

**Enhancing the post-stroke patient experience
at mealtime through participatory design:
Eliciting, connecting and supporting multi-voicedness**

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Volume II

Appendices

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Appendices

Appendix A: The designing of the mealtime into daily practice with restaurateurs

This study was conducted with restaurateurs to obtain insights into the daily practice of designing the mealtime for a customer experience. By having restaurateurs participate in the research, I wanted to understand who has experience on what is designing for the customer experience at the mealtime, and what should be considered to deliver an enjoyable and pleasant mealtime experience?

I initially intended to collect a diversity of views from professionals working at different types of restaurants, for example, fast food and dining restaurants. However, contacting restaurants can be challenging due to the heavy demands on my time spent meeting them to discuss the study and receive their feedback and interest to take part in the research. For example, four restaurants were contacted in Glasgow but only two restaurateurs participated in the study. Both showed their interest in sharing their work experience related to the mealtime for customer experience. I conducted interviews focused on how restaurateurs create the mealtime for their customers' experiencing. In each interview, open-ended questions were prompted to create dialogues in order to explore the restaurateurs' views about designing.

A.1 Inviting restaurateurs

I started by making a list of restaurants and then I contacted them by email to present the study aims and inviting them to participate. Here I received their feedback on whether they were to participate or not and consequently a meeting was scheduled. Meeting restaurateurs was to explain and discuss issues about the study and, consequently, define a schedule to conduct the study. Later, we met to discuss the designing of the mealtime. The meeting before the interview was significant because it allowed me to personally express to the restaurateurs how I considered their participation to be significant to this study but also it allowed the restaurateur to get to know me. The preparation and planning took place over the period of three months.

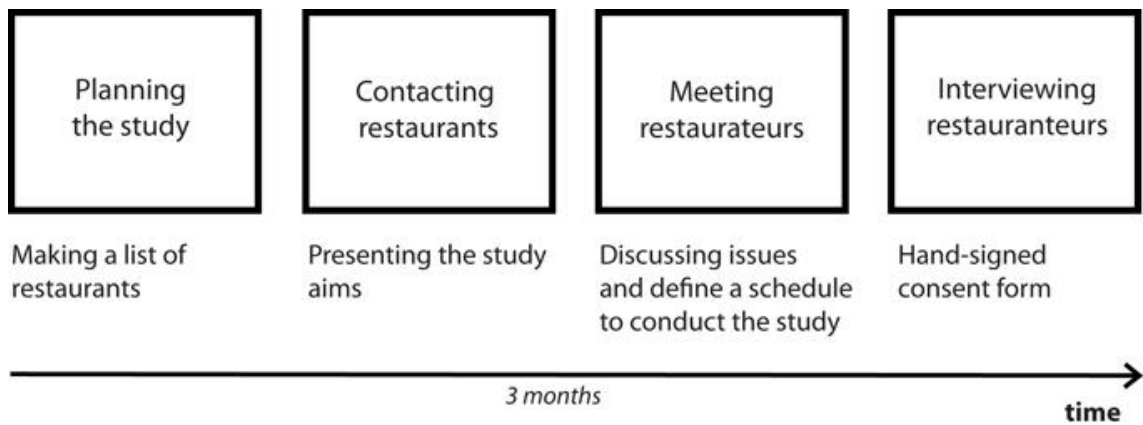


Figure 1: An overview of the invitation process.

A.2 Who participated?

There were two participants in this part of the study (see Table 1), both restaurateurs of dining restaurants. Those restaurateurs were a manager and a chef, as these individuals are considered experts in planning and creating the mealtime into daily practice for customer experience.

| Restaurateur | Specialism | Work experience (in years) | Type of restaurant | Gender |
|---------------------|-------------------|-----------------------------------|---------------------------|---------------|
| R1 | Manager | 18 | Dining | Man |
| R2 | Chef | 28 | Dining | Man |

Table 1: The restaurateurs who participated in the study.

The table illustrates who participated, demonstrating the characteristics of the restaurateur in relation to their unique identifier code, specialism, work experience and gender. By illustrating the restaurateurs' characteristics, I have introduced those who participated in this study. In what follows I will focus on describing how the interviews were conducted.

A.3 Interviews

Two interviews were conducted which took place in the restaurateurs' work places. In each interview, I began by thanking the restaurateur for his participation and recapitulating the aims of the study to them in order to clarify any issue. Our dialogue was audio-recorded. I conducted these interviews following ethical principles, including voluntary participation and informed consent form. Starting the dialogue (see Figure 2) with each restaurateur, I invited them to talk about their experiences and practices in designing the mealtime with

an aim to explore information related to the experiential considerations. In what follows I will illustrate the restaurateurs' voices from their participation in these interviews.



Figure 2: The environmental overview of the interviews conducted with restaurateurs.

A.4 Analysis

Analysing the information involved transcribing all the audio-recorded interviews verbatim, and reading and re-reading the transcripts. These interviews were predetermined by the question of how to design the mealtime for customer experience. To become familiar with the data, I organised and managed the information collected within this thematic issue. I especially studied the parts of the audio-recorded interviews where participants explained their views on creating the mealtime. The following section provides a sample of the issues identified in discussing the designing of the mealtime with restaurateurs.

A.5 Restaurateur 1

In prompting the question *what kind of experience do you want to create at the mealtime?* the restaurateur revealed his thoughts related with a combination of experiential aspects. He said:

R1: It's not just the food that matters (...) the environment and the way the room looks and how the person interacts with their server, the music that's playing, so every

single facet of what going on around the table is very important and has a really strong bearing on the experience to the person who's eating and how they enjoy it.

This view from Restaurateur 1 shows that designing the mealtime is not only a focus on food. The restaurateur highlights attention to the importance of environment and social context. Think for example, of his views related with sensorial aspects and people's interactions. In continuing our conversation, I was interested in knowing more about how the restaurateur 'constructs' the mealtime to respond to the enjoyable experience. He expressed thoughts in this way:

R1: This place is quite old fashioned which is why we use antique roses, antique roses are quite difficult to find (...) but it's important (...) it's the same kind of flower every time because people (...) they're used to it and it's something unique to coming here.

R1: We use (...) antique cups (...) when you get your cup of coffee or cup of tea at the end of your meal (...) every single, guys appreciate it (...) but usually it's women when they get their cup they look at it and thing oh my god and they look underneath to see where it came from and they look at the spoon and they're already enjoying it before they've even tasted it.

R1: When the customer walks in through the door first thing they've got to feel is warm especially in Scotland, so when you walk in here you feel a little bit cosy (...) before you sit (...) you get your drink in the bar it's got to look spectacular it's got to taste perfect (...) when you sit down (...) your table it's got to look spectacular.

R1: The waiter, the pleasant comment the smile.

R1: When they get their food put down on the plate (...) something pretty (...) the cutlery (...) matches the food that you're going to have (...) it should be a feast for their eyes from start to finish.

According to this restaurateur, the designing of the mealtime is in creating a stronger emotional connection with the customers in particular when the customers' expectations are leaning towards to experience something that he called "unique". Simultaneously, it highlights attention to this idea of designing to provide what customers appreciate. Here the restaurateur demonstrated a focus on designing the mealtime in ways of making people feel appreciated. This view also shows the importance of social context in experiencing. Consider, for example the people who are serving the customer promoting social pleasure

by revealing pleasant comments and facial expression. Another interesting point is this view of “to look spectacular” which perhaps shows a design intention to seduce or surprise the customer through visual appearance. Afterwards, our discussion was related on how the restaurateur does coordinate all elements, for example, food, people, tableware and others. According to him, it is important to establish a collaborative process, involving people with specific roles to work together and in sequential coordination to deliver the best experience. He expressed:

R1: They're from the kitchen to the dining room (...) everyone who is working is very (...) clear in what they are doing (...) there's usually two managers (...) one will be doing (...) the orders from the customers, the other one will be watching the door and making sure everything's ok (...) the waiters are specifically given certain jobs (...) some of them (...) they'll be doing the wine. Some of them (...) they'll be (...) carrying trays of food (...) when it comes to the chef's they're very (...) more specific (...) there will be pastry chefs that only do desserts, there'll be larder chefs who only do starters, there'll be grill chefs who only cook meat and fish (...) then there's usually a chef on the pass, there's usually the head chef (...) everything has to pass his eyes (...) before the plate goes in the lift to get sent down the head chef does the final garnish so his eyes see everything single thing that goes before it gets to the customer.

This view of Restaurateur 1 demonstrated a “mechanistic” process, revealing interconnected services such as ordering, preparing and delivering where a multidisciplinary team with different roles are involved in the designing of the mealtime. What seems to be highlighted here is the significance of multidisciplinary roles at the mealtime in order to create a diversity of elements required to promote an enjoyable experience at the mealtime.

In concluding this conversation, I asked the restaurateur if he had to design a mealtime experience for a stroke patient, what did he think would be important to consider for the person in that situation? According to him, the sensorial aspects become important but also the ritual of the mealtime such as “things that actually go around the actual food (...) the ritual of having a napkin”. The restaurateur seems to show thoughts associated with considerations to enhance the environmental experience when eating food can be restricted.

A.6 Restaurateur 2

In prompting the question *what kind of experience do you want to create at the mealtime?* the restaurateur began by expressing what he considered important as an experience at the start of the mealtime. For example:

R2: The customer comes in and (...) as they sit down they are given some bread (...) I want the customer to feel relaxed and I want the food to be tactile (...) really touchy feely so they pick the bread from the basket straight into the dip (...) they have a drink immediately (...) then you relax and read the menu.

What is emphasised from this restaurateur is that designing the mealtime in this context of customer experience is stimulating people's sensing and feeling. Think, for example, the restaurateur expressed thoughts on how designing the mealtime is intentionally created to promote certain emotional responses such as relaxed and or what he called a sort of "touchy feely". It seems to show similar views with Restaurateur 1 within this idea of designing the mealtime in ways of making people feel appreciated. As our discussion proceeded, he added:

R2: The food is now more what people know and like (...) designing a menu (...) you have to know what people want but you have to know who your customer is.

R2: It's got to look like someone really cared about making (...) somebody who's in the kitchen (...) loves cooking, and loves the food you've got (...) you've got to make that relationship between you and the customer (...) about how the customer is going to eat it, how's the customer going to approach it (...) is it familiar to the customer (...) it's trust.

What seems to be highlighted in this view is the designing of the mealtime involving a customer-centred approach. Consider, for example, how designing the menu involves obtaining an understanding of what people like and want to eat. There is also this view of experiencing "loveliness". According to the restaurateur, showing passion and care about designing the mealtime can influence in creating a positive relationship which he called "trust" between those who prepare and those who experience. This view of trust seems to be significant to influence the customer to experience again. In contrast with Restaurateur 1, food here is an element continuously highlighted. For example:

R2: It should be easy to eat.

R2: There always has to be some colour in food, I think green is a really important colour (...) green looks healthy and it tastes healthy (...) visually (...) the food comes and it's like wow (...) smell (...) it make you hungry (...) it's like 70% of your enjoyment of food is in the visuals and the smells and the other 30% is in eating of it.

The view from the restaurateur shows designing the mealtime is taking considerations on how people are going to eat. Consider, for example, the restaurateur expressed thoughts that food should be easy to eat. Simultaneously, the food visual appearance should be coloured in order to promote enjoyment. Following this line of thinking, the restaurateur expressed thoughts revealing the importance of personalising the mealtime. Creating personalisation, as he expressed, is emotionally appreciated.

R2: I've got a vegetarian (...) what does this person want to eat (...) what's going to make them feel good and then how do I make it looks good and how do I give them the right amount (...) there was one guy who used to come once a week and he would (...) have haddock fish cake poached egg and béarnaise sauce and he said to me one day you know this is the happiest hour in my week (...) that's how it can affect you (...) presenting it carefully and making it visually nice (...) people appreciated it more (...) it does emotionally.

What is emphasised from Restaurateur 2 here is the designing of the mealtime as a personalising service to promote personal experience. By saying “what’s going to make them feel good”, shows an intention in creating what people appreciate. In return it might evoke a positive emotional response.

By prompting the question *if you had to design a mealtime experience for a stroke patient what do you think would be important for the person in that situation?* the restaurateur expressed his views by demonstrating considerations to personalise. He said:

R2: It depends on where you're coming from, there's so much you can do (...) something like that easy to eat, but it looks spectacular, it also someone's really made an effort for you and that's going to make you feel good (...) a bit of fun at mealtime as well.

By prompting this question, I intended to gain an understanding of what the restaurateur would consider valuable to promote the quality of the patient experience at the mealtime. Fundamentally, it was to give him the opportunity to express his opinions about it. The views from the restaurateur show an emphasis on the significance of designing personalisation by combining elements of aesthetic and joy.

Appendix B: Exploring the present mealtime situation with healthcare professionals in Portugal

In this appendix, I will outline a similar study, as described in Chapter 6, but in the context of stroke in rehabilitation centre (day hospital) in Portugal. The aim of this study was to obtain an understanding of the present situation at the mealtime in stroke rehabilitation from the healthcare professionals' experiences "voices". Fundamentally, I intended to highlight issues about the patient experience at the mealtime.

B.1 Inviting Healthcare professionals

I started by planning the study, involving developing a proposal and conceiving the study tools. The first contact with the day hospital was with the Nurse Manager by email where I presented the study aims and revealed the criteria for healthcare professionals' participation. Afterwards, I was informed that I would need to send a proposal of the study, describing the aims and issues of confidentiality, by email to the clinical committee to obtain approval to conduct the study in the rehabilitation centre (day hospital). In doing so, I obtained approval and then I contacted the Nurse Manager by email to discuss issues and define a schedule for I conduct the study. Through our e-mails we discussed the potential participants. The Nurse Manager, on my behalf, discussed the study first-hand with healthcare professionals and collected their informed decision on whether they were to participate or not. Then I met the healthcare professionals to develop the study. This process took place over the period of three months.

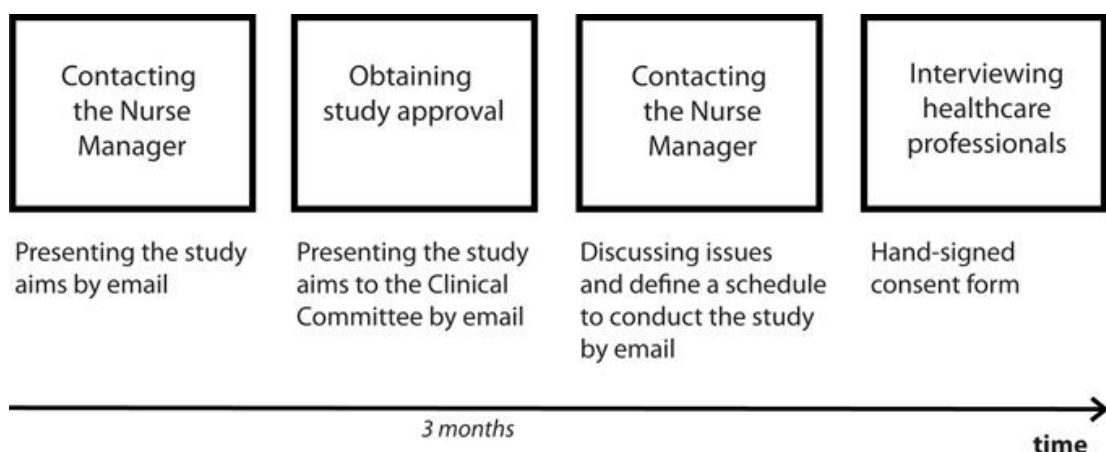


Figure 1: An overview of the invitation process.

B.2 Who participated?

Participants in this study were four healthcare professionals: all clinical practitioners in the rehabilitation centre. These healthcare professionals were a nurse, a speech therapist, an occupational therapist and a dietician, as these individuals are considered to constitute the multidisciplinary team who work with patients at the mealtime within stroke rehabilitation.

