 6)

6. Designing online templates (outside the timescale of the original project)

Stage 1. Identifying and mapping existing aphasia resources

Because aphasia is not widely known and is often misunderstood amongst the general population (Code et al., 2016; Sherratt, 2011), we searched first for existing resources used by aphasia specialists. These included speech and language therapists, researchers with experience of aphasia research, and voluntary sector organisations. We contacted organizations and networks including NIHR researchers, universities, speech and language therapy training departments, and national and international aphasia alliances from the United Kingdom, Ireland, South Africa, New Zealand, Australia, Canada and the United States of America. We requested to view their resources or images, and enlisted their assistance in identifying other resources using their own contacts and networks. We also contacted other relevant organisations (e.g., those supporting people with learning disabilities) that used or had developed their own information accessible images in their publications or work, and that might also have had resources to enhance communication exchanges. This stage had international English-speaking reach and sought to identify and collate both examples of good practice, and also resources that could be used as building blocks for enhancing accessibility. Through this process, we identified 22 resources for consideration.

Stage 2. Engaging with stroke and aphasia researchers

Using loosely structured interviews (Skype, email, telephone) with researchers involved in stroke and/or aphasia research, we explored their concerns and personally perceived challenges of engaging people with aphasia. The discussions were semi-structured in order to identify what researchers knew about aphasia, their knowledge of making conversations and written material more accessible, how they currently included people in research, and what would help them to be more inclusive in future stroke research. The conversations confirmed that researchers lacked the skills and the resources to make their research more accessible. Researchers reported variations in ethics committees' responses to images and adapted text for people with aphasia in documentation; celebrated by one committee as a beacon of good practice and rejected by another committee as 'inappropriate'.

Stage 3. Establishing a user group

It was essential that the project involved those most expert in judging whether resources are accessible, and in being authentic, the project process had to role model accessibility and support for people with aphasia. We established an ethos of respect, recognising, revealing and valuing the competence of all group members in their role as experts. Potential threats to authentic collaboration (e.g. group dynamics, power relations) were identified and carefully considered. For example, we considered the pacing and support needed for discussions to allow those with more effortful communication to have their views heard, established a level ground for all participants (e.g. the form of address the same for all people at the meetings, removal of markers of achievements from the premises, and the sharing of hosting and

timekeeping duties). Attention to these aspects set the scene for maximum engagement working purposefully towards delivery of a quality resource.

Working within an established project timeline, with limited opportunity for lead-in time or training, we needed people with aphasia and carers who could quickly become involved, and who had experience of working to a timeframe and an existing brief. We met this challenge by working with people via existing relevant experience from within the membership of Speakeasy, a specialist aphasia charity. Based in the North West of England, Speakeasy provides long term support, therapy and opportunity for people with aphasia and their carers (www.buryspeakeasy.org.uk). In addition to the core work of the charity, members become involved in project work such as research advisory groups, translating research literature, public health information, and equipment instructions into an easy read or aphasia accessible format. As such, Speakeasy membership provided access to people with aphasia with expertise in improving readability of written materials, in training professionals to improve their communication skills and their practices, and in research. The consultation group comprised nine people with aphasia and a carer (spouse); the carer was included as they were often called upon in research to assist with the recruitment and consent process, and their views on resources was felt to be important. Previous experience demonstrated that a group of this size worked well allowing for absence (inevitable when the group members are living with often complex long term disabilities) yet still supported access to diverse opinions and good discussions. Members had: (1) personal experience of aphasia which affected the ability to read standard written information; (2) ability to contribute to group discussions with communication

support; and (3) previous experience of contributing to designing aphasia accessible resources, preferably within a research project. The group met in an appropriate and accessible community venue.

The project manager had considerable experience of facilitating many similar projects and discussion groups with people who have aphasia, and drew on this experience to inform the project. Speakeasy staff provided additional support for the process as required. We also used good practice guidelines for supporting user involvement (e.g., NIHR https://www.crn.nihr.ac.uk/wp-content/uploads/mentalhealth/UserCarerResearcherGuidelinesMay2014_FIN_AL.pdf and INVOLVE <http://www.invo.org.uk>), and developed them further for people with aphasia. This approach permeated all aspects of the group's work. Meetings were timed and structured with consideration for minimising fatigue, and agreement of and adherence to group meeting rules. (e.g. turn taking, use of strategies to assist with reducing memory load, revision and recap). Meeting processes were as accessible as possible, achieved using pre-prepared accessible PowerPoint presentations, creative use of flip charts, communication support resources, and trained staff with experience in providing communication support. Fourteen (14) user group meetings were held, lasting between three and four hours each, including refreshment breaks. Meetings initially focused on engaging with the project brief, establishing timelines, and agreeing on a realistic way forward. Subsequent meetings focused on the activities in stages four and five of the project.

Stage 4. Identifying preferences for resources

The user group identified existing materials varied considerably in style and quality. Members' comments and reactions were noted with attention to the overall look, the design, the degree of difficulty in understanding the content both without help initially, and when support was provided. This process assisted with identifying particular phrases, words or ways of presenting materials, which were unhelpful. Few projects or organisations had a corporate or professional style to their resources. Some materials adhered to aphasia accessible principles as identified in the literature and applied them albeit haphazardly (e.g., small amount of information per page on the participant information form, but not on the consent form). Some resources applied only a few of the principles (font size) whilst ignoring other principles (the need to use bold for highlighting rather than capitals and underlining). Some materials used images that were not helpful in assisting comprehension, were culturally inappropriate, or were considered childish.

People with aphasia find images helpful to aid comprehension of written materials (Rose et al., 2011). Specifically, graphics are considered to make information interesting; help with understanding, reading and remembering; make information easier and quicker to read; help orient to the topic; and add humour/ enjoyment (Rose et al., 2011). Often organisations had developed a distinctive style of images and graphics for use in their materials. In informal conversation with these organisations, it was clear that decisions about style were largely based upon convenience. Reasons included availability of an artist, personal connections, someone who would provide the service at a reasonable cost, or decisions made by an individual or small group of people with aphasia. This project presented an opportunity to identify a preference for

style based on a free choice and through seeking out the views of a wider group of people with aphasia. The group was instrumental in developing a new approach to graphics. Following considerable discussion and debate, the group identified three options (all in colour): photographs, line drawing/cartoons, and computer-generated graphics (pictures created using computers with help from specialised graphical software). The project manager and user group sought input from many people with aphasia (four local aphasia group visits, national and international survey), devising materials to communicate the request and options, and enable others to indicate their preference and record comments. There were 265 replies from people with aphasia, who preferred computer-generated images. Carers and professionals tended to prefer cartoon style images more. User feedback highlighted that computer-generated images could:

- depict internal medical shots without being too graphic (medical images were very difficult for some people to view particularly when it related to the brain and stroke)
- convey information that was medically accurate
- be appropriate for more than one meaning depending on the context
- show a range of people of different ages, gender or ethnicity without the need for separate images (those are meant to be “like me, but not me”)

Stage 5. Developing new images and associated text

A graphics designer was identified through a tendering process and invited to attend the group meeting to understand more about aphasia and to engage

more fully with the project brief. The group discussed how to identify the images most appropriate for supporting stroke research. They agreed that it was helpful to work around the story of a stroke, what causes it, the impact, the treatment and rehabilitation. Explanation of specific aspects such as the cause of stroke (ischemic or haemorrhagic stroke) would support researchers in explaining inclusion or exclusion criteria. Consequently, considerable time in the meetings was dedicated to writing the story with the most significant or prevalent aspects in an aphasia accessible style; the group considered this with great attention to detail towards supporting people with aphasia to understand. Support from PowerPoint technology was part of the process for making collective decisions in the group, via presenting information, getting feedback about accessibility and individuals' preferences, making alterations for further discussions, and continuing to refine the story of the stroke until together the group reached the decision that the text was accessible and unambiguous.

Using the stroke story, the group then identified the images required to support comprehension. With great attention, the group embarked on a process to design each image, and: (1) evaluated existing options for ideas using those sourced from the mapping process of the project and also the internet; and (2) posed or took photos using an iPad, reviewed and re-posed them as necessary. Group members became models for the photos alongside willing healthcare professionals and family members. In this way models were taken from the groups they are to represent where possible. The graphic artist 'drew' round the photos using appropriate software (Figure 1). The group then reviewed images and suggested alterations, and this process was repeated

as necessary. At a meeting later in the process, each image was revisited to check that it portrayed the correct meaning. This process also allowed for adjustments in such aspects as skin tone, body shape and gender specific features to make them more representative of the country. This process continued until there was consensus that each image was appropriate. Principles (e.g. white background) were applied to all images as relevant. Images were designed as a set with: (1) colour coding that assisted with enhancing meaning, specifically an item of clothing shaded in purple for people affected by a stroke (chosen to reflect the sole UK stroke organisation using a corporate/ professional theme) and orange for researchers; (2) the same style for each image; (3) reflecting a diverse population; and (4) multiple uses if possible without compromising meanings.

In addition to the stroke related images, people with aphasia need to be able to understand research concepts such as time, confidentiality, randomization, etc. The group explored options for appropriate graphics using the Internet and identifying which aspects of images were good and could be developed; the facilitation for this process required considerable creativity, using flip chart drawings with many revisions. From these, the graphics artist developed computerized images. Some concepts such as a Randomised Controlled Trial (Figure 2) and Transient Ischaemic Attack (Figure 3) were particularly complex and required many revisions. Images for internal shots (Figure 4) particularly of the brain were often difficult viewing for the group members; only one had a medical background, and others found some images extremely distressing thus clearly demonstrating the need for caution when selecting images for use with the general population. Simple changes made a

significant difference, for example, the graphic for showing the brain was much more acceptable when hair was added to the image showing a head with the top of the cranium removed to reveal the brain. At all times, the group considered whether a minor revision would allow for multiple uses to extend the options for researchers (Figure 5). This process produced over 200 images suitable for use with people who have aphasia and stroke. Finally, the stroke story and general research images were combined into one document in order to assist researchers to find the text and images they require (Figure 6).