Table 1: The healthcare professionals who participated in the interviews.

| Healthcare professionals | Specialism | Work experience (in years) | Gender |
|--------------------------|------------------------|----------------------------|--------|
| HP1_PT | Nurse | 6 | Women |
| HP2_PT | Speech therapist | 6 | Women |
| PH3_PT | Occupational therapist | 28 | Women |
| PH4_PT | Dietician | - | Women |

The table above illustrates who participated, demonstrating the characteristics of the healthcare professionals in relation to their unique identifier code, specialism, work experience and gender. The following sections will focus on describing how the interviews were conducted.

B.3 Interviews, conversations and observations

Table 2 gives an overview of each interview, conversation and observation to demonstrate each design situation: who was interviewed and who was observed, in which space, and the length of time.

Table 2: Conducting interviews, conversations and observations.

| Interviewing | Observing | Interviewing | Talking | | Observing |
|--------------------------------------|--|---------------------|----------------|-----------------|------------------------------------|
| Nurse | <i>Patients and Healthcare professionals</i> | Speech T. | Dietician | Occupational T. | <i>Cooking /plating up process</i> |
| 1 hour | <i>1 hour</i> | 47 minutes | 15 minutes | 15 minutes | <i>1 hour</i> |
| Room | <i>Dining room</i> | Room | Room | Room | <i>Kitchen</i> |
| Rehabilitation centre (Day hospital) | | | | | |

Before I start to describe how these interviews, conversations and observations were conducted, it is important to explain first how these socialised and materialised situations were created in order to promote valuable dialogues and collect useful information (see Figure 2).



Figure 2: The environmental overview of the interviews/talks with healthcare professionals.

This process started with me individually interviewing the nurse. After I interviewed the nurse, she showed me where patients had their mealtimes, revealing a dining room. This provided the opportunity to explore issues by talking while watching. In each interview/conversation, I began by thanking the healthcare professional for his participation and recapitulating the aims of the study to them in order to clarify any issues. The nurse and the speech therapist dialogues were audio-recorded the others were not. I had conversations rather than interviews with the occupational therapist and dietician, following them in their work practices. I conducted these interviews/conversations following ethical principles, including voluntary participation and providing information about the study and asking them to sign a consent form.

Starting the dialogue with the nurse and the speech therapist, I invited them to talk about their experiences and practices in stroke rehabilitation, following the topic guide (see Appendix E).

B.4 Analysis

Analysing the information involved transcribing all the audio-recorded interviews verbatim, and reading and re-reading the transcripts. These interviews were predetermined by the three main themes: i) the main impacts of stroke, ii) the stroke pathway, and iii) the mealtime for patients in rehabilitation centre. To become familiar with the data, I developed a visual map (see Figure 3), grouping the information in each theme by each individual and also the information collected using a notebook and digital camera.

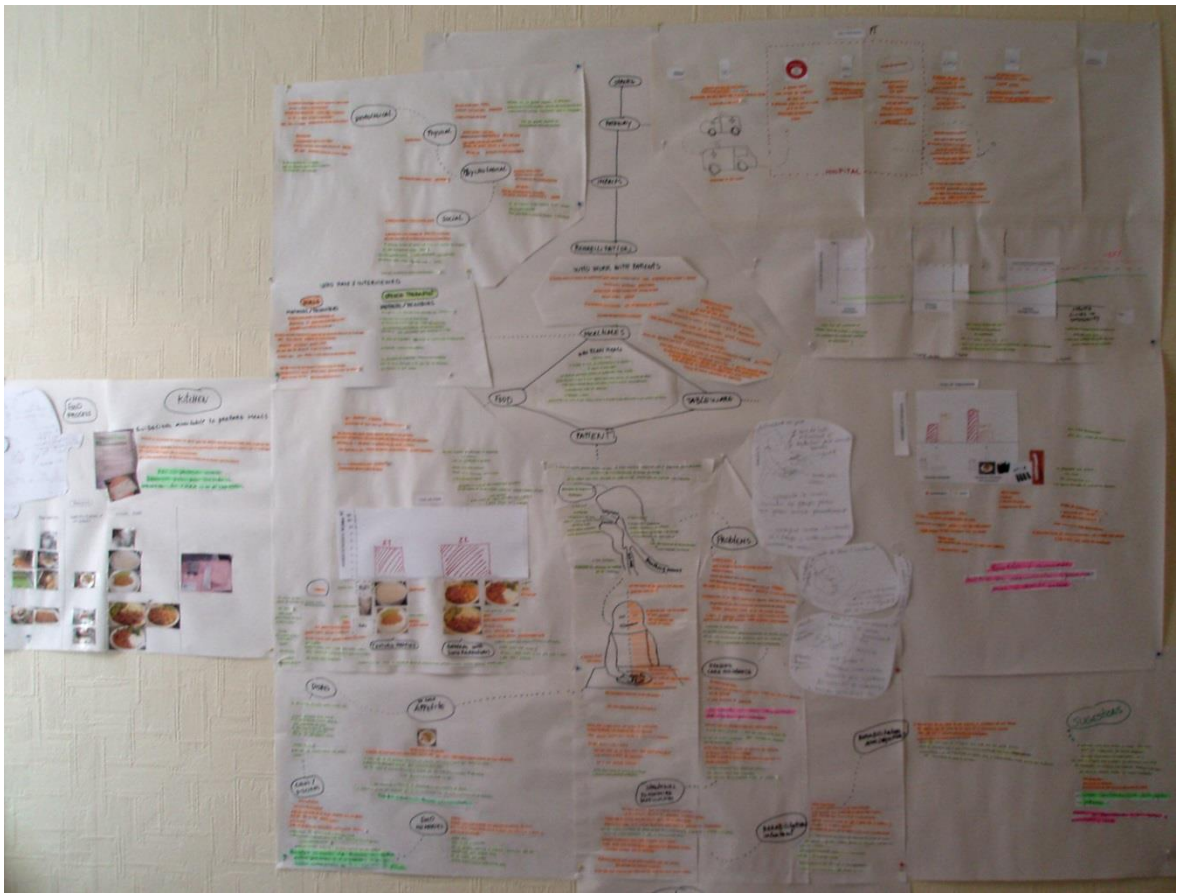


Figure 3: Mapping the information reported by the healthcare professionals and collected in the notebook and by the digital camera. Here the healthcare professionals' voices were underlined as HP1_PT (orange), HP2_PT (yellow), HP3_PT (rose) and HP4_PT (green) to help identify who the insights come from.

The following section provides, from the analysis of data, a sample of some of the issues identified in discussing the theme about the mealtime, using samples of quotes/statements made by the healthcare professionals.

B.5 The mealtime in rehabilitation centre

The healthcare professionals' views related with the patient's conditions at the mealtime.

HP2_PT_Speech therapist: Patients with swallowing difficulties requires texture modified, everything is gradual in rehabilitation, if the patient starts with a purée then goes to soft food and then onto habitual food.

(Há uma suspeita da alteração da deglutição é pastoso tudo na reabilitação é gradual se iniciou com uma pastosa depois vai-se avançado para a mole e da mole para a geral).

HP1_PT_Nurse: At mealtimes monitoring is done every day because we stand with them at all their mealtimes. At mealtimes a check is done to see if the patient choked, or make more of an effort to swallow a particular food, if they take a long time to chew, if they put food on their mouth and don't realize they still have food in their

mouth. We need to be at their side to alert them. Our aim is to record their meals for our colleagues to access the information and pass it to the dietician.

(O acompanhamento em refeitório é feito diariamente por nós, porque somos nós que estamos com os utentes no refeitório todas as refeições. Na refeição é feita uma vigilância para ver se o doente se engasga, ou se fez mais força para engolir um determinado alimento, se demora mais tempo a mastigar, se mete a comida à boca e não se apercebe que tem lá a comida acumulada. Nós temos que estar ao pé deles [para] chamar à atenção. A nossa preocupação é deixar isso registado na colheita de dados para todos os colegas terem acesso e passar essa informação à dietista para ela ter em atenção).

HP2_PT_Speech therapist: Initially, it is made an assessment. If the stroke patient has communication difficulties speech therapy is carried out in terms of coordination of breathing to enable speech, joint movements for reading and practice to check if they have the abilities to develop speech. Regarding swallowing, an evaluation is done to check if they have problems and with what type of food whether it is solids or liquids.

(Sessão inicial é feita a avaliação. Se o utente com AVC tem uma alteração da comunicação é feita uma intervenção ao nível da fala em termos da coordenação da respiração para falar, de movimentos articulatorios, de leitura e prática para ver se tem capacidades para desenvolver a fala. No caso das alterações da deglutição fazemos uma avaliação em que tipo de alimentos é que há alteração, se nos líquidos se nos sólidos).

HP3_PT_Occupational therapist: In the first week, an assessment is done with the patient to evaluate their abilities. In the second week, an action plan is developed for the patient relearning movements, functions which enable the patient have maximum autonomy.

(Na primeira semana é feita uma avaliação do doente, quais são as suas capacidades. Na segunda semana vamos planear uma estratégia com o doente para reaprender movimentos, funções para que ele possa obter o máximo de autonomia possível).

HP4_PT_Dietician: Trying to understand the cause of food refusal, it is the smell, look; it is trying to respond to the patients' expectations. The doctor and the dietician plan their meals.

(Perceber a causa da recusa alimentar, é o cheiro, o aspecto, tentar responder às expectativas do doente. O médico e a dietista planeiam as refeições).

The healthcare professionals expressed their views through a diagram that illustrated different types of food involving six scales of textures: a) smooth and pourable: b) smooth

and thin: c) smooth and thick purée: d) moist and some texture: e) soft and moist; and f) solid (see Figure 4).

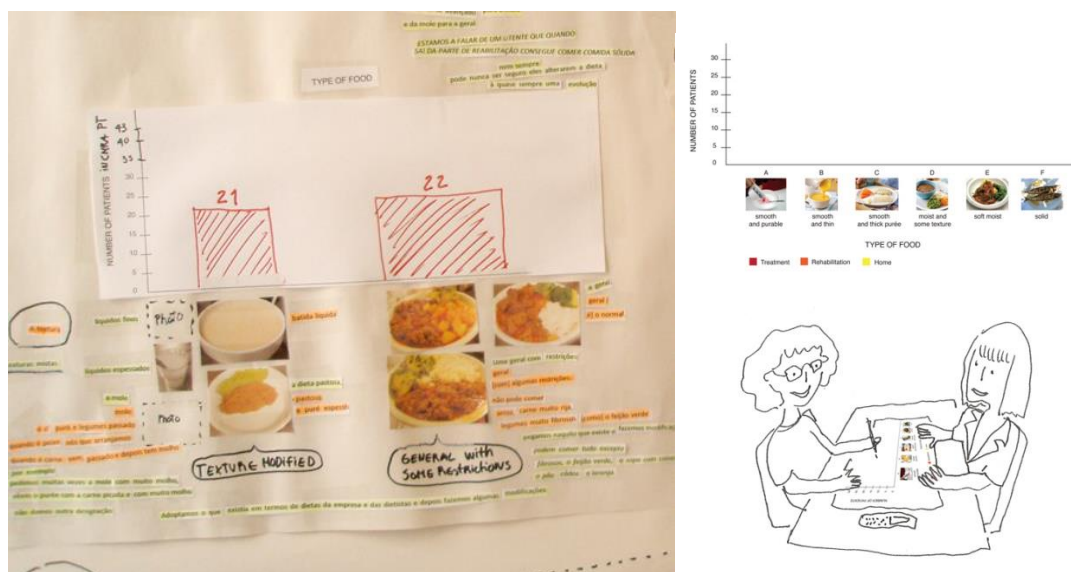


Figure 4: The healthcare professionals' views in the interview focusing on the texture of food for patients affected by stroke.

HP2_PT_Speech therapist: *The diet changing from habitual to modified (...) the patient isn't used to it, the unpleasant look, the food which is the same as only the colour and smell change. The patient loses their interest to eat.*

(Alteração da dieta geral para uma dieta pastosa ou dieta mole (...) a pessoa (...) não está habituada, o aspecto desagradável é tudo igual só a cor é que muda e o odor (...) a pessoa perde o interesse pela alimentação).



Figure 5: The researcher's observations in the kitchen focusing on the texture-modified food.

Figure 5 illustrates a type of texture-modified food as a meal for patients. Although the researcher was looking at meat and peas, they all have the same grade of texture suited to a particular patient's needs. Observations were performed in the kitchen environment, which identified a cooking and plating up food process, demonstrating that food is cooked on-site following the dietician's recommendations for each individual patient.

The healthcare professionals expressed their views through a diagram that illustrated three different types of tableware: a) standard tableware; b) standard tableware with adaptations; and c) specialised (or specially adapted) tableware (see Figure 6).

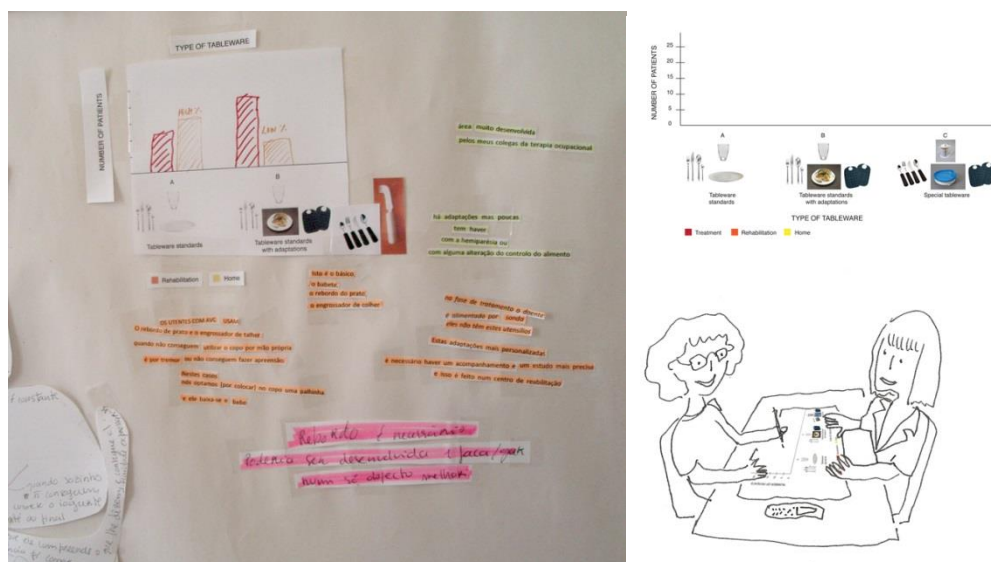


Figure 6: The healthcare professionals' views in the interview focusing on the tableware.

HP1_PT_Nurse: The bib, the plastic food guard on the plate and thickening of the spoon handle and a straw for the patient who has a tremor.

(O bafete, o rebordo de prato, o engrossador de colher, e a palhinha para o utente que tem tremor).

The healthcare professionals showed their views related with patients eating.

HP1_PT_Nurse: They are going to depend on others to alert them that there is food on the other side and turning around the plate.

(Vão estar dependente de outra pessoa para chamar a atenção que à alimentos daquele lado, ir chamando a atenção para ir rodando o prato).

HP1_PT_Nurse: Encouraging the patient never to talk while they eat, and not to put more food in while they already have food in their mouth, to be able to chew food well. It is necessary to be near them to explain everything because they need practical stimulus.

(Incentivar a pessoa a nunca falar enquanto está a comer, a não meter mais comida na boca enquanto tiver alimentos na boca, a conseguir mastigar bem os alimentos. É preciso estar sempre ao pé deles, a explicar-lhes tudo, porque eles precisam de estímulo na prática).