Stage 6. Designing online templates

Designing aphasia accessible documents is generally a long process even with appropriate resources available. To assist researchers, the consultation group designed sample consent forms or templates. The same principles of options, comments, improvements and repeated revisions produced a consent template in a 'cut and paste' format. It included the essential elements for consent as required through the ethics process, and also additional optional elements (e.g. consent for taking and using photographs or videos). Other Speakeasy members were invited to comment at this stage to bring a fresh perspective, however few improvements were suggested and most were minor adjustments such as making the person in the image seem less miserable.

The project was completed to the given brief within the timeframe. However, discussions arising from the user group, project manager and NIHR staff identified that an extension to the work could considerably enhance the

resources and the support for researchers. Additional funding was provided to produce a range of templates for designing research literature; some of this stage was outside the original timeline. The templates were designed to offer flexibility for customising literature (Figure 7 and Figure 8), with a structure that automatically enhanced the accessibility, and in a wider range of forms suitable for all stages of the research process. They were built from the resources designed by the consultation group. This set of templates comprises: a Participant Information Form, Consent Form, Summary Reminder about the research project, Letter of Invitation to a meeting or assessment, and a Summary of the research findings. The project manager sent the prototype of the templates to various researchers for testing and feedback.

The Participant Information Form templates contain drop down menus for selecting from the phrases as listed in the stroke story with space for insertion of an appropriate image. Any open boxes for free text contained built-in constraints to ensure that text was the required font size and type, and that spacing and layout was appropriate. Due to restrictions in the available space on the NIHR website where the resources are stored, it was not possible to offer selection from the images in a searchable library; the images are instead available throughout the resources as part of the stroke story. These templates are linked together as part of a set. A project theme assists participants in recognising correspondence or information about a particular project. Any information inserted into one template is automatically populated into the others, for example, the photo and contact details for the researcher, and the research project title.

The final stage of the project required collation of the resources and information from the process by which the materials were created for inclusion on the NIHR website with open access. It included information to assist researchers with designing and planning for all stages of research projects that would include people with aphasia. This guidance was structured under the following headings:

- What is aphasia?
- Prepare yourself and the research team
- Cost implications for including people with aphasia in research
- Communication skills
- Better conversations with people who have aphasia
- Set the scene
- Help someone to understand
- Help someone to express themselves
- Writing for people with aphasia
- Using images

Mindful of not duplicating existing resources, there are links to other sources of help, both aphasia-specific and those of value from other related fields. Guidance includes ideas of how the resources can be complemented by other ways of presenting information. Hosting the information on the NIHR website

will reinforce why changes are necessary to better include people with aphasia in research, provide an increased knowledge of the issues around planning and preparation and development of new skills, and provide practical resources and ways in which these principles can be applied. The intention was to convince researchers of the need to make adjustments and to equip them to make adjustments in ways that had been endorsed by all the people with aphasia who contributed their comments, ideas and expertise during this project process. Finally, the project resources have been disseminated at stroke and aphasia events such as the United Kingdom Stroke Forum 2014 Conference (a coalition of 30 organisations), and through existing NIHR dissemination channels, specifically the Clinical Research Network: Stroke (<http://crn.nihr.ac.uk/aphasia>). They are freely available if the NIHR is credited in the research process.

DISCUSSION

This project represents the first step towards enabling people with post-stroke aphasia to participate more fully in stroke research. It involved the development of quality aphasia-specific resources for researchers to use in the initial research project process. These resources are much needed (Jayes & Palmer, 2014; Penn et al., 2009). The project manager members of the project team, research consultants with aphasia, and collaborators were committed to involving people with aphasia from the outset. They also pursued the common goal to ensure that resources were fit for purpose and acceptable for their intended audience.

On reflection, there are several questions that need consideration if people with aphasia are to participate fully in stroke research, which extend beyond this study. The first asks how to assist researchers to engage with these resources as a way towards a fundamental shift in attitude moving away from a tick box approach to inclusion. The templates, images, and text resources are only a starting point for researchers. The background for the need to make adjustments and principles for aphasia accessibility are summarized in the final project document providing researchers with a full rationale (<http://crn.nihr.ac.uk/aphasia>). These outputs from the project are not designed to stand-alone; rather, used collectively, they have potential to support the researcher into a deeper understanding to facilitate authentic involvement throughout all aspects of the research process. This would include making adjustments to address the influence of the inevitable inequality between researchers and participants.

The second question asks how to build aphasia involvement into the research framework from the start, including how to involve user groups and trial management committees, as well as how to design materials, timescales and funding issues. The third asks how researchers can use readily available and affordable guidance and training to enhance their own interpersonal communication skills so that people with aphasia are not excluded. The fourth and final question asks how we can support the development of skills amongst people with aphasia so that they can be fully and appropriately engaged as contributors to the research process.

In summary, this project represents organizational commitment from the NIHR in the United Kingdom, and it also reflects a systems-level change in the

development of resources for researchers for the purpose of benefiting the research community globally. However, it is only the beginning of a long-term process to make stroke research accessible to people with aphasia and thus representative of the wider stroke population. This project supports one component of the supported informed consent process for participants with aphasia (Penn et al. 2009). Nevertheless, further investigation of more components is needed to move the field forward.