HP2_PT_Speech therapist: Many of them need assistance, not only to cut food but also to control speed and the quantity of food put [in the mouth]. If they have dysphagia (...) they need to eat using some techniques of head flexion otherwise they will choke, spit or vomit.

(Muitos deles necessitam de terceira pessoa, não só, para fracionarem os alimentos como em controlar a velocidade e a quantidade de alimento que é introduzida [na boca]. No caso de existir a “*dysphagia*” (...) tem de ingerir utilizando algumas técnicas, flexão da cabeça, caso contrario vão-se engasgar, cuspir ou vomitar).

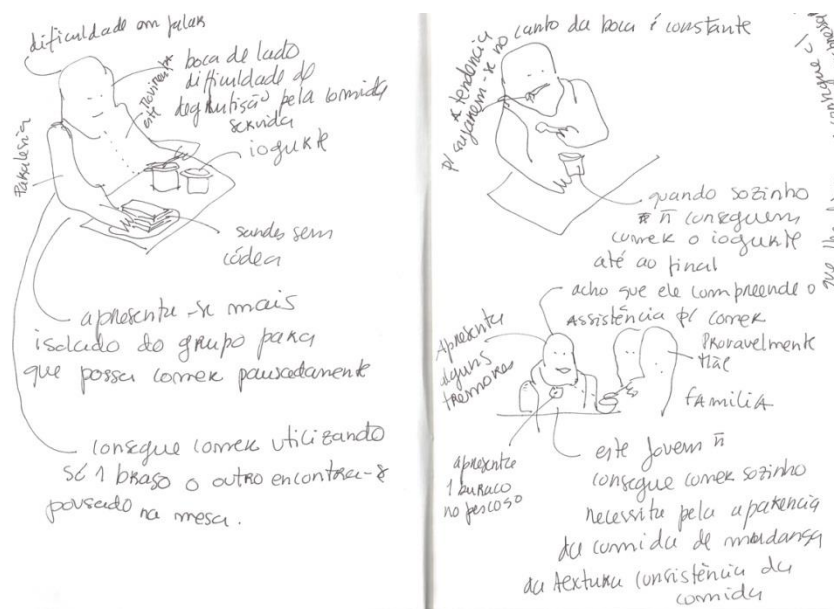


Figure 7: The researcher’s observations while patients were eating.

Figure 7 illustrates notebook notes and illustrations made in the dining room environment, demonstrating some patients’ difficulties to eat and healthcare professionals or family around helping. Moreover, the healthcare professionals also expressed their views about patients at their mealtimes in this way:

HP2_PT_Speech therapist: *Patients are usually seated at long tables to interact with others which is good as they can see other patients with more or less acute eating problems and it gives a perspective of how they can improve which is important to adapt to living with their difficulties.*

(Utentes geralmente estão distribuídos por mesas muito longas e acabam por socializar entre eles, o que é bom porque vêem outras pessoas com problemas de alimentação que dá uma perspectiva de que podem evoluir ou que há outros como eles e acaba por ser importante habitua-se a viver com essas dificuldades).

HP2_PT_Speech therapist: *For some patients it was important to eat alone in a very peaceful environment to enable them to take control of all strategies such as not speaking and being attentive.*

(Há utentes que era importante comerem sozinhos, num ambiente muito calmo para terem um controlo de todas as estratégias, inclusivamente o de não falar, de não estarem desatentos. Portanto para alguns utentes é necessário um afastamento da confusão).

Appendix C: Ethical approval by the Health Research Authority in the UK



Health Research Authority

NRES Committee West Midlands - Solihull

East Midlands REC Centre

~~The Old Chapel~~

Royal Standard Place

Nottingham

NG1 6FS

Telephone: 0115 8839390

Facsimile: 0115 8839294

09 August 2012

Ms Sandra Neves
Flat 2/2
16 Grantely Gardens
Shawlands
Glasgow
G41 3PZ

Dear Ms Neves

Study title: Using people-centred design methods to co-design a new stroke mealtime experience in rehabilitation
REC reference: 12/WM/0265
IRAS Project reference: 109686

The Proportionate Review Sub-committee of the NRES Committee West Midlands - Solihull reviewed the above application on 08 August 2012.

Ethical opinion

Discussion

- The Committee agreed that this is a difficult area to research in that mealtimes can be a very sensitive area for patients who have had a stroke. However, they agreed that it is a very important area.
- The Committee agreed that as Rehabilitation Professionals will be participating in workshops, there is potential to identify malpractice or neglect.
- The Consent Forms state that interviews will be audio recorded, and workshops audio and video recorded. There is a brief mention of this in the Participant Information Sheets. However, this should also be made more explicit and prominent.

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Additional conditions:-

1. There should be a statement in the Participant Information Sheet for Rehabilitation Professionals stating that 'If any malpractice or neglect is identified whilst participating in the research it is professional practice to report this'.
2. The Consent Forms states that interviews will be audio recorded and workshops audio and video recorded. There is a brief mention of this in the Participant Information Sheets that interviews will be audio recorded and workshops audio and video recorded. However, the Committee request that this be made more explicit and prominent.

You must notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Approved documents

The documents reviewed and approved were:

| <i>Document</i> | <i>Version</i> | <i>Date</i> |
|------------------------------------|--------------------------------|--------------|
| Evidence of insurance or indemnity | | 06 July 2012 |
| Interview Schedules/Topic Guides | Stroke Survivors V1 | 30 July 2012 |
| Investigator CV | Sandra M P Neves | 30 July 2012 |
| Investigator CV | Professor Alastair S Macdonald | |

| | | |
|--|---------------------|----------------|
| Letter from Sponsor | 31/07/2012 | |
| Other: Workshop Design Overview (Stroke Survivors) | 1 | 30 July 2012 |
| Other: Workshop Design Overview Sheet (Rehabilitation Professionals) | 1 | 30 July 2012 |
| Participant Consent Form: Rehabilitation Professionals (Workshop) | 3 | 01 August 2012 |
| Participant Consent Form: Stroke Survivors (Interview) | 3 | 01 August 2012 |
| Participant Consent Form: Stroke Survivors (Workshop) | 3 | 01 August 2012 |
| Participant Information Sheet: Rehabilitation Professionals | 1 | 30 July 2012 |
| Participant Information Sheet: Stroke Survivors | 1 | 30 July 2012 |
| Protocol | 2 | 30 July 2012 |
| REC application | 109686/347342/1/975 | 30 July 2012 |

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

| | |
|-------------------|---|
| 12/WM/0265 | Please quote this number on all correspondence |
|-------------------|---|

With the Committee's best wishes for the success of this project

Yours sincerely


PP **Dr Rex J Polson**
Chair

Email: trish.wheat@nottspct.nhs.uk

Enclosures: List of names and professions of members who took part in the review

"After ethical review – guidance for researchers"

Copy to: Alison Hay, The Glasgow School of Art

Mr Raymond Hamill, R&D Department Corporate Services Building

Professor Alastair Macdonald – Academic Supervisor

NRES Committee West Midlands - Solihull

Attendance at PRS Sub-Committee of the REC meeting on 08 August 2012

Committee Members:

| <i>Name</i> | <i>Profession</i> | <i>Present</i> | <i>Notes</i> |
|-------------------|--|----------------|--------------|
| Mrs Irene Linder | Assistant Manager, Local Authority - Retired | Yes | |
| Dr Rex J Polson | Consultant Physician - Chair | Yes | |
| Dr Timothy Priest | Consultant in Anaesthesia & Pain Management - Vice Chair | Yes | |
| Ms Gill Tomlinson | Head of Radiology, Solihull Hospital | Yes | |

Also in attendance:

| <i>Name</i> | <i>Position (or reason for attending)</i> |
|------------------|---|
| Mrs Lisa Gregory | Committee Coordinator |
| Ms Trish Wheat | Committee Coordinator |

**RESEARCH IN HUMAN SUBJECTS OTHER THAN CLINICAL TRIALS OF
INVESTIGATIONAL MEDICINAL PRODUCTS**

After ethical review – guidance for sponsors and investigators

This document sets out important guidance for sponsors and investigators on the conduct and management of research with a favourable opinion from a NHS Research Ethics Committee. Please read the guidance carefully. A failure to follow the guidance could lead to the committee reviewing its opinion on the research.

1. Further communications with the Research Ethics Committee
 - 1.1 Further communications during the research with the Research Ethics Committee that gave the favourable ethical opinion (hereafter referred to in this document as “the Committee”) are the personal responsibility of the Chief Investigator.

2. Commencement of the research
 - 2.1 It is assumed that the research will commence within 12 months of the date of the favourable ethical opinion.
 - 2.2 The research must not commence at any site until the local Principal Investigator (PI) or research collaborator has obtained management permission or approval from the organisation with responsibility for the research participants at the site.
 - 2.3 Should the research not commence within 12 months, the Chief Investigator should give a written explanation for the delay
 - 2.4 Should the research not commence within 24 months, the Committee may review its opinion.

3. Duration of ethical approval
 - 3.1 The favourable opinion for the research generally applies for the duration of the research. If it is proposed to extend the duration of the study as specified in the application form, the Committee should be notified.

3.2 Where the research involves the use of "relevant material" for the purposes of the Human Tissue Act 2004, authority to hold the material under the terms of the ethical approval applies until the end of the period declared in the application and approved by the Committee.

4. Progress reports

4.1 Research Ethics Committees are expected to keep a favourable opinion under review in the light of progress reports and any developments in the study. The Chief Investigator should submit a progress report to the Committee 12 months after the date on which the favourable opinion was given. Annual progress reports should be submitted thereafter.

4.2 Progress reports should be in the format prescribed by NRES and published on the website (see www.nres.npsa.nhs.uk/applicants/after-ethical-review/).

4.3 The Chief Investigator may be requested to attend a meeting of the Committee or Sub-Committee to discuss the progress of the research.

5. Amendments

5.1 If it is proposed to make a substantial amendment to the research, the Chief Investigator should submit a notice of amendment to the Committee.

5.2 A substantial amendment is any amendment to the terms of the application for ethical review, or to the protocol or other supporting documentation approved by the Committee, that is likely to affect to a significant degree:

- (a) the safety or physical or mental integrity of the trial participants
- (b) the scientific value of the trial
- (c) the conduct or management of the trial.

5.3 Notices of amendment should be in the format prescribed by NRES and published on the website, and should be personally signed by the Chief Investigator. The agreement of the sponsor should be sought before submitting the notice of amendment.

5.4 A substantial amendment should not be implemented until a favourable ethical opinion has been given by the Committee, unless the changes to the research are urgent safety measures (see section 7). The Committee is required to give an opinion within 35 days of the date of receiving a valid notice of amendment.

5.5 Amendments that are not substantial amendments ("minor amendments") may be made at any time and do not need to be notified to the Committee.

6. Changes to sites

Management permission (all studies)

6.1 For all studies, management permission should be obtained from the host organisation where it is proposed to:

- include a new site in the research, not included in the list of proposed research sites in the original REC application
- appoint a new PI or Local Collaborator at a research site
- make any other significant change to the conduct or management of a research site.

In the case of any new NHS site, the Site-Specific Information (SSI) Form should be submitted to the R&D office for review as part of the R&D application.

Site-specific assessment (where required)

6.2 The following guidance applies only to studies requiring site-specific assessment (SSA) as part of ethical review.

6.3 In the case of *NHS/HSC sites*, SSA responsibilities are undertaken on behalf of the REC by the relevant R&D office as part of the research governance review. The Committee's favourable opinion for the study will apply to any new sites and other changes at sites provided that management permission is obtained. There is no need to notify the Committee (or any other REC) about new sites or other changes, or to provide a copy of the SSI Form.

6.4 Changes at *non-NHS sites* require review by the local REC responsible for site-specific assessment (SSA REC). Please submit the SSI Form (or revised SSI Form as appropriate) to the SSA REC together with relevant supporting documentation. The SSA REC will advise the main REC whether it has any objection to the new site/PI or other change. The main REC will notify the Chief Investigator and sponsor of its opinion within a maximum of 35 days from the date on which a valid SSA application has been received by the SSA REC.

Studies not requiring SSA

6.5 For studies designated by the Committee as not requiring SSA, there is no requirement to notify the Committee of the inclusion of new sites or other changes at sites, either for NHS or non-NHS sites. However, management permission should still be obtained from the responsible host organisation (see 6.1 above).

7. Urgent safety measures

7.1 The sponsor or the Chief Investigator, or the local Principal Investigator at a trial site, may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety.

7.2 The Committee must be notified within three days that such measures have been taken, the reasons why and the plan for further action.

8. Serious Adverse Events

- 8.1 A Serious Adverse Event (SAE) is an untoward occurrence that:
- (a) results in death
 - (b) is life-threatening
 - (c) requires hospitalisation or prolongation of existing hospitalisation
 - (d) results in persistent or significant disability or incapacity
 - (e) consists of a congenital anomaly or birth defect
 - (f) is otherwise considered medically significant by the investigator.
- 8.2 A SAE occurring to a research participant should be reported to the Committee where in the opinion of the Chief Investigator the event was related to administration of any of the research procedures, and was an unexpected occurrence.
- 8.3 Reports of SAEs should be provided to the Committee within 15 days of the Chief Investigator becoming aware of the event, in the format prescribed by NRES and published on the website.
- 8.4 The Chief Investigator may be requested to attend a meeting of the Committee or Sub-Committee to discuss any concerns about the health or safety of research subjects.
- 8.5 Reports should not be sent to other RECs in the case of multi-site studies.
9. Conclusion or early termination of the research
- 9.1 The Chief Investigator should notify the Committee in writing that the research has ended within 90 days of its conclusion. The conclusion of the research is defined as the final date or event specified in the protocol, not the completion of data analysis or publication of the results.
- 9.2 If the research is terminated early, the Chief Investigator should notify the Committee within 15 days of the date of termination. An explanation of the reasons for early termination should be given.
- 9.3 Reports of conclusion or early termination should be submitted in the form prescribed by NRES and published on the website.
10. Final report
- 10.1 A summary of the final report on the research should be provided to the Committee within 12 months of the conclusion of the study. This should include information on whether the study achieved its objectives, the main findings, and arrangements for publication or dissemination of the research including any feedback to participants.
11. Review of ethical opinion
- 11.1 The Committee may review its opinion at any time in the light of any relevant information it receives.

- 11.2 The Chief Investigator may at any time request that the Committee reviews its opinion, or seek advice from the Committee on any ethical issue relating to the research.



Sandra Neves
 Fat 2/2
 16 Grantely Gardens
 Shawlands
 Glasgow, G41 3PZ

R&D Department
 Corporate Services Building
 Monklands Hospital
 Monkscourt Avenue
 AIRDRIE
 ML6 0JS

Date 27 August 2012
 Enquiries to Margaret Stewart
 R&D Facilitator
 Direct Line 01236 712445
 Email Margaret.stewart@lanarkshire.scot.nhs.uk

Dear Sandra

PROJECT TITLE: Using people-centred design methods to co-design a new stroke mealtime experience in rehabilitation

R&D ID NUMBER: L12050

I am writing to you as Chief Investigator of the above study to advise that R&D Management approval has been granted for the conduct of your study within NHS Lanarkshire as detailed below:

| NAME | TITLE | ROLE | NHSL SITE TO WHICH APPROVAL APPLIES |
|-----------------|---|---|-------------------------------------|
| Katrina Brennan | Stroke Managed Clinical Network Manager | Local Collaborator / Principal Investigator | Monklands Hospital |

For the study to be carried out you are subject to the conditions outlined overleaf:

Cont/...