Implications

Quality aphasia-specific resources are now available for stroke researchers to use in their project documentation and materials. These are freely available, with some significant degree of flexibility and customization. Anecdotal reports of use by researchers in the UK suggest the documentation is easy to follow, and materials are easy to produce. Some researchers may desire further experimental evidence of benefit before taking up these resources (see Future directions below). Nonetheless the project has demonstrated the substantial and valid role that people with aphasia can have as research consultants. It also has highlighted the value of integrally involving end-users who live with the condition in the development process when designing research.

Future directions

The project resources that resulted from this work can support researchers to include people with aphasia more effectively in their studies; however, there are several areas for future research and further development. Regarding research, experimental evaluation of the benefit of these resources is needed.

This includes investigating: (1) the value of these resources from the perspective of a much larger group of people with aphasia whether other people with aphasia (2) whether people with aphasia accept the resources (i.e., the increased length of materials does not detract from choosing or preferring the accessible version); (3) how to achieve a maximal gain in comprehension from accessible materials compared to standard materials; (4) whether participants with aphasia prefer accessible materials, with a subsequent gain in comprehension of the research study being considered; (5) whether stroke survivors without aphasia consider the accessible materials acceptable for use and achieve an equitable level of comprehension as would be achieved with standard materials, meaning the same materials could be used for all participants; and (6) whether the cost-benefit of creating accessible materials for local projects is justified.

Regarding further development, first, stroke research has a wide variety of foci, and the current images are limited to around 200. The production of additional graphics would support researchers on both more diverse stroke related topics and those related to different methodologies and designs (e.g., participant observation and ethnographical research). Second, research information has traditionally relied on written and paper-based explanations; however, when working with people who have aphasia, more interactive formats for delivery may support greater comprehension and engagement. Formats such as PowerPoint presentations, and audio and video formats are now more easily produced using features available as part of most standard computer systems. The addition of guidelines or templates for alternative formats would support creativity and variety as required when working with

people who have aphasia. Third, research instruments such as written questionnaires can be particularly problematic for people with aphasia; a summary of the processes to increase accessibility could complement the existing project resources to assist researchers. Finally, systemic changes are needed to increase adoption of new attitudes and methods. Researchers need to engage with, educate, and exert influence over decision makers such as research ethics committee members who may be unfamiliar with both aphasia and the need to make adjustments to research materials and processes.

The current resources could be enhanced by including the case for the necessary adjustments, and in due course, further research findings on their benefit. Future project work could aspire to influence early uptake in the research process. This might be achieved by targeting ethics committees and research funders, with the intention that both might elect and eventually mandate the use of these project resources as essential for all projects involving participants with aphasia.

Stroke research staff have identified further training needs regarding consenting participants with impaired communication, specifically training on communication techniques, strategies, tools, and aids; legislation; aphasia; communication assessments/ screening tools; and the development of information materials for participants (Jays & Palmer, 2014). More research is also needed into how speech and language therapists can contribute to the decision-making and informed consent process as currently their role and

contribution to the process is unclear (Aldous et al., 2014), although others argue that it is clear that there is a role for language specialists' involvement in this work (Mental Capacity Act 2005 Code of Practice, 2007; Penn et al., 2009).

CONCLUSION

This work adds to the evidence that complex information, including information related to aspects of the research process that are essential for obtaining informed consent, can be communicated in an accessible manner for people with aphasia. This increases the likelihood of enabling people with aphasia to have the right and means to engage in research that has a bearing on their lives. To achieve this outcome, we combined prior research evidence with the collective expertise of consultants with aphasia, the clinically experienced project manager, and a graphic designer to produce resources that are professional, transparent, and succinct in explaining research. The challenge now lies in evaluating the effectiveness of these resources in practice. If their effectiveness is supported, the next step will be to achieve widespread dissemination and uptake of these resources by the wider research community.

REFERENCES

Aldous, K., Tolmie, R., Worrall, L., Ferguson, A. (2014). Speech-language pathologists' contribution to the assessment of decision-making capacity in aphasia: A survey of common practices. *International Journal of Speech-Language Pathology*, 16(3), 231-241.

Aleligay, A., Worrall, L., & Rose, T. (2009). Readability of written health information provided to people with aphasia. *Aphasiology*, 22(4), 383-407.

Brady, M., A. Frederick, and B. Williams, People with aphasia: capacity to consent, research participation and intervention inequalities. *International Journal of Stroke*, 2012. 8: p. 193-196.

Brookshire, C., Wilson, J., Nadeau, S., Rothi, L., & Kendall, D. (2014). Frequency, nature and predictors of alexia in a convenience sample of individuals with chronic aphasia. *Aphasiology*, 28(12), 1464-1480.

Code, C., Papathasiou, I., Rubio-Bruno, S., de la Paz Cabana, M., Villanueva, M., Haalan-Johansen, L., Prizl-Jakovac, T., Leko, A., Zemva, N., Patterson, R., Berry, R., Rochon, E., Leonard, C., & Robert, A. (2016). International patterns of the public awareness of aphasia. *International Journal of Language and Communication Disorders*, 51(3), 276-284.

Dalemans, R., Wade, D., van den Heuvel, W., & Witte, L. (2009). Facilitating the participation of people with aphasia in research: A description of strategies. *Clinical Rehabilitation*, 23, 948-959.

Horton, S., Lane, K., & Shiggins, C. (2016). Supporting communication for people with aphasia in stroke rehabilitation: Transfer of training in a multidisciplinary stroke team. *Aphasiology*, 30(5), 629-656.

Jayes, M. & Palmer, R. (2014). Stroke research staff's experiences of taking consent from people with communication difficulties: Results of a national online survey. *Topics in Stroke Rehabilitation*, 21(5), 443-451.

Jensen, L., Lovholt, A., Sorensen, I., Bludnikow, A., Iversen, H., Hougaard, A., Mathiesen, L., & Forchhammer, H. (2015). Implementation of supported conversation for communication between nursing staff and in-hospital patients with aphasia. *Aphasiology*, 29(1), 57-80.

Kagan, A. (1995). Revealing the competence of aphasic adults through conversation: A challenge to health professionals. *Topics in Stroke Rehabilitation*, 2(1), 15-28.

Kagan, A. & Kimelman, M. (1995). Informed consent in aphasia research: Myth or reality? *Clinical Aphasiology*, 23, 65-75.

Mental Capacity Act 2005 Code of Practice. (2007). *Mental Capacity Act 2005 Code of Practice*. Crown Copyright. Accessed on 23 May 2016 from https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/497253/Mental-capacity-act-code-of-practice.pdf

Palmer, R. & Paterson, G. (2013). To what extent can people with communication difficulties contribute to health research? *Nurse Researcher*, 20(3), 12-16.

Penn, C., Frankel, T., Watermeyer, J., & Mueller, M. (2009). Informed consent and aphasia: Evidence of pitfalls in the process. *Aphasiology*, 23(1), 3-32.

Rose, T., Worrall, L., Hickson, L., & Hoffmann, T. (2011). Aphasia friendly written health information: Content and design characteristics. *International Journal of Speech-Language Pathology*, 14(4), 335-347.

Rose, T., Worrall, L., Hickson, L., & Hoffmann, T. (2011). Exploring the use of graphics in written health information for people with aphasia. *Aphasiology*, 25(12), 1579-1599.

Rose, T., Worrall, L., Hickson, L., & Hoffmann, T. (2012). Guiding principles for printed education materials: Design preferences for people with aphasia. *International Journal of Speech-Language Pathology*, 14(1), 11-23.

Rose, T., Worrall, L., & McKenna, K. (2003). The effectiveness of aphasia-friendly principles for printed health education materials for people with aphasia following stroke. *Aphasiology*, 17(10), 947-963.

Sherratt, S. (2011). Written media coverage of aphasia: A review. *Aphasiology*, 25(10), 1132-1152.

Simmons-Mackie, N., Kagan, A., O'Neill Christie, C., Huijbregts, M., McEwen, S., & Willems, J. (2007). Communicative access and decision making for people with aphasia: Implementing sustainable healthcare systems change. *Aphasiology*, 21(1), 39-66.

Simmons-Mackie, N., Raymer, A., Armstrong, E., Holland, A., & Cherney, L. (2010). Communication partner training in aphasia: A systematic review. *Archives of Physical Medicine and Rehabilitation*, 91(12), 1814-1837.

Smith, J., Forster, A., House, A., Knapp, P., Wright, J., & Young, J. (2008). Information provision for stroke patients and their caregivers. *Cochrane Database Systematic Reviews*, (2): CD001919.

Townend, E., Brady, M., & McLaughlan, K. (2007). Exclusion and inclusion criteria for people with aphasia in studies of depression following stroke: A systematic review and future recommendations. *Neuroepidemiology*, 29, 1-17.

Worrall, L., Rose, T., Howe, T., McKenna, K., & Hickson, L. (2007). Developing an evidence-base for accessibility for people with aphasia. *Aphasiology*, 21(1), 124-136.