Conditions

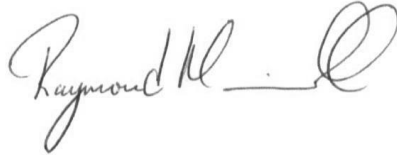
- You are required to comply with Good Clinical Practice, Ethics Guidelines, Health & Safety Act 1999 and the Data Protection Act 1998.
- The research is carried out in accordance with the Scottish Executive's Research Governance Framework for Health and Community Care (copy available via the Chief Scientist Office website:

<http://www.show.scot.nhs.uk/cso/> or the Research & Development Intranet site:
<http://firstport/sites/randd/default.aspx>.

- You must ensure that all confidential information is maintained in secure storage. You are further obligated under this agreement to report to the NHS Lanarkshire Data Protection Office and the Research & Development Office infringements, either by accident or otherwise, which constitutes a breach of confidentiality.
- Clinical trial agreements (if applicable), or any other agreements in relation to the study, have been signed off by all relevant signatories.
- You must contact the R&D Department if/when the project is subject to any minor or substantial amendments so that these can be appropriately assessed, and approved, where necessary.
- You notify the R&D Department if any additional researchers become involved in the project within NHS Lanarkshire.
- You notify the R&D Department when you have completed your research, or if you decide to terminate it prematurely.
- You must send brief annual reports followed by a final report and summary to the R&D office in hard copy and electronic formats as well as any publications.
- If the research involves any investigators who are not employed by NHS Lanarkshire, but who will be dealing with NHS Lanarkshire patients, there may be a requirement for an SCRO check and occupational health assessment. If this is the case then please contact the R&D Department to make arrangements for this to be undertaken and an honorary contract issued.

I trust these conditions are acceptable to you.

Yours sincerely,



Raymond Hamill
Research & Development Manager

cc.

| NAME | TITLE | CONTACT ADDRESS | ROLE |
|-----------------|---|---------------------------|---|
| Katrina Brennan | Stroke Managed Clinical Network Manager | Coathill Hospital | Principal Investigator / Local Collaborator |
| Dr Alison Hay | | The Glasgow School of Art | Sponsor Contact |

Appendix D: Ethics application via IRAS

NHS REC Form

Reference:
12/WS/0193

IRAS Version 3.4

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please enter a short title for this project (maximum 70 characters)
Using people-centred design methods to co-design a new stroke mealtime

1. Is your project research?

Yes No

2. Select one category from the list below:

- Clinical trial of an investigational medicinal product
- Clinical investigation or other study of a medical device
- Combined trial of an investigational medicinal product and an investigational medical device
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
- Basic science study involving procedures with human participants
- Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- Study involving qualitative methods only
- Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
- Study limited to working with data (specific project only)
- Research tissue bank
- Research database

If your work does not fit any of these categories, select the option below

Other study

2a. Please answer the following question(s):

- a) Does the study involve the use of any ionising radiation? Yes No
- b) Will you be taking new human tissue samples (or other human biological samples)? Yes No
- c) Will you be using existing human tissue samples (or other human biological samples)? Yes No

3. In which countries of the UK will the research sites be located? (Tick all that apply)

- England
- Scotland
- Wales
- Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

Date: 31/07/2012

1

109686/347342/1/975

- England
 Scotland
 Wales
 Northern Ireland
 This study does not involve the NHS

4. Which review bodies are you applying to?

- NHS/HSC Research and Development offices
 Research Ethics Committee
 National Information Governance Board for Health and Social Care (NIGB)
 Ministry of Justice (MoJ)
 National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

5. Will any research sites in this study be NHS organisations?

- Yes No

6. Do you plan to include any participants who are children?

- Yes No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

- Yes No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the NIGB Ethics and Confidentiality Committee to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

- Yes No

9. Is the study or any part of it being undertaken as an educational project?

- Yes No

Please describe briefly the involvement of the student(s):
The student is the chief investigator which will be involved in designing and conducting the research project such as carrying out interviews and workshops.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

- Yes No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of

its divisions, agencies or programs?

Yes No

Integrated Research Application System
Application Form for Research involving qualitative methods only


Application to NHS/HSC Research Ethics Committee

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting [Help](#).

Please define any terms or acronyms that might not be familiar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
 Using people-centred design methods to co-design a new stroke mealtime

Please complete these details after you have booked the REC application for review.

REC Name:

West of Scotland REC 5

REC Reference Number:

12/WS/0193

Submission date:

31/07/2012

PART A: Core study information
1. ADMINISTRATIVE DETAILS
A1. Full title of the research:

Using people-centred design methods to co-design a new stroke mealtime experience in rehabilitation

A2-1. Educational projects

Name and contact details of student(s):

Student 1

| | | | |
|-----------|---|-------------------|---------|
| | Title | Forename/Initials | Surname |
| | Ms | Sandra | Neves |
| Address | Flat 2/2 16 Grantely Gardens Shawlands Glasgow | | |
| Post Code | G41 3PZ | | |
| E-mail | s.neves1@student.gsa.ac.uk | | |
| Telephone | 01413534442 | | |
| Fax | | | |

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:
Doctor of Philosophy in Design

Name of educational establishment:
The Glasgow School of Art

Name and contact details of academic supervisor(s):

Academic supervisor 1

| | | | |
|-----------|---|-------------------|-----------|
| | Title | Forename/Initials | Surname |
| | Professor | Alastair | Macdonald |
| Address | The Glasgow School of Art 167 Renfrew Street Glasgow | | |
| Post Code | G3 6RQ | | |
| E-mail | a.macdonald@gsa.ac.uk | | |
| Telephone | 01413534715 | | |
| Fax | | | |

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

| Student(s) | Academic supervisor(s) |
|---------------------------|--|
| Student 1 Ms Sandra Neves | <input checked="" type="checkbox"/> Professor Alastair Macdonald |

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- Student
- Academic supervisor
- Other

A3-1. Chief Investigator:

| | | | |
|----------------|--|-------------------|---------|
| | Title | Forename/Initials | Surname |
| | Ms | Sandra | Neves |
| Post | Student | | |
| Qualifications | Postgraduate degree in Inclusive Design Graduate in Product and Interior Design | | |
| Employer | | | |
| Work Address | The Glasgow School of Art 167 Renfrew Street Glasgow | | |
| Post Code | G3 6RQ | | |

| | |
|-----------------------------|----------------------------|
| Work E-mail | s.neves1@student.gsa.ac.uk |
| * Personal E-mail | snevesp@gmail.com |
| Work Telephone | 01413534442 |
| * Personal Telephone/Mobile | 07554975212 |
| Fax | |

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.*

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and R&D reviewers that is sent to the CI.

| | |
|-----------|---|
| | Title Forename/Initials Surname |
| | Dr Alison Hay |
| Address | The Glasgow School of Art 167 Renfrew Street Glasgow |
| Post Code | G3 6RQ |
| E-mail | a.hay@gsa.ac.uk |
| Telephone | 01415661408 |
| Fax | |

A5-1. Research reference numbers. *Please give any relevant references for your study:*

| | |
|---|----------------------|
| Applicant's/organisation's own reference number, e.g. R & D (if available): | SNEVES/MEALTIMES/001 |
| Sponsor's/protocol number: | |
| Protocol Version: | N/A |
| Protocol Date: | |
| Funder's reference number: | Scholarship |
| Project website: | |

Additional reference number(s):

| Ref.Number | Description | Reference Number |
|------------|-------------|------------------|
| | | |

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

Yes No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, this summary will be published on the website of the National Research Ethics Service following the ethical review.*

Design involvement with healthcare has been influenced by co-design approaches, which considers patients' and professionals' collaborations in the research design process. Stroke impacts on peoples' abilities to eat creating a number of physical, cognitive and psychological difficulties, which require rehabilitation with mealtimes currently structured more on clinical/functionalist models. The aim of this research is to co-design a new mealtime experience with stroke survivors and rehabilitation professionals.

Stage 1

The chief investigator (CI) views stroke survivors' voices as significant to express their lived experiences about their mealtimes in the post-stroke phase. This research aims to interview stroke survivors to collect their retrospective accounts of their mealtime experiences during their stroke rehabilitation in hospital. The semi-structured interviews will be conducted with six stroke survivors face-to-face using a topic guide which will allow their thoughts and feelings to be put into words. This will provide new data and insights into the experiences of stroke survivors through their individual responses. Participants will also be invited to participate in the next stage of this study.

Stage 2

The chief investigator also considers stroke survivors as experts who can bring new ideas based on their past experiences. As this research aims to use co-design approaches through workshop methods both stroke survivors and rehabilitation professionals will be asked to participate in separate workshops. These workshops will bring new knowledge through the sharing of ideas about how the stroke mealtime experience could be improved in the future with less focus on the functional model and more focus on the sensorial and emotional models.

This research believes through the design techniques and tools used in both workshops the chief investigator will collect new insights, which will help in designing a new stroke mealtime experience for future stroke survivors.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, R&D office or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

As the purpose of this study is to explore the mealtime experience with stroke survivors and rehabilitation professionals, the main ethical issues to be addressed are around recruitment, informed consent, confidentiality and data protection.

Stroke survivors

Interviews: The stroke manager for NHS Lanarkshire will identify potential participants through the local community stroke survivors support group and introduce the chief investigator to the group/s. The CI will be invited to present the study to the support group members and provide information sheets and criteria for participation (see appendices attached). She will be on hand to answer any questions or queries regarding the study and arrange with the members of the support group a date and time to return to recruit potential participants. Prior to gaining written informed consent the CI will ensure participants meet the study criteria and fully understand the purpose of the study.

Study participants will be interviewed individually at a time and place, which is convenient and suitable for them. Any information which is collected about the study participants, or is provided during the study, will be kept strictly confidential. Participants' personal details will be removed so that they will only be identifiable by a project number and only the CI and her supervisory team will have access to their details. All information will be held securely for a period of 10 years, as required by Glasgow School of Art. However, any audio-recorded information gathered from participants during the interviews will be destroyed once the project is completed.

Workshop: At the end of the interview participants will be invited to attend a workshop to share their ideas on the co-design of a new mealtime experience. Again they will be informed that their participation is voluntary and they can withdraw at any time. The CI will liaise with potential participants on a date venue and time that will be suitable for the majority. Potential participants will be provided with an overview of the workshop programme and written informed consent gained prior to their participation in the workshop.

Any information, which is collected about the study participants, or is provided during the study, will be kept strictly confidential. Participants' personal details will be removed so that they will only be identifiable by a project number and only the CI and her supervisory team will have access to their details. All information will be held securely for a period of 10 years, as required by Glasgow School of Art. However, any audio/video-recorded information gathered from participants during the workshop will be destroyed once the project is completed.

Rehabilitation professionals

Workshop: The stroke manager for NHS Lanarkshire will identify potential rehabilitation therapists who represent the multidisciplinary team involved in stroke care. The stroke manager will organise a meeting with them to meet the Chief Investigator (CI) who will be invited to present her study. The CI will discuss their participation in the study and provide them with information sheets (see appendix attached). The CI will be on hand to answer any questions or queries regarding the study and arrange to contact the therapists several days later to discuss their full participation in the workshop. A date and time will be organised for the workshop where informed consent will be gained. The workshop for rehabilitation professionals will be conducted in a meeting space at The Glasgow School of Art campus in Glasgow. Lunch and transport costs will be provided.

Any information, which is collected about the therapists, or is provided during the study, will be kept strictly confidential. The therapists' personal details will be removed so that they will only be identifiable by a project number and only the CI and her supervisory team will have access to their details. All information will be held securely for a period of 10 years, as required by Glasgow school of Art. However, any audio/video-recorded information gathered from the therapists during the workshop will be destroyed once the project is completed.

A6-3. Proportionate review of REC application *The initial project filter has identified that your study may be suitable for proportionate review by a REC sub-committee. Please consult the current guidance notes from NRES and indicate whether you wish to apply through the proportionate review service or, taking into account your answer to A6-2, you consider there are ethical issues that require consideration at a full REC meeting.*

Yes - proportionate review No - review by full REC meeting

Further comments (optional):

Following the table as a guide of the PRS SOPs V1 1 - No Material Ethical Issues Tool, the Chief Investigator considers, IV- Questionnaire research that does NOT include highly sensitive areas or where accidental disclosure would NOT have serious consequences, the category appropriate for proportionate review for this study.

Note: This question only applies to the REC application.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. Please tick all that apply:

- Case series/ case note review
- Case control
- Cohort observation
- Controlled trial without randomisation
- Cross-sectional study
- Database analysis
- Epidemiology
- Feasibility/ pilot study
- Laboratory study
- Metanalysis
- Qualitative research
- Questionnaire, interview or observation study
- Randomised controlled trial
- Other (please specify)

A 10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

(How) could design bring mealtime experience improvements for stroke rehabilitation patients?

A 11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

Could people-centred design methods help in identifying opportunities for improving the mealtime experience?

At which point in the stroke mealtime model would design interventions benefit patient non-functional needs?

What kind of design interventions could best address sensorial and emotional aspects missing from the stroke mealtime model?

A 12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

This research aims to explore the current thinking in design literature about patients and professionals collaboration in the research design process help to bring healthcare improvements (Cottam and Leadbeater 2004; Bate and Robert 2007).

A 13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

This study is an explorative qualitative study using both semi-structured interviews and workshop methods with the aim of co-designing a new mealtime experience for stroke survivors. A qualitative methodology is appropriate as the focus of the study is to gather the experiences both past and present of stroke survivors and rehabilitation professionals involved in their care. This study has three linked phases:

i) Phase 1 (which has been completed) was a review of stroke and stroke rehabilitation literature and a pilot observation of the rehabilitation practices in stroke mealtimes. The main findings from the literature review and the observations identified that there is an overall lack of studies exploring the mealtime experience with the focus primarily on the functional aspects of eating. These findings influenced the design and development of phase two of the study.

ii) Phase 2 (which has been completed) was a review of mealtime experience (non-stroke) literature and a pilot observation of restaurants' practices in customer mealtimes. The main findings from this phase identified the mealtime experience as an emotional and sensorial experience. These findings influenced the design and development of phase three of the study.

iii) Phase 3 (which is in progress) involves a review of design methods literature and the co-designing of a new mealtime experience with stroke survivors and rehabilitation professionals. This phase will include two stages. Stage 1 will adopt one semi-structured interview with a minimum of six stroke survivors and stage 2 will adopt two workshops one with a group of six stroke survivors and one with a group of four rehabilitation professionals involved in stroke care.

Stage 1 - Interviews

Aim is to explore the mealtime experience with stroke survivors.

Sample – a convenience sample of at least six stroke survivors recruited from a local support group who meet the following criteria (see appendix attach).

Method – a face-to-face semi-structured interview will be conducted using a topic guide, which will allow their thoughts and feelings to be put into words. The topic guide will be designed and developed from the findings of my literature reviews. All interviews will be digital recorded and transcribed per verbatim.

Analysis – a framework analysis of the data will allow for the transparent and rigorous data management using a thematic framework (Green and Thorogood, 2004). This will provide mapping and interpreting new insights into the mealtime experience of stroke survivors through their individual accounts.

Stage 2 - Workshops

Aim is to map ideas to redesign a new mealtime experience with stroke survivors and rehabilitation professionals.

Sample – a group of six stroke survivors recruited from a local support group and a group of four rehabilitation professionals involved in stroke care.

Method – two separate semi-structured activities will be conducted using design techniques and tools, which will allow stroke survivors and rehabilitation professionals' ideas to be translated into visual maps. The design techniques and tools will be designed and developed from the findings of the literature review. Both workshops will be audio/video-recorded and transcribed per verbatim.

Analysis – a framework analysis of the data will allow for the transparent and rigorous data management using a thematic framework (Green and Thorogood, 2004). This will provide mapping and interpreting of new insights into the improvement of the mealtime experience of stroke survivors and rehabilitation professional through their ideas.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- Design of the research
 Management of the research
 Undertaking the research
 Analysis of results
 Dissemination of findings
 None of the above

Give details of involvement, or if none please justify the absence of involvement.

This study is to involve the Chief investigator and the study participants, which the CI around recruitment, informed consent, confidentiality and data protection and the study participants in learning and sharing knowledge and experiences of the mealtimes.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

This study considers two lists of inclusion criteria one for stroke survivors and one for rehabilitation professionals.

Stroke survivors

- . Clinical diagnosis of stroke
- . Post-acute stroke rehabilitation in hospital
- . Of either gender
- . Age ≥25 years
- . Have English first language
- . Had swallowing difficulty and care assistance during mealtimes in acute rehabilitation.
- . Able to understand and follow simple instructions
- . Able to give informed consent when assisted to do so with suitable communication aids if required.

Rehabilitation professionals

- . Clinical rehabilitation professionals
- . Have English first language
- . Have involved with stroke rehabilitation care at mealtimes
- . Able to give informed consent
- . Have represented a specific role at mealtimes
- . A nurse
- . A speech therapist
- . An occupational therapist
- . A dietitian

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

| |
|---|
| <p>Exclusion criteria</p> <p>Stroke survivors</p> <ul style="list-style-type: none"> . Severe visual or cognitive problems precluding participation study . Involved in another research study <p>Rehabilitation professionals</p> <ul style="list-style-type: none"> . Involved in another research study |
|---|

RESEARCH PROCEDURES, RISKS AND BENEFITS

A 18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. These include seeking consent, interviews, non-clinical observations and use of questionnaires.

- Please complete the columns for each intervention/procedure as follows:
1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
 2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
 3. Average time taken per intervention/procedure (minutes, hours or days)
 4. Details of who will conduct the intervention/procedure, and where it will take place.

| Intervention or procedure | 1 | 2 | 3 | 4 |
|---------------------------------------|---|---|----|---|
| Stroke survivors Interviews | 4 | - | 9h | i) The stroke manager for NHS Lanarkshire will identify potential participants through the local community stroke survivors support group and introduce the chief investigator to the group's. (1h) ii) The CI will be invited to present the study to the support group members and provide information sheets and criteria for participation (see appendices attached). She will be on hand to answer any questions or queries regarding the study and arrange with the members of the support group a date and time to return to recruit potential participants. (1h) iii) Prior to gaining written informed consent the CI will ensure participants meet the study criteria and fully understand the purpose of the study. (1h) iv) Study participants will be interviewed individually at a time and place, which is convenient and suitable for them. Each interview will allow participants individually share with the CI their retrospective accounts of their mealtime experience during their stroke rehabilitation in hospital. (1h each (x6)) |
| Stroke survivors Workshop | 3 | - | 9h | i) At the end of the interview participants will be invited to attend a workshop to share their ideas on the co-design of a new mealtime experience. Again they will be informed that their participation is voluntary and they can withdraw at any time. (30 minutes each (x6)) ii) The CI will liaise with potential participants on a date venue and time that will be suitable for the majority. Potential participants will be provided with an overview of the workshop programme and written informed consent gained prior to their participation in the workshop. (2h) iii) A group of study participants will be participating in a workshop at a time and place, which is convenient and suitable for them. The workshop will allow which participants share with the CI and other similar participants their ideas about how the stroke mealtime experience could be improved in the future. (3h) |
| Rehabilitation professionals Workshop | 4 | - | 6h | i) The stroke manager for NHS Lanarkshire will identify potential rehabilitation therapists who represent the multidisciplinary team involved in stroke care. (1h) ii) The stroke manager will organise a meeting with them to meet the Chief Investigator who will be invited to present her study. The CI will discuss their participation in the study and provide them with information sheets (see appendix attached). The CI will be on hand to answer any questions or queries regarding the study. (1h) iii) The CI will contact the therapists several days later to arrange a date venue and time that will be suitable for them. Therapists will be provided with an overview of the workshop programme and written informed consent gained prior to their participation |

in the workshop. (1h)
iv) A multidisciplinary group of therapists will be participating in a workshop at a time, which is suitable for them and a designated space at The Glasgow School of Art campus in Glasgow. The workshop will allow which the therapists share with the CI and other therapists their ideas about how the stroke mealtime could be improved in the future. (3h)

A21. How long do you expect each participant to be in the study in total?

Stroke survivors: participants and the chief investigator will meet twice, once for an interview and once for a workshop. The interview will last between thirty minutes and one hour depending on how much participants have to say. The interview will take place towards the end of their meeting group to discuss their experiences at the mealtimes during their rehabilitation in hospital. The workshop will take place over 3 hours to discuss and share participants' ideas with the CI and other similar participants of how we could bring improvements to the mealtime experience in rehabilitation. The interviews and workshop will be arranged at a time and date that suits participants within the support group site. The CI will secure a space where participants feel comfortable to participate in both interview and workshop.

Rehabilitation professionals: participants and the chief investigator will meet once for a workshop. The workshop will be during 3 hours to discuss and share ideas with the CI and other rehabilitation professionals to improve the mealtime in rehabilitation. The workshop will take place at The Glasgow School of Art campus in Glasgow. The workshop will be arranged at a time and date that suits the participants.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

It is unlikely that study participants will come to any harm as a result of taking part in the study, and no special arrangements have been put place for compensation. If study participants have any concerns about the way they are approached or treated during the course of the study, they can contact the academic supervisor or alternatively they can contact the normal National Health Service complaints mechanisms which will be available to them.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

Yes No

A24. What is the potential for benefit to research participants?

The chief investigator cannot promise that taking part in this study will be of direct benefit to the participants but by telling the CI their experiences and ideas they will help to give to this study in design a great understanding of what are the experiences and ideas of stroke survivors and rehabilitation professionals which might help to contribute in improving the mealtimes for other people in rehabilitation in the future. However, the CI aims to enable social interaction between study participants through the participatory research process, and an opportunity to share experiences as an informed, workshop based environment.

A26. What are the potential risks for the researchers themselves? (if any)

It is unlikely that the chief investigator will come to any harm as a result of conducting this study. However, the CI will follow some security procedures such as prior informing the stroke manager and academic supervisor about the location, date and time of the study. On the day, the CI will phone call and/or text her academic supervisor to inform him that she is able to safely conduct the study which will start and involve x hours. When the study will finish she will also phone call and/or text her academic supervisor to inform him that she is well and safe.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for

different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used? For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).

Stroke survivors

The stroke manager for NHS Lanarkshire will identify potential participants through the local community stroke survivors support group and introduce the chief investigator to the group/s. The CI will be invited to present the study to the support group members and provide information sheets and criteria for participation (see appendices attached).

Rehabilitation professionals

The stroke manager for NHS Lanarkshire will also identify potential rehabilitation therapists who represent the multidisciplinary team involved in stroke care. The stroke manager will organise a meeting with them to meet the chief investigator who will be invited to present her study, provide information sheets and criteria for participation (see appendices attached).

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

Yes No

Please give details below:

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

Yes No

A29. How and by whom will potential participants first be approached?

All participants will be firstly approached by the stroke manager for NHS Lanarkshire.

A30-1. Will you obtain informed consent from or on behalf of research participants?

Yes No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

This study aims to require consent for participation both interviews and workshop(s). The chief investigator will speak with potential participants about the study, check if they are willing to take part of the study and if they agree the CI will then ask them to sign a standard consent form and study participants will be given a copy of this to keep (see appendix attached).

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

Yes No

A31. How long will you allow potential participants to decide whether or not to take part?

The nurse specialist NHS Lanarkshire will give stroke survivors the study information sheet on the chief investigator behalf and stroke survivors will inform her/him if they permit them to pass on their contact details to me. If stroke survivors have given permission the CI will contact them over the next three to four days to give stroke survivors time to consider whether they wish to take part in the study. When the CI contacts stroke survivors, she will discuss the study with them and answer any questions they may have. If they are considering taking part in the study the CI will arrange to meet them at their next support group meeting. At that meeting the CI will speak with stroke survivors about the study again and check that they are still willing to take part, if they agree the CI will then ask them to sign a standard consent form and study participants will be given a copy of this to keep.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? (e.g. translation, use of interpreters)

This study will provide different ways of presenting information using verbal, written and visual such as diagrams and illustrations to facilitate communication.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? Tick one option only.

- The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- The participant would continue to be included in the study.
- Not applicable – informed consent will not be sought from any participants in this research.
- Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform participants about this when seeking their consent initially.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study**A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? (Tick as appropriate)**

- Access to medical records by those outside the direct healthcare team
- Electronic transfer by magnetic or optical media, email or computer networks
- Sharing of personal data with other organisations
- Export of personal data outside the EEA
- Use of personal addresses, postcodes, faxes, emails or telephone numbers
- Publication of direct quotations from respondents
- Publication of data that might allow identification of individuals
- Use of audio/visual recording devices
- Storage of personal data on any of the following:

- Manual files including X-rays
- NHS computers
- Home or other personal computers
- University computers
- Private company computers
- Laptop computers

Further details:

A38. How will you ensure the confidentiality of personal data? Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.

Any information on this study will be kept confidential and anonymous.

Stroke survivor interviews: Any information, which is collected about the study participants, or is provided during the study, will be kept strictly confidential. Participants' personal details will be removed so that they will only be identifiable by a project number and only the CI and her supervisory team will have access to their details. All information will be held securely for a period of 10 years, as required by Glasgow School of Art. However, any audio-recorded information gathered from participants during the interviews will be destroyed once the project is completed.

Stroke survivor workshop: Any information, which is collected about the study participants, or is provided during the study, will be kept strictly confidential. Participants' personal details will be removed so that they will only be identifiable by a project number and only the CI and her supervisory team will have access to their details. All information will be held securely for a period of 10 years, as required by Glasgow School of Art. However, any audio/video-recorded information gathered from participants during the workshop will be destroyed once the project is completed.

Rehabilitation professional workshop: Any information, which is collected about the therapists, or is provided during the study, will be kept strictly confidential. The therapists' personal details will be removed so that they will only be identifiable by a project number and only the CI and her supervisory team will have access to their details. All information will be held securely for a period of 10 years, as required by Glasgow School of Art. However, any audio/video-recorded information gathered from the therapists during the workshop will be destroyed once the project is completed.

A40. Who will have access to participants' personal data during the study? Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.

Any participants' personal data information will be managed by the chief investigator. However, this study will require a transcriber to transcribe audio-data. The transcriber will have access to the interview recording once the interview has taken place but as that recording will not contain anything personal or any identifiable marks that could trace this to a particular stroke survivor, there is no issue on confidentiality.

Storage and use of data after the end of the study

A43. How long will personal data be stored or accessed after the study has ended?

- Less than 3 months
- 3 – 6 months
- 6 – 12 months
- 12 months – 3 years
- Over 3 years

If longer than 12 months, please justify:

When the results of the study have been analysed, a PhD thesis will be prepared to present at The Glasgow School of Art and also reports will be prepared for publication in journals and presentation at conferences. Any study participants' personal information will be anonymised.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

Yes No

If Yes, please give details. For monetary payments, indicate how much and on what basis this has been determined.
The workshop for rehabilitation professionals will be conducted in a meeting space at The Glasgow School of Art campus. Lunch and transport cost will be provided.

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

Yes No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

Yes No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

Yes No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

Yes No

Please give details, or justify if not registering the research.

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? Tick as appropriate:

- Peer reviewed scientific journals
- Internal report
- Conference presentation
- Publication on website
- Other publication
- Submission to regulatory authorities

- Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- No plans to report or disseminate the results
- Other (please specify)
- Thesis

A53. Will you inform participants of the results?

Yes No

Please give details of how you will inform participants or justify if not doing so.

When the results of the study have been analysed, a summary of the results of the study will also be available for the participants if they wish. The chief investigator will discuss this individually with each participant at the final of the study.

5. Scientific and Statistical Review**A54. How has the scientific quality of the research been assessed? Tick as appropriate:**

- Independent external review
- Review within a company
- Review within a multi-centre research group
- Review within the Chief Investigator's institution or host organisation
- Review within the research team
- Review by educational supervisor
- Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:

This study has followed two stages of ethics review procedures.

Stage 1

A Preliminary Ethical Assessment Form at The Glasgow School of Art was completed with an overview of the study attached and reviewed by internal Ethics co-ordinator. Through the review some issues emerged such as the collaborator and rehabilitation professionals referred on the study are in the employ of NHS organizations. Advice by the Scottish Research Ethics Service was requested to clarify if the study involve to follow NHS Ethics review process.

Stage 2

This study will be an approval via IRAS, local NHS Research & Development Office, The Glasgow School of Art Ethics co-ordinator's and academic supervisor's reviews.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/institution.

A59. What is the sample size for the research? How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.

Total UK sample size: 10

Total international sample size (including UK): 10

Total in European Economic Area: 10

Further details:

The sample selected to this study reflects particular features, or specific groups within, the population under study. The sample selected is not intended, non-required to be statistically representative. The basis of selection is on the key characteristic of the specific population being studied (Ritchie and Lewis 2006). To achieve the aim, the chief

investigator needs to collect information-rich accounts from both stroke survivors and rehabilitation professionals. This study selects the sample, which will best answer the research questions.

Stroke survivors

The chief investigator decided on a sample size, a minimum of six adults was deemed large enough to capture the types of sources of information, which the study need, which are their experiences and ideas. The sample will be from a range of experiences across a number of eating difficulties associated with impacts of stroke.

Interviews will gather six participant's 'stories' accounts.

A workshop will collect a map of participant's ideas.

Rehabilitation professionals

The chief investigator decided on a sample size of four professionals who represent a multidisciplinary team involved with stroke care - a nurse, a speech therapist, an occupational therapist and a dietitian - was deemed large enough to capture the types of sources of information which the study need which are their ideas. The sample will be from a range of expertise involved to plan the mealtime in rehabilitation.

A workshop will collect a map of participants' ideas.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

As the purpose of this study is to give voice to participants and represent their experiences and ideas, the chief investigator indicates the sample selected to this study reflects the population under study.

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

This study is not intended, nor requires to be statistically representative. The methods of analysis will be appropriate for qualitative research by which the data will be analysis through a framework analysis which provides a step-by-step guide to assist the chief investigator to manager, conceptualise and describe the data (Green and Thorogood, 2004). The study aims to bring a descriptive proposal for a co-designed new mealtime experience.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

| | |
|----------------|--|
| | Title Forename/Initials Surname |
| | Mrs Katrina Brennan |
| Post | Stroke Managed Clinical Network Manager |
| Qualifications | RGN |
| Employer | NHS Lanarkshire |
| Work Address | GrenLyon Building, Coathill Hospital, Coatbridge |
| Post Code | ML5 4DN |
| Telephone | 01236707724 |
| Fax | |
| Mobile | 07909111642 |
| Work Email | katrina.Brennan@lanarkshire.scot.nhs.uk |

A64. Details of research sponsor(s)

A64-1. Sponsor**Lead Sponsor**Status: NHS or HSC care organisation

Commercial status:

 Academic Pharmaceutical industry Medical device industry Local Authority Other social care provider (including voluntary sector or private organisation) Other*If Other, please specify:***Contact person**

Name of organisation The Glasgow School of Art

Given name Alison

Family name Hay

Address 167 Renfrew Street

Town/city Glasgow

Post code G3 6RQ

Country UNITED KINGDOM

Telephone 01415661408

Fax

E-mail a.hay@gsa.ac.uk

Is the sponsor based outside the UK? Yes No*Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.***A65. Has external funding for the research been secured?** Funding secured from one or more funders External funding application to one or more funders in progress No application for external funding will be made

What type of research project is this?

 Standalone project Project that is part of a programme grant Project that is part of a Centre grant Project that is part of a fellowship/ personal award/ research training award Other

Other – please state:

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another

country?