Figure Legend

Figure 1. Photo and graphic pair

Figure 2. Graphic depiction of randomized controlled trial

Figure 3. Graphic depiction of Transient Ischemic Attack

Figure 4. Graphic depiction of an aneurysm/ weak blood vessels

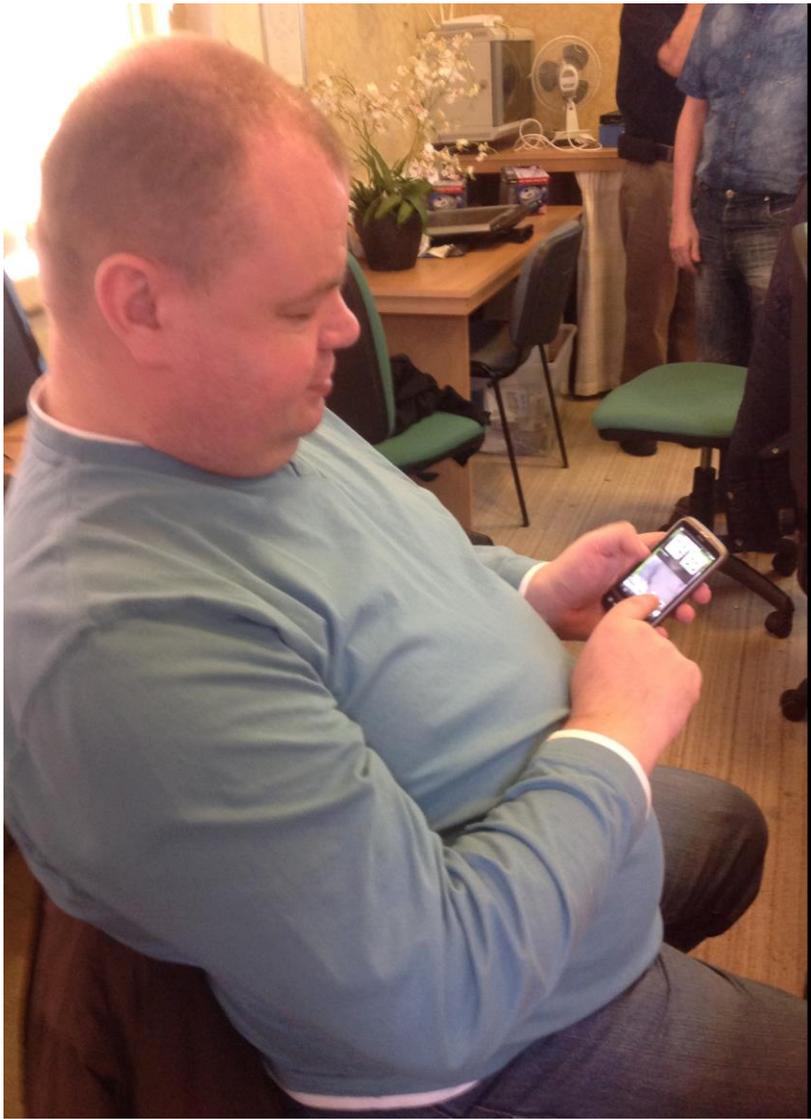
Figure 5. Graphic depiction of multiple uses image

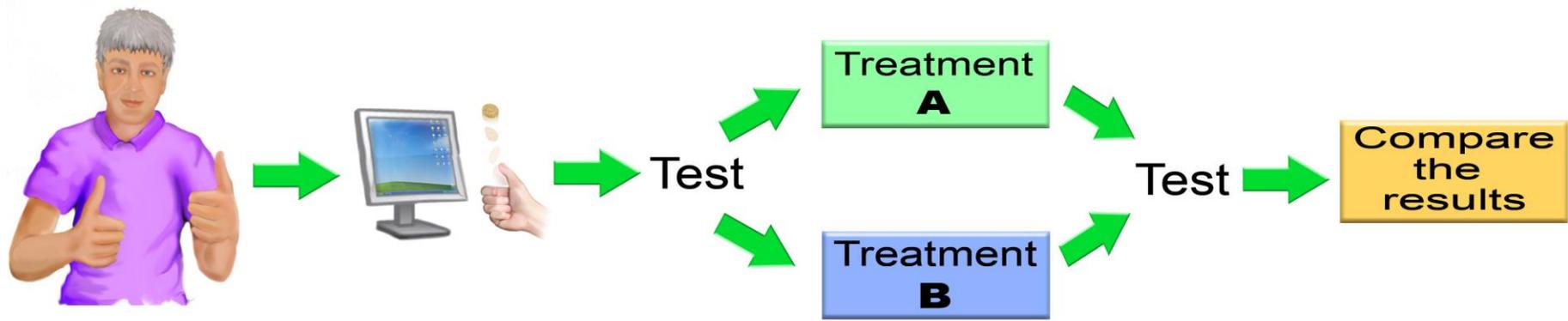
Figure 6. Snap shot of part of the stroke story with associated graphics

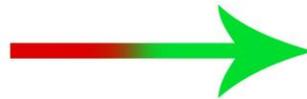
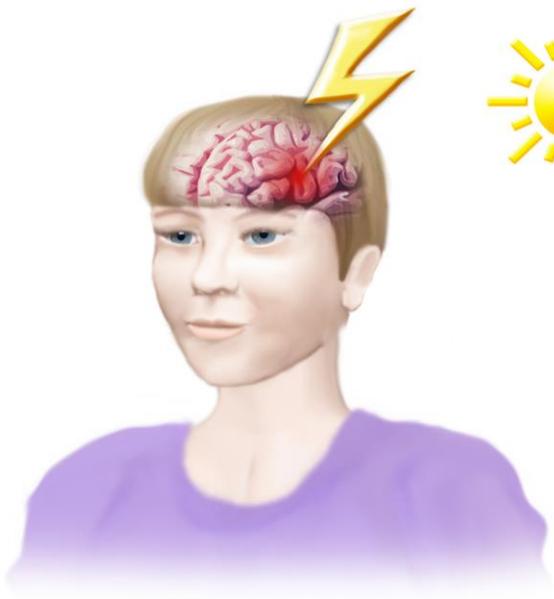
Figure 7. Drop down menu of items to customize a Consent Form