Yes No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68. Give details of the lead NHS R&D contact for this research:

| | |
|--------------|--|
| | Title Forename/Initials Surname |
| | Mr Raymond Hamill |
| Organisation | R&D Department Corporate Services Building |
| Address | Monkscourt Avenue Airdrie |
| Post Code | ML6 0JS |
| Work Email | raymond.hamill@lanarkshire.scot.nhs.uk |
| Telephone | 01236712460 |
| Fax | |
| Mobile | 07779161388 |

Details can be obtained from the NHS R&D Forum website: <http://www.rdforum.nhs.uk>

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/09/2012

Planned end date: 01/12/2012

Total duration:

Years: 0 Months: 3 Days: 0

A71-2. Where will the research take place? (Tick as appropriate)

- England
 Scotland
 Wales
 Northern Ireland
 Other countries in European Economic Area

Total UK sites in study

Does this trial involve countries outside the EU?

Yes No

A72. What host organisations (NHS or other) in the UK will be responsible for the research sites? Please indicate the type of organisation by ticking the box and give approximate numbers of planned research sites:

- NHS organisations in England
 NHS organisations in Wales
 NHS organisations in Scotland 1
 HSC organisations in Northern Ireland

| | | |
|-------------------------------------|----------------------------------|---|
| <input type="checkbox"/> | GP practices in England | |
| <input type="checkbox"/> | GP practices in Wales | |
| <input type="checkbox"/> | GP practices in Scotland | |
| <input type="checkbox"/> | GP practices in Northern Ireland | |
| <input type="checkbox"/> | Social care organisations | |
| <input type="checkbox"/> | Phase 1 trial units | |
| <input type="checkbox"/> | Prison establishments | |
| <input type="checkbox"/> | Probation areas | |
| <input type="checkbox"/> | Independent hospitals | |
| <input checked="" type="checkbox"/> | Educational establishments | 1 |
| <input type="checkbox"/> | Independent research units | |
| <input type="checkbox"/> | Other (give details) | |
| Total UK sites in study: | | 2 |

A76. Insurance/ indemnity to meet potential legal liabilities

Note: in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? Please tick box(es) as applicable.

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

- NHS indemnity scheme will apply (NHS sponsors only)
 Other insurance or indemnity arrangements will apply (give details below)

The Glasgow School of Art possess indemnity cover with company to be determined to the value of £2,000,000 for the management of the research.

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? Please tick box(es) as applicable.

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

- NHS indemnity scheme will apply (protocol authors with NHS contracts only)
 Other insurance or indemnity arrangements will apply (give details below)

The Glasgow School of Art possess indemnity cover with company to be determined to the value of £2,000,000 for the design of the research.

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

- NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)
 Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

The Glasgow School of Art possess indemnity cover with company to be determined to the value of £2,000,000 for the conduct of the research.

Please enclose a copy of relevant documents.

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.

| Research site | | Investigator/ Collaborator/ Contact | |
|------------------|------------------------------------|-------------------------------------|---------|
| Institution name | NHS Lanarkshire | Title | Mrs |
| Department name | Stroke MCN | First name/ Initials | Katrina |
| Street address | Coathill Hospital, Hospital Street | Surname | Brennan |
| Town/city | Coatbridge | | |
| Post Code | ML5 4DN | | |
| | | | |
| Institution name | The Glasgow School of Art | Title | Ms |
| Department name | Design | First name/ Initials | Sandra |
| Street address | 167 Renfrew Street | Surname | Neves |
| Town/city | Glasgow | | |
| Post Code | G3 6RQ | | |

PART D: Declarations**D1. Declaration by Chief Investigator**

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.
4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.
5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.
7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.
9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
 - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
 - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
 - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
 - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.
11. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication*(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

- Chief Investigator
 Sponsor

- Study co-ordinator
 Student
 Other – please give details
 None

Access to application for training purposes (Not applicable for R&D Forms)*Optional – please tick as appropriate:*

I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

Signature:

Sandra Neves

Print Name:

Sandra Neves

Date:

30/07/2012

(dd/mm/yyyy)

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.
2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.
3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.
4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.
7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Signature:



Print Name:

Dr Ken Neil

Post:

Acting Head of Research & Graduate School

Organisation:

The Glasgow School of Art

Date:

30/07/2012

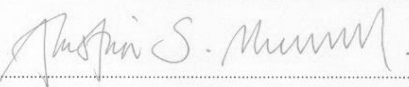
(dd/mm/yyyy)

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.
2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.
3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.
4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

Signature:



Print Name:

Professor Alastair Macdonald

Post:

Senior Researcher School of Design

Organisation:

The Glasgow School of Art

Date:

30/07/2012 (dd/mm/yyyy)

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please enter a short title for this project (maximum 70 characters)
-centred design methods to co-design a new stroke mealtime

1. Is your project research?

Yes No

2. Select one category from the list below:

- Clinical trial of an investigational medicinal product
- Clinical investigation or other study of a medical device
- Combined trial of an investigational medicinal product and an investigational medical device
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
- Basic science study involving procedures with human participants
- Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- Study involving qualitative methods only
- Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
- Study limited to working with data (specific project only)
- Research tissue bank
- Research database

If your work does not fit any of these categories, select the option below:

Other study

2a. Please answer the following question(s):

- a) Does the study involve the use of any ionising radiation? Yes No
- b) Will you be taking new human tissue samples (or other human biological samples)? Yes No
- c) Will you be using existing human tissue samples (or other human biological samples)? Yes No

3. In which countries of the UK will the research sites be located? (Tick all that apply)

- England
- Scotland
- Wales
- Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- England
 Scotland
 Wales
 Northern Ireland
 This study does not involve the NHS

4. Which review bodies are you applying to?

- NHS/HSC Research and Development offices
 Research Ethics Committee
 National Information Governance Board for Health and Social Care (NIGB)
 Ministry of Justice (MoJ)
 National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

5. Will any research sites in this study be NHS organisations?

- Yes No

6. Do you plan to include any participants who are children?

- Yes No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

- Yes No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the NIGB Ethics and Confidentiality Committee to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

- Yes No

9. Is the study or any part of it being undertaken as an educational project?

- Yes No

Please describe briefly the involvement of the student(s):
The student is the chief investigator which will be involved in designing and conducting the research project such as carrying out interviews and workshops.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

- Yes No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of

its divisions, agencies or programs?

Yes No

Integrated Research Application System
Application Form for Research involving qualitative methods only

NHS/HSC R&D Form (project information)

Please refer to the *Submission and Checklist* tabs for instructions on submitting R&D applications.

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting [Help](#).

Please define any terms or acronyms that might not be familiar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
 Using people-centred design methods to co-design a new stroke mealtime

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Using people-centred design methods to co-design a new stroke mealtime experience in rehabilitation

A2-1. Educational projects

Name and contact details of student(s):

Student 1

| | | | |
|-----------|---|-------------------|---------|
| | Title | Forename/Initials | Surname |
| | Ms | Sandra | Neves |
| Address | Flat 2/2 16 Grantely Gardens Shawlands Glasgow | | |
| Post Code | G41 3PZ | | |
| E-mail | s.neves1@student.gsa.ac.uk | | |
| Telephone | 01413534442 | | |
| Fax | | | |

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:
 Doctor of Philosophy in Design

Name of educational establishment:
 The Glasgow School of Art

Name and contact details of academic supervisor(s):

Academic supervisor 1

| | | | |
|-----------|---|-------------------|-----------|
| | Title | Forename/Initials | Surname |
| | Professor | Alastair | Macdonald |
| Address | The Glasgow School of Art 167 Renfrew Street Glasgow | | |
| Post Code | G3 6RQ | | |
| E-mail | a.macdonald@gsa.ac.uk | | |
| Telephone | 01413534715 | | |
| Fax | | | |

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

| Student(s) | Academic supervisor(s) |
|---------------------------|--|
| Student 1 Ms Sandra Neves | <input checked="" type="checkbox"/> Professor Alastair Macdonald |

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- Student
- Academic supervisor
- Other

A3-1. Chief Investigator:

| | | | |
|-----------------------------|--|-------------------|---------|
| | Title | Forename/Initials | Surname |
| | Ms | Sandra | Neves |
| Post | Student | | |
| Qualifications | Postgraduate degree in Inclusive Design Graduate in Product and Interior Design | | |
| Employer | | | |
| Work Address | The Glasgow School of Art 167 Renfrew Street Glasgow | | |
| Post Code | G3 6RQ | | |
| Work E-mail | s.neves1@student.gsa.ac.uk | | |
| * Personal E-mail | snevesp@gmail.com | | |
| Work Telephone | 01413534442 | | |
| * Personal Telephone/Mobile | 07554975212 | | |
| Fax | | | |

* This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and R&D reviewers that is sent to the CI.

| | |
|-----------|---|
| | Title Forename/Initials Surname Dr Alison Hay |
| Address | The Glasgow School of Art 167 Renfrew Street Glasgow |
| Post Code | G3 6RQ |
| E-mail | a.hay@gsa.ac.uk |
| Telephone | 01415661408 |
| Fax | |

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available): SNEVES/MEALTIMES/001

Sponsor's/protocol number:

Protocol Version: N/A

Protocol Date:

Funder's reference number: Scholarship

Project website:

Additional reference number(s):

| Ref.Number | Description | Reference Number |
|------------|-------------|------------------|
| | | |

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

Yes No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, this summary will be published on the website of the National Research Ethics Service following the ethical review.*

Design involvement with healthcare has been influenced by co-design approaches, which considers patients' and professionals' collaborations in the research design process. Stroke impacts on peoples' abilities to eat creating a number of physical, cognitive and psychological difficulties, which require rehabilitation with mealtimes currently structured more on clinical/functionalist models. The aim of this research is to co-design a new mealtime experience with stroke survivors and rehabilitation professionals.

Stage 1
The chief investigator (CI) views stroke survivors' voices as significant to express their lived experiences about their mealtimes in the post-stroke phase. This research aims to interview stroke survivors to collect their retrospective

accounts of their mealtime experiences during their stroke rehabilitation in hospital. The semi-structured interviews will be conducted with six stroke survivors face-to-face using a topic guide which will allow their thoughts and feelings to be put into words. This will provide new data and insights into the experiences of stroke survivors through their individual responses. Participants will also be invited to participate in the next stage of this study.

Stage 2

The chief investigator also considers stroke survivors as experts who can bring new ideas based on their past experiences. As this research aims to use co-design approaches through workshop methods both stroke survivors and rehabilitation professionals will be asked to participate in separate workshops. These workshops will bring new knowledge through the sharing of ideas about how the stroke mealtime experience could be improved in the future with less focus on the functional model and more focus on the sensorial and emotional models.

This research believes through the design techniques and tools used in both workshops the chief investigator will collect new insights, which will help in designing a new stroke mealtime experience for future stroke survivors.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, R&D office or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

As the purpose of this study is to explore the mealtime experience with stroke survivors and rehabilitation professionals, the main ethical issues to be addressed are around recruitment, informed consent, confidentiality and data protection.

Stroke survivors

Interviews: The stroke manager for NHS Lanarkshire will identify potential participants through the local community stroke survivors support group and introduce the chief investigator to the group/s. The CI will be invited to present the study to the support group members and provide information sheets and criteria for participation (see appendices attached). She will be on hand to answer any questions or queries regarding the study and arrange with the members of the support group a date and time to return to recruit potential participants. Prior to gaining written informed consent the CI will ensure participants meet the study criteria and fully understand the purpose of the study. Study participants will be interviewed individually at a time and place, which is convenient and suitable for them. Any information which is collected about the study participants, or is provided during the study, will be kept strictly confidential. Participants' personal details will be removed so that they will only be identifiable by a project number and only the CI and her supervisory team will have access to their details. All information will be held securely for a period of 10 years, as required by Glasgow School of Art. However, any audio-recorded information gathered from participants during the interviews will be destroyed once the project is completed.

Workshop: At the end of the interview participants will be invited to attend a workshop to share their ideas on the co-design of a new mealtime experience. Again they will be informed that their participation is voluntary and they can withdraw at any time. The CI will liaise with potential participants on a date venue and time that will be suitable for the majority. Potential participants will be provided with an overview of the workshop programme and written informed consent gained prior to their participation in the workshop. Any information, which is collected about the study participants, or is provided during the study, will be kept strictly confidential. Participants' personal details will be removed so that they will only be identifiable by a project number and only the CI and her supervisory team will have access to their details. All information will be held securely for a period of 10 years, as required by Glasgow School of Art. However, any audio/video-recorded information gathered from participants during the workshop will be destroyed once the project is completed.

Rehabilitation professionals

Workshop: The stroke manager for NHS Lanarkshire will identify potential rehabilitation therapists who represent the multidisciplinary team involved in stroke care. The stroke manager will organise a meeting with them to meet the Chief Investigator (CI) who will be invited to present her study. The CI will discuss their participation in the study and provide them with information sheets (see appendix attached). The CI will be on hand to answer any questions or queries regarding the study and arrange to contact the therapists several days later to discuss their full participation in the workshop. A date and time will be organised for the workshop where informed consent will be gained. The workshop for rehabilitation professionals will be conducted in a meeting space at The Glasgow School of Art campus in

Glasgow. Lunch and transport costs will be provided.
 Any information, which is collected about the therapists, or is provided during the study, will be kept strictly confidential. The therapists' personal details will be removed so that they will only be identifiable by a project number and only the CI and her supervisory team will have access to their details. All information will be held securely for a period of 10 years, as required by Glasgow school of Art. However, any audio/video-recorded information gathered from the therapists during the workshop will be destroyed once the project is completed.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. Please tick all that apply.

- Case series/ case note review
- Case control
- Cohort observation
- Controlled trial without randomisation
- Cross-sectional study
- Database analysis
- Epidemiology
- Feasibility/ pilot study
- Laboratory study
- Metanalysis
- Qualitative research
- Questionnaire, interview or observation study
- Randomised controlled trial
- Other (please specify)

A10. What is the principal research question/objective? Please put this in language comprehensible to a lay person.

(How) could design bring mealtime experience improvements for stroke rehabilitation patients?

A11. What are the secondary research questions/objectives if applicable? Please put this in language comprehensible to a lay person.

Could people-centred design methods help in identifying opportunities for improving the mealtime experience?

At which point in the stroke mealtime model would design interventions benefit patient non-functional needs?

What kind of design interventions could best address sensorial and emotional aspects missing from the stroke mealtime model?

A12. What is the scientific justification for the research? Please put this in language comprehensible to a lay person.

This research aims to explore the current thinking in design literature about patients and professionals collaboration in the research design process help to bring healthcare improvements(Cottam and Leadbeater 2004; Bate and Robert 2007).

A13. Please summarise your design and methodology. It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.

This study is an explorative qualitative study using both semi-structured interviews and workshop methods with the aim of co-designing a new mealtime experience for stroke survivors. A qualitative methodology is appropriate as the focus of the study is to gather the experiences both past and present of stroke survivors and rehabilitation professionals involved in their care. This study has three linked phases:

i)Phase 1 (which has been completed) was a review of stroke and stroke rehabilitation literature and a pilot observation of the rehabilitation practices in stroke mealtimes. The main findings from the literature review and the observations identified that there is an overall lack of studies exploring the mealtime experience with the focus primarily on the functional aspects of eating. These findings influenced the design and development of phase two of the study.

ii)Phase 2 (which has been completed) was a review of mealtime experience (non-stroke) literature and a pilot observation of restaurants' practices in customer mealtimes. The main findings from this phase identified the mealtime experience as an emotional and sensorial experience. These findings influenced the design and development of phase three of the study.

iii)Phase 3 (which is in progress) involves a review of design methods literature and the co-designing of a new mealtime experience with stroke survivors and rehabilitation professionals. This phase will include two stages. Stage 1 will adopt one semi-structured interview with a minimum of six stroke survivors and stage 2 will adopt two workshops one with a group of six stroke survivors and one with a group of four rehabilitation professionals involved in stroke care.

Stage 1 - Interviews

Aim is to explore the mealtime experience with stroke survivors.