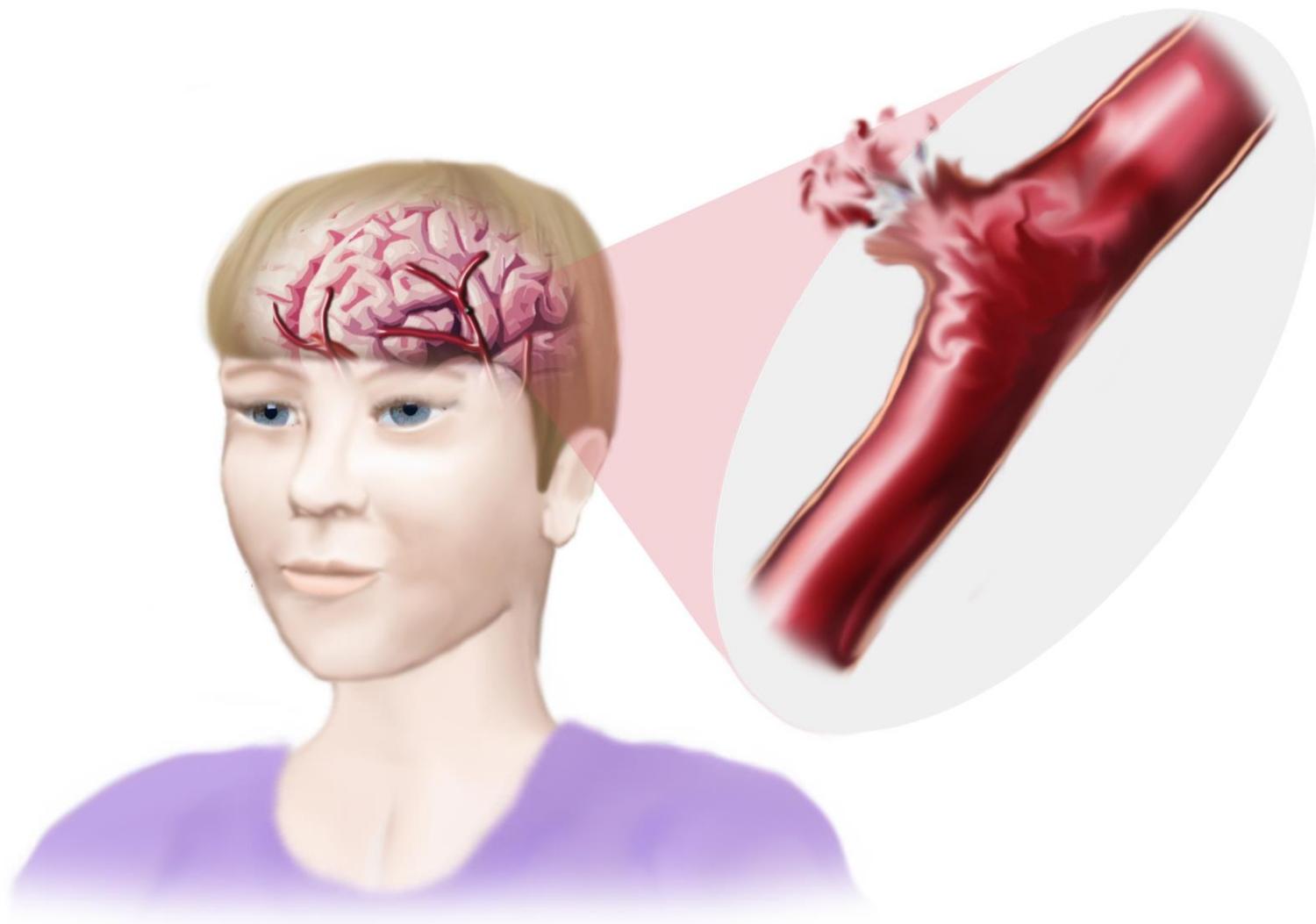
Figure 8. Resultant Consent Form created using drop down menu in Figure 7

All images are available free of charge but are the property of UK NIHR Clinical Research Network.













The therapists do **assessments**



They find out more about any difficulties



They plan for **therapy**



They **talk to** any **family**

They tell them about the **therapy**



They **teach** how to **help**



The therapy **plan** may have **exercises**

These should be **repeated often**



Therapists use **equipment** in **therapy**



They may give **equipment to use** all the time

Consent Form List [Add/Edit Consent Form Options](#)