Sample – a convenience sample of at least six stroke survivors recruited from a local support group who meet the following criteria (see appendix attach).

Method – a face-to-face semi-structured interview will be conducted using a topic guide, which will allow their thoughts and feelings to be put into words. The topic guide will be designed and developed from the findings of my literature reviews. All interviews will be digital recorded and transcribed per verbatim.

Analysis – a framework analysis of the data will allow for the transparent and rigorous data management using a thematic framework (Green and Thorogood, 2004). This will provide mapping and interpreting new insights into the mealtime experience of stroke survivors through their individual accounts.

Stage 2 - Workshops

Aim is to map ideas to redesign a new mealtime experience with stroke survivors and rehabilitation professionals.

Sample – a group of six stroke survivors recruited from a local support group and a group of four rehabilitation professionals involved in stroke care.

Method – two separate semi-structured activities will be conducted using design techniques and tools, which will allow stroke survivors and rehabilitation professionals' ideas to be translated into visual maps. The design techniques and tools will be designed and developed from the findings of the literature review. Both workshops will be audio/video-recorded and transcribed per verbatim.

Analysis – a framework analysis of the data will allow for the transparent and rigorous data management using a thematic framework (Green and Thorogood, 2004). This will provide mapping and interpreting of new insights into the improvement of the mealtime experience of stroke survivors and rehabilitation professional through their ideas.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- Design of the research
- Management of the research
- Undertaking the research
- Analysis of results
- Dissemination of findings
- None of the above

Give details of involvement, or if none please justify the absence of involvement.

This study is to involve the Chief investigator and the study participants, which the CI around recruitment, informed consent, confidentiality and data protection and the study participants in learning and sharing knowledge and experiences of the mealtimes.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- Blood
- Cancer
- Cardiovascular
- Congenital Disorders
- Dementias and Neurodegenerative Diseases
- Diabetes
- Ear
- Eye
- Generic Health Relevance
- Infection
- Inflammatory and Immune System
- Injuries and Accidents
- Mental Health
- Metabolic and Endocrine
- Musculoskeletal
- Neurological
- Oral and Gastrointestinal
- Paediatrics
- Renal and Urogenital
- Reproductive Health and Childbirth
- Respiratory
- Skin
- Stroke

Gender: Male and female participants

Lower age limit: 25 Years

Upper age limit: 70 Years

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

This study considers two lists of inclusion criteria one for stroke survivors and one for rehabilitation professionals.

Stroke survivors

- . Clinical diagnosis of stroke
- . Post-acute stroke rehabilitation in hospital
- . Of either gender
- . Age ≥25 years
- . Have English first language
- . Had swallowing difficulty and care assistance during mealtimes in acute rehabilitation.
- . Able to understand and follow simple instructions
- . Able to give informed consent when assisted to do so with suitable communication aids if required.

Rehabilitation professionals

- . Clinical rehabilitation professionals
- . Have English first language
- . Have involved with stroke rehabilitation care at mealtimes
- . Able to give informed consent
- . Have represented a specific role at mealtimes
- . A nurse
- . A speech therapist
- . An occupational therapist
- . A dietitian

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

Exclusion criteria

Stroke survivors

- . Severe visual or cognitive problems precluding participation study
- . Involved in another research study

Rehabilitation professionals

- . Involved in another research study

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. These include seeking consent, interviews, non-clinical observations and use of questionnaires.

- Please complete the columns for each intervention/procedure as follows:
1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
 2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
 3. Average time taken per intervention/procedure (minutes, hours or days)
 4. Details of who will conduct the intervention/procedure, and where it will take place.

| Intervention or procedure | 1 | 2 | 3 | 4 |
|-----------------------------|---|---|----|---|
| Stroke survivors Interviews | 4 | - | 9h | i) The stroke manager for NHS Lanarkshire will identify potential participants through the local community stroke survivors support group and introduce the chief investigator to the group/s. (1h) ii) The CI will be invited to present the study to the support group members and provide information sheets and criteria for participation (see appendices attached). She will be on hand to answer any questions or queries regarding the study and arrange with the members of the support group a date and time to return to recruit potential participants. (1h) iii) Prior to gaining written informed consent the CI will ensure participants meet the study criteria and fully understand the purpose of the study. (1h) iv) Study participants will be interviewed individually at a time and place, which is convenient and suitable for them. Each interview will allow participants individually share with the CI their retrospective accounts of their mealtime experience during their stroke rehabilitation in hospital. (1h each (x6)) |
| Stroke survivors Workshop | 3 | - | 9h | i) At the end of the interview participants will be invited to attend a workshop to share their ideas on the co-design of a new mealtime experience. Again they will be informed that their participation is voluntary and they can withdraw at any time. (30 minutes each (x6)) ii) The CI will liaise with potential participants on a date venue and time that will be suitable for the majority. Potential participants will be provided with an overview of the workshop programme and written informed consent gained prior to their participation in the workshop. (2h) |

| | | | | |
|---------------------------------------|---|---|----|--|
| | | | | <p>iii) A group of study participants will be participating in a workshop at a time and place, which is convenient and suitable for them. The workshop will allow which participants share with the CI and other similar participants their ideas about how the stroke mealtime experience could be improved in the future. (3h)</p> |
| Rehabilitation professionals Workshop | 4 | - | 6h | <p>i) The stroke manager for NHS Lanarkshire will identify potential rehabilitation therapists who represent the multidisciplinary team involved in stroke care. (1h)</p> <p>ii) The stroke manager will organise a meeting with them to meet the Chief Investigator who will be invited to present her study. The CI will discuss their participation in the study and provide them with information sheets (see appendix attached). The CI will be on hand to answer any questions or queries regarding the study. (1h)</p> <p>iii) The CI will contact the therapists several days later to arrange a date venue and time that will be suitable for them. Therapists will be provided with an overview of the workshop programme and written informed consent gained prior to their participation in the workshop. (1h)</p> <p>iv) A multidisciplinary group of therapists will be participating in a workshop at a time, which is suitable for them and a designated space at The Glasgow School of Art campus in Glasgow. The workshop will allow which the therapists share with the CI and other therapists their ideas about how the stroke mealtime could be improved in the future. (3h)</p> |

A21. How long do you expect each participant to be in the study in total?

Stroke survivors: participants and the chief investigator will meet twice, once for an interview and once for a workshop. The interview will last between thirty minutes and one hour depending on how much participants have to say. The interview will take place towards the end of their meeting group to discuss their experiences at the mealtimes during their rehabilitation in hospital. The workshop will take place over 3 hours to discuss and share participants' ideas with the CI and other similar participants of how we could bring improvements to the mealtime experience in rehabilitation. The interviews and workshop will be arranged at a time and date that suits participants within the support group site. The CI will secure a space where participants feel comfortable to participate in both interview and workshop.

Rehabilitation professionals: participants and the chief investigator will meet once for a workshop. The workshop will be during 3 hours to discuss and share ideas with the CI and other rehabilitation professionals to improve the mealtime in rehabilitation. The workshop will take place at The Glasgow School of Art campus in Glasgow. The workshop will be arranged at a time and date that suits the participants.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

It is unlikely that study participants will come to any harm as a result of taking part in the study, and no special arrangements have been put place for compensation. If study participants have any concerns about the way they are approached or treated during the course of the study, they can contact the academic supervisor or alternatively they can contact the normal National Health Service complaints mechanisms which will be available to them.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

Yes No

A24. What is the potential for benefit to research participants?

The chief investigator cannot promise that taking part in this study will be of direct benefit to the participants but by telling the CI their experiences and ideas they will help to give to this study in design a great understanding of what are the experiences and ideas of stroke survivors and rehabilitation professionals which might help to contribute in improving the mealtimes for other people in rehabilitation in the future. However, the CI aims to enable social interaction between study participants through the participatory research process, and an opportunity to share experiences as an informed, workshop based environment.

A26. What are the potential risks for the researchers themselves? (if any)

It is unlikely that the chief investigator will come to any harm as a result of conducting this study. However, the CI will follow some security procedures such as prior informing the stroke manager and academic supervisor about the location, date and time of the study. On the day, the CI will phone call and/or text her academic supervisor to inform him that she is able to safely conduct the study which will start and involve x hours. When the study will finish she will also phone call and/or text her academic supervisor to inform him that she is well and safe.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used? For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).

Stroke survivors

The stroke manager for NHS Lanarkshire will identify potential participants through the local community stroke survivors support group and introduce the chief investigator to the group/s. The CI will be invited to present the study to the support group members and provide information sheets and criteria for participation (see appendices attached).

Rehabilitation professionals

The stroke manager for NHS Lanarkshire will also identify potential rehabilitation therapists who represent the multidisciplinary team involved in stroke care. The stroke manager will organise a meeting with them to meet the chief investigator who will be invited to present her study, provide information sheets and criteria for participation (see appendices attached).

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

Yes No

Please give details below:

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

Yes No

A29. How and by whom will potential participants first be approached?

All participants will be firstly approached by the stroke manager for NHS Lanarkshire.

A30-1. Will you obtain informed consent from or on behalf of research participants?

Yes No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

This study aims to require consent for participation both interviews and workshop(s). The chief investigator will speak with potential participants about the study, check if they are willing to take part of the study and if they agree the CI will

then ask them to sign a standard consent form and study participants will be given a copy of this to keep (see appendix attached).

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

Yes No

A31. How long will you allow potential participants to decide whether or not to take part?

The nurse specialist NHS Lanarkshire will give stroke survivors the study information sheet on the chief investigator behalf and stroke survivors will inform her/him if they permit them to pass on their contact details to me. If stroke survivors have given permission the CI will contact them over the next three to four days to give stroke survivors time to consider whether they wish to take part in the study. When the CI contacts stroke survivors, she will discuss the study with them and answer any questions they may have. If they are considering taking part in the study the CI will arrange to meet them at their next support group meeting. At that meeting the CI will speak with stroke survivors about the study again and check that they are still willing to take part, if they agree the CI will then ask them to sign a standard consent form and study participants will be given a copy of this to keep.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?(e.g. translation, use of interpreters)

This study will provide different ways of presenting information using verbal, written and visual such as diagrams and illustrations to facilitate communication.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? Tick one option only.

- The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- The participant would continue to be included in the study.
- Not applicable – informed consent will not be sought from any participants in this research.
- Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform participants about this when seeking their consent initially.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?(Tick as appropriate)

- Access to medical records by those outside the direct healthcare team
- Electronic transfer by magnetic or optical media, email or computer networks
- Sharing of personal data with other organisations
- Export of personal data outside the EEA
- Use of personal addresses, postcodes, faxes, emails or telephone numbers
- Publication of direct quotations from respondents
- Publication of data that might allow identification of individuals
- Use of audio/visual recording devices
- Storage of personal data on any of the following:
 - Manual files including X-rays
 - NHS computers
 - Home or other personal computers
 - University computers
 - Private company computers
 - Laptop computers

Further details:

A37. Please describe the physical security arrangements for storage of personal data during the study?

Any information in this study will be locked filing cabinet.

A38. How will you ensure the confidentiality of personal data? Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.

Any information on this study will be kept confidential and anonymous.

Stroke survivor interviews: Any information, which is collected about the study participants, or is provided during the study, will be kept strictly confidential. Participants' personal details will be removed so that they will only be identifiable by a project number and only the CI and her supervisory team will have access to their details. All information will be held securely for a period of 10 years, as required by Glasgow School of Art. However, any audio-recorded information gathered from participants during the interviews will be destroyed once the project is completed.

Stroke survivor workshop: Any information, which is collected about the study participants, or is provided during the study, will be kept strictly confidential. Participants' personal details will be removed so that they will only be identifiable by a project number and only the CI and her supervisory team will have access to their details. All information will be held securely for a period of 10 years, as required by Glasgow School of Art. However, any audio/video-recorded information gathered from participants during the workshop will be destroyed once the project is completed.

Rehabilitation professional workshop: Any information, which is collected about the therapists, or is provided during the study, will be kept strictly confidential. The therapists' personal details will be removed so that they will only be identifiable by a project number and only the CI and her supervisory team will have access to their details. All information will be held securely for a period of 10 years, as required by Glasgow School of Art. However, any audio/video-recorded information gathered from the therapists during the workshop will be destroyed once the project is completed.

A40. Who will have access to participants' personal data during the study? Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.

Any participants' personal data information will be managed by the chief investigator. However, this study will require a transcriber to transcribe audio-data. The transcriber will have access to the interview recording once the interview has taken place but as that recording will not contain anything personal or any identifiable marks that could trace this to a particular stroke survivor, there is no issue on confidentiality.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

The data collected will be analysed by Sandra, the Chief investigator at The Glasgow School of Art.

A42. Who will have control of and act as the custodian for the data generated by the study?

| | |
|----------------|--|
| | Title Forename/Initials Surname |
| | Ms Sandra Neves |
| Post | Student |
| Qualifications | Postgraduate Degree in Inclusive Design Graduate in Product and Interior Design |
| Work Address | The Glasgow School of Art 167 Renfrew Street Glasgow |
| Post Code | G3 6RQ |
| Work Email | s.neves1@student.gsa.ac.uk |
| Work Telephone | 01413534442 |
| Fax | |

A43. How long will personal data be stored or accessed after the study has ended?

- Less than 3 months
 3 – 6 months
 6 – 12 months
 12 months – 3 years
 Over 3 years

If longer than 12 months, please justify:

When the results of the study have been analysed, a PhD thesis will be prepared to present at The Glasgow School of Art and also reports will be prepared for publication in journals and presentation at conferences. Any study participants' personal information will be anonymised.

A44. For how long will you store research data generated by the study?

Years: 2
Months:

A45. Please give details of the long term arrangements for storage of research data after the study has ended. Say where data will be stored, who will have access and the arrangements to ensure security.

Any information related to audio/video will be password protected files and locked filing cabinet. The chief investigator will lodge hard and electronic copies with her academic supervisor. The academic supervisor has to comply with the GSA Data Protection Policy.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

Yes No

If Yes, please give details. For monetary payments, indicate how much and on what basis this has been determined.
The workshop for rehabilitation professionals will be conducted in a meeting space at The Glasgow School of Art campus. Lunch and transport cost will be provided.

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

Yes No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

Yes No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

Yes No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

Yes No

Please give details, or justify if not registering the research.

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? Tick as appropriate:

- Peer reviewed scientific journals
- Internal report
- Conference presentation
- Publication on website
- Other publication
- Submission to regulatory authorities
- Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- No plans to report or disseminate the results
- Other (please specify)

Thesis

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

N/A

A53. Will you inform participants of the results?

Yes No

Please give details of how you will inform participants or justify if not doing so.

When the results of the study have been analysed, a summary of the results of the study will also be available for the participants if they wish. The chief investigator will discuss this individually with each participant at the final of the study.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? Tick as appropriate:

- Independent external review
- Review within a company
- Review within a multi-centre research group
- Review within the Chief Investigator's institution or host organisation
- Review within the research team
- Review by educational supervisor
- Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:

This study has followed two stages of ethics review procedures.

Stage 1

A Preliminary Ethical Assessment Form at The Glasgow School of Art was completed with an overview of the study attached and reviewed by internal Ethics co-ordinator. Through the review some issues emerged such as the collaborator and rehabilitation professionals referred on the study are in the employ of NHS organizations. Advice by the Scottish Research Ethics Service was requested to clarify if the study involve to follow NHS Ethics review process.

Stage 2

This study will be an approval via IRAS, local NHS Research & Development Office, The Glasgow School of Art Ethics co-ordinator's and academic supervisor's reviews.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A59. What is the sample size for the research? How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.

Total UK sample size: 10
 Total international sample size (including UK): 10
 Total in European Economic Area: 10

Further details:

The sample selected to this study reflects particular features, or specific groups within, the population under study. The sample selected is not intended, non-required to be statistically representative. The basis of selection is on the key characteristic of the specific population being studied (Ritchie and Lewis 2006). To achieve the aim, the chief investigator needs to collect information-rich accounts from both stroke survivors and rehabilitation professionals. This

study selects the sample, which will best answer the research questions.