⌘ Edit	Include	Description	Order
▶	<input checked="" type="checkbox"/>	I understand that my GP (doctor) will be told that I am taking part in research	10
	<input checked="" type="checkbox"/>	I understand that researchers will need information from my medical records	12
	<input checked="" type="checkbox"/>	I understand that the results may include what I said but not use my name	14
	<input checked="" type="checkbox"/>	I understand that I will need to have special tests for my writing	16
	<input type="checkbox"/>	I understand I will get information about these tests	18
	<input type="checkbox"/>	I understand that researchers may share my results with other researchers in this country	20
	<input type="checkbox"/>	I understand that researchers may share my results with researchers in other countries	22
	<input type="checkbox"/>	I understand that the researcher may take photographs	24
	<input type="checkbox"/>	I understand that researchers may use photographs of me when the results are shared	26
	<input type="checkbox"/>	I understand that the researcher may make sound recordings	28
	<input type="checkbox"/>	I understand that the researcher may make video recordings	30
	<input type="checkbox"/>	If I stop being in the research information already collected about me will still be used unless	32
	<input checked="" type="checkbox"/>	If I become unwell for any reason I may not be able to make decisions If this happens I would li	34

**Preview
Consent
Form**

Double-click the tick boxes above to add to or remove from the consent form. Click the "Edit" button on the left to edit the item.

Taking part in research about

Study Title Example

Study Description Example

Please mark   



I have read the information about the research

 
yes no



I have had the chance to ask questions about the research

 
yes no



I am happy with the answers to my questions

 
yes no



I understand that information about me will be kept safe

 
yes no



It will not be shared with anyone outside the research team

 
yes no



I understand that when results are shared the researcher will not use my name

 
yes no



I understand that I can stop being in the research at any time

 
yes no



If I stop I do not have to give a reason ...and I will still get my normal care

 
yes no

Continuing Education Questions

1. Previous research has found that people with aphasia prefer written information with the following design characteristics:
 - A. Digits, 14-point font, Times Roman font and double spacing
 - B. Digits, 14-point font, Verdana font and 1.5 line spacing
 - C. Digits, 16-point font, Verdana font and double spacing

2. Previous research has found that people with aphasia:
 - A. Statistically benefit from illustrations in terms of faster reading and prefer illustrations as they aid understanding
 - B. Do not statistically benefit from illustrations in terms of faster reading but prefer black and white line drawings
 - C. Do not statistically benefit from illustrations in terms of faster reading but prefer graphic illustrations as they aid understanding

3. Graphics are considered helpful for comprehension because they:
 - A. Substitute meaning for written words
 - B. Help orient the reader to the topic
 - C. Are more visually acceptable than written words

4. The 6-stage project outlined in this manuscript included the important stage of:
 - A. Establishing a user group of people with aphasia
 - B. Establishing a user group of speech language therapists
 - C. Extensive consultation to repurpose existing images

5. In addition to the resources, guidance was produced for researchers and included which of the following:
 - A. An explanation of aphasia, ideas on how to support cognitive impairments, and how to help someone express themselves
 - B. An explanation of aphasia, ideas on how to have better conversations with someone with aphasia, and the cost implications of including people with aphasia in research
 - C. Ideas on how to have better conversations, impact of cognition on reading, and how to help someone with aphasia understand

Supplemental Digital Content

Introduction to Materials to Support Participation of People with Aphasia in Research on Stroke

The voice of people with aphasia is vital to stroke research. Their involvement is key to its relevance, how it is run, and its reach. It can have a positive effect on their sense of personal wellbeing at a time of great personal challenge. It is often fulfilling for the researchers and health professionals who work with them. These resources (<http://crn.nihr.ac.uk/aphasia>), which have been developed in partnership with people with aphasia, aim to guide stroke researchers and give them the confidence to be inclusive in the way they work. They contain a wealth of helpful information as well as ready-to-use materials and links to other sources of advice. A resource like this does not in itself remove barriers to involvement. However, in the hands of the committed research team that is willing to put its contents into practice, I have no doubt it will. They must be supported in this commitment by those around them including people with aphasia and carers. Making research more inclusive of our diverse communities is one of the challenges of our times. This resource focuses on one particular group of people who have much to give to research. But, given the universality of many of its messages, I hope it will be picked up and used by colleagues in other areas of research as well.

Simon Denegri, National Director for Patients and the Public of the National Institute for Health Research (NIHR) in the United Kingdom and Chair, INVOLVE

Author Biographies

Gill Pearl MPhil. Dip Hum Commun. MRCSLT is a speech and language therapist currently the Chief Executive of a multi-award winning aphasia charity (Speakeasy). Following a Health Foundation Research Fellowship at Manchester University, Gill is a published researcher in volunteering for people with aphasia. Gill is a regular speaker and trainer at conventions on aphasia and has extensive links with the national and international aphasia community and is a founder of the UK Aphasia Alliance. She links with University departments, stroke, and research groups. In 2015, she received the International Robin Tavistock award for inspiration and making a significant difference for people living with aphasia.

Dr. Madeline Cruice is an experienced certified speech and language therapist (Bachelor of Speech Pathology Honours I, PhD, MRCSLT, FHEA) and Senior Lecturer in the Division of Language and Communication Science, City, The University of London, in the United Kingdom (UK). Dr. Cruice has published widely in the field of aphasia specifically in quality of life, teaches pre- and post-registration courses in aphasia, and is an Advisor on aphasia to The Stroke Association in the UK. She is the Lead for Working Group 5 Societal Impact and Reintegration Research, in the European-wide COST Action IS1208 Collaboration of Aphasia Trialists.