Stroke survivors
 The chief investigator decided on a sample size, a minimum of six adults was deemed large enough to capture the types of sources of information, which the study need, which are their experiences and ideas. The sample will be from a range of experiences across a number of eating difficulties associated with impacts of stroke.
 Interviews will gather six participant's 'stories' accounts.
 A workshop will collect a map of participant's ideas.

Rehabilitation professionals
 The chief investigator decided on a sample size of four professionals who represent a multidisciplinary team involved with stroke care - a nurse, a speech therapist, an occupational therapist and a dietitian - was deemed large enough to capture the types of sources of information which the study need which are their ideas. The sample will be from a range of expertise involved to plan the mealtime in rehabilitation.
 A workshop will collect a map of participants' ideas.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

As the purpose of this study is to give voice to participants and represent their experiences and ideas, the chief investigator indicates the sample selected to this study reflects the population under study.

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

This study is not intended, nor requires to be statistically representative. The methods of analysis will be appropriate for qualitative research by which the data will be analysis through a framework analysis which provides a step-by-step guide to assist the chief investigator to manager, conceptualise and describe the data (Green and Thorogood, 2004). The study aims to bring a descriptive proposal for a co-designed new mealtime experience.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

| | |
|----------------|--|
| | Title Forename/Initials Surname |
| | Mrs Katrina Brennan |
| Post | Stroke Managed Clinical Network Manager |
| Qualifications | RGN |
| Employer | NHS Lanarkshire |
| Work Address | GrenLyon Building, Coathill Hospital, Coatbridge |
| Post Code | ML5 4DN |
| Telephone | 01236707724 |
| Fax | |
| Mobile | 07909111642 |
| Work Email | katrina.Brennan@lanarkshire.scot.nhs.uk |

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status: NHS or HSC care organisation Commercial status:
 Academic
 Pharmaceutical industry
 Medical device industry
 Local Authority
 Other social care provider (including voluntary sector or private organisation)
 Other

If Other, please specify:

Contact person

Name of organisation The Glasgow School of Art
 Given name Alison
 Family name Hay
 Address 167 Renfrew Street
 Town/city Glasgow
 Post code G3 6RQ
 Country UNITED KINGDOM
 Telephone 01415661408
 Fax
 E-mail a.hay@gsa.ac.uk

Is the sponsor based outside the UK?
 Yes No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A65. Has external funding for the research been secured?

Funding secured from one or more funders
 External funding application to one or more funders in progress
 No application for external funding will be made

What type of research project is this?

Standalone project
 Project that is part of a programme grant
 Project that is part of a Centre grant
 Project that is part of a fellowship/ personal award/ research training award
 Other

Other – please state:

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? Please give details of subcontractors if applicable.

Yes No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

Yes No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68. Give details of the lead NHS R&D contact for this research:

| | |
|--------------|--|
| | Title Forename/Initials Surname |
| | Mr Raymond Hamill |
| Organisation | R&D Department Corporate Services Building |
| Address | Monkscourt Avenue Airdrie |
| Post Code | ML6 0JS |
| Work Email | raymond.hamill@lanarkshire.scot.nhs.uk |
| Telephone | 01236712460 |
| Fax | |
| Mobile | 07779161388 |

Details can be obtained from the NHS R&D Forum website: <http://www.rdforum.nhs.uk>

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/09/2012

Planned end date: 01/12/2012

Total duration:

Years: 0 Months: 3 Days: 0

A71-1. Is this study?

Single centre
 Multicentre

A71-2. Where will the research take place? (Tick as appropriate)

England
 Scotland
 Wales
 Northern Ireland
 Other countries in European Economic Area

Total UK sites in study

Does this trial involve countries outside the EU?

Yes No

A72. What host organisations (NHS or other) in the UK will be responsible for the research sites? *Please indicate the type of organisation by ticking the box and give approximate numbers of planned research sites:*

- NHS organisations in England
- NHS organisations in Wales
- NHS organisations in Scotland 1
- HSC organisations in Northern Ireland
- GP practices in England
- GP practices in Wales
- GP practices in Scotland
- GP practices in Northern Ireland
- Social care organisations
- Phase 1 trial units
- Prison establishments
- Probation areas
- Independent hospitals
- Educational establishments 1
- Independent research units
- Other (give details)

Total UK sites in study: 2

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

Yes No

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

This study will be reviewed regularly by the Director of Studies as a standing agenda item. The Research Developer from the Research Ethics Committee at The Glasgow School of Art will advice and monitor ethical issues.

A76. Insurance/ indemnity to meet potential legal liabilities

Note: in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

- NHS indemnity scheme will apply (NHS sponsors only)
- Other insurance or indemnity arrangements will apply (give details below)

The Glasgow School of Art possess indemnity cover with company to be determined to the value of £2,000,000 for the management of the research.

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? Please tick box(es) as applicable.

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

- NHS indemnity scheme will apply (protocol authors with NHS contracts only)
 Other insurance or indemnity arrangements will apply (give details below)

The Glasgow School of Art possess indemnity cover with company to be determined to the value of £2,000,000 for the design of the research.

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

- NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)
 Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

The Glasgow School of Art possess indemnity cover with company to be determined to the value of £2,000,000 for the conduct of the research.

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

- Yes No Not sure

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.

| Research site | | Investigator/ Collaborator/ Contact | |
|------------------|------------------------------------|-------------------------------------|---------|
| Institution name | NHS Lanarkshire | Title | Mrs |
| Department name | Stroke MCN | First name/ Initials | Katrina |
| Street address | Coathill Hospital, Hospital Street | Surname | Brennan |
| Town/city | Coatbridge | | |
| Post Code | ML5 4DN | | |
| Institution name | The Glasgow School of Art | Title | Ms |
| Department name | Design | First name/ Initials | Sandra |
| Street address | 167 Renfrew Street | Surname | Neves |
| Town/city | Glasgow | | |
| Post Code | G3 6RQ | | |

PART D: Declarations**D1. Declaration by Chief Investigator**

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.
4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.
5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.
7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.
9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
 - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
 - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
 - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
 - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.
11. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication *(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

- Chief Investigator
 Sponsor

- Study co-ordinator
- Student
- Other – please give details
- None

Access to application for training purposes (Not applicable for R&D Forms)

Optional – please tick as appropriate:

I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

Signature:

Sandra Neves

Print Name:

Sandra Neves

Date:

30/07/2012

(dd/mm/yyyy)

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.
2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.
3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.
4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.
7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Signature:



Print Name:

Dr Ken Neil

Post:

Acting Head of Research & Graduate School

Organisation:

The Glasgow School of Art

Date:

30/07/2012

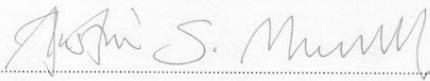
(dd/mm/yyyy)

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.
2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.
3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.
4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

Signature:



Print Name:

Professor Alastair Macdonald

Post:

Senior Researcher School of Design

Organisation:

The Glasgow School of Art

Date:

30/07/2012 (dd/mm/yyyy)

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please enter a short title for this project (maximum 70 characters)
Using people-centred design methods to co-design a new stroke mealtime

1. Is your project research?

Yes No

2. Select one category from the list below:

- Clinical trial of an investigational medicinal product
- Clinical investigation or other study of a medical device
- Combined trial of an investigational medicinal product and an investigational medical device
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
- Basic science study involving procedures with human participants
- Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- Study involving qualitative methods only
- Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
- Study limited to working with data (specific project only)
- Research tissue bank
- Research database

If your work does not fit any of these categories, select the option below:

Other study

2a. Please answer the following question(s):

- a) Does the study involve the use of any ionising radiation? Yes No
- b) Will you be taking new human tissue samples (or other human biological samples)? Yes No
- c) Will you be using existing human tissue samples (or other human biological samples)? Yes No

3. In which countries of the UK will the research sites be located?(Tick all that apply)

- England
- Scotland
- Wales
- Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- England
 Scotland
 Wales
 Northern Ireland
 This study does not involve the NHS

4. Which review bodies are you applying to?

- NHS/HSC Research and Development offices
 Research Ethics Committee
 National Information Governance Board for Health and Social Care (NIGB)
 Ministry of Justice (MoJ)
 National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

5. Will any research sites in this study be NHS organisations?

- Yes No

6. Do you plan to include any participants who are children?

- Yes No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

- Yes No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the NIGB Ethics and Confidentiality Committee to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

- Yes No

9. Is the study or any part of it being undertaken as an educational project?

- Yes No

Please describe briefly the involvement of the student(s):
The student is the chief investigator which will be involved in designing and conducting the research project such as carrying out interviews and workshops.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

- Yes No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of

its divisions, agencies or programs?

Yes No

Site-Specific Information Form (NHS sites)

Is the site hosting this research a NHS site or a non-NHS site? NHS sites include Health and Social Care organisations in Northern Ireland. The sites hosting the research are the sites in which or through which research procedures are conducted. For NHS sites, this includes sites where NHS staff are participants.

- NHS site
- Non-NHS site

This question must be completed before proceeding. The filter will customise the form, disabling questions which are not relevant to this application.

One Site-Specific Information Form should be completed for each research site and submitted to the relevant R&D office with the documents in the checklist. See guidance notes.

The data in this box is populated from Part A:

Title of research:
Using people-centred design methods to co-design a new stroke mealtime experience in rehabilitation

Short title: Using people-centred design methods to co-design a new stroke mealtime

Chief Investigator: Title Forename/Initials Surname
Ms Sandra Neves

Name of NHS Research Ethics Committee to which application for ethical review is being made:
West of Scotland REC 5

Project reference number from above REC: 12/WS/0193

1-1. Give the name of the NHS organisation responsible for this research site

NHS Lanarkshire

1-2. In which country is the research site located?

- England
- Wales
- Scotland
- Northern Ireland

1-3. Is the research site a GP practice or other Primary Care Organisation?

Yes No

2. Who is the Principal Investigator or Local Collaborator for this research at this site?

Select the appropriate title: Principal Investigator
 Local Collaborator

Title Forename/Initials Surname
 Mrs Katrina Brennan

Post Stroke Managed Clinical Network Manager

Qualifications RGN

Organisation NHS Lanarkshire

Work Address GlenLyon Building, Coathill Hospital, Coatbridge

PostCode ML5 4DN

Work E-mail katrina.Brennan@lanarkshire.scot.nhs.uk

Work Telephone 01236707724

Mobile 07909111642

Fax

a) Approximately how much time will this person allocate to conducting this research? *Please provide your response in terms of Whole Time Equivalent (WTE).*
 0.1 WTE

b) Does this person hold a current substantive employment contract, Honorary Clinical Contract or Honorary Research Contract with the NHS organisation or accepted by the NHS organisation? Yes No

A copy of a current CV for the Principal Investigator (maximum 2 pages of A4) must be submitted with this form.

3. Please give details of all locations, departments, groups or units at which or through which research procedures will be conducted at this site and describe the activity that will take place.

Please list all locations/departments etc where research procedures will be conducted within the NHS organisation, describing the involvement in a few words. Where access to specific facilities will be required these should also be listed for each location.

Name the main location/department first. Give details of any research procedures to be carried out off site, for example in participants' homes.

| Location | Activity/facilities |
|--|---|
| 1 Ward 21, Monklands Hospital NHS Lanarkshire | Staff will have a meeting out with this location at Glasgow School of Art |

5. Please give details of all other members of the research team at this site.

6. Does the Principal Investigator or any other member of the site research team have any direct personal involvement (e.g. financial, share-holding, personal relationship etc) in the organisation sponsoring or funding the research that may give rise to a possible conflict of interest?

Yes No

7. What is the proposed local start and end date for the research at this site?

Start date: 01/09/2012

| | |
|--------------------|------------|
| End date: | 01/12/2012 |
| Duration (Months): | 3 |

8-1. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. (These include seeking consent, interviews, non-clinical observations and use of questionnaires.)

Columns 1-4 have been completed with information from A18 as below:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention would have been routinely given to participants as part of their care, how many of the total would have been routine?
3. Average time taken per intervention (minutes, hours or days)
4. Details of who will conduct the procedure, and where it will take place

Please complete Column 5 with details of the names of individuals or names of staff groups who will conduct the procedure at this site.

| Intervention or procedure | 1 | 2 | 3 | 4 | 5 |
|---------------------------------------|---|---|----|---|--|
| Stroke survivors Interviews | 4 | - | 9h | i) The stroke manager for NHS Lanarkshire will identify potential participants through the local community stroke survivors support group and introduce the chief investigator to the group/s. (1h) ii) The CI will be invited to present the study to the support group members and provide information sheets and criteria for participation (see appendices attached). She will be on hand to answer any questions or queries regarding the study and arrange with the members of the support group a date and time to return to recruit potential participants. (1h) iii) Prior to gaining written informed consent the CI will ensure participants meet the study criteria and fully understand the purpose of the study. (1h) iv) Study participants will be interviewed individually at a time and place, which is convenient and suitable for them. Each interview will allow participants individually share with the CI their retrospective accounts of their mealtime experience during their stroke rehabilitation in hospital. (1h each (x6)) | i) Mrs Katrina Brennan ii) Mrs Katrina Brennan and Ms Sandra Neves iii) Ms Sandra Neves iv) Ms Sandra Neves |
| Stroke survivors Workshop | 3 | - | 9h | i) At the end of the interview participants will be invited to attend a workshop to share their ideas on the co-design of a new mealtime experience. Again they will be informed that their participation is voluntary and they can withdraw at any time. (30 minutes each (x6)) ii) The CI will liaise with potential participants on a date venue and time that will be suitable for the majority. Potential participants will be provided with an overview of the workshop programme and written informed consent gained prior to their participation in the workshop. (2h) iii) A group of study participants will be participating in a workshop at a time and place, which is convenient and suitable for them. The workshop will allow which participants share with the CI and other similar participants their ideas about how the stroke mealtime experience could be improved in the future. (3h) | i) Ms Sandra Neves ii) Ms Sandra Neves iii) Ms Sandra Neves |
| Rehabilitation professionals Workshop | 4 | - | 6h | i) The stroke manager for NHS Lanarkshire will identify potential rehabilitation therapists who represent the multidisciplinary team involved in stroke care. (1h) ii) The stroke manager will organise a meeting with them to meet the Chief Investigator who will be invited to present her study. The CI will discuss their participation in the study and provide them with information sheets (see appendix attached). The CI will be on hand to answer any questions or queries regarding the study. (1h) iii) The CI will contact the therapists several days later to arrange a date venue and time that will be suitable for them. Therapists will be provided with an overview of the workshop programme and written | i) Mrs Katrina Brennan ii) Mrs Katrina Brennan and Ms Sandra Neves iii) Ms Sandra Neves iv) Ms Sandra Neves |

informed consent gained prior to their participation in the workshop. (1h)
 iv) A multidisciplinary group of therapists will be participating in a workshop at a time, which is suitable for them and a designated space at The Glasgow School of Art campus in Glasgow. The workshop will allow which the therapists share with the CI and other therapists their ideas about how the stroke mealtime could be improved in the future. (3h)

8-2. Will any aspects of the research at this site be conducted in a different way to that described in Part A or the protocol?

Yes No

If Yes, please note any relevant changes to the information in the above table.

Are there any changes other than those noted in the table?

10. How many research participants/samples is it expected will be recruited/obtained from this site?

Stroke survivor people, Adults (N=6) to interview and participate in a workshop.

NHS rehabilitation professionals (N=4) to participate in a workshop.

11. Give details of how potential participants will be identified locally and who will be making the first approach to them to take part in the study.

The person that has agreed to collaborate with this research proposal is Mrs Katrina Brennan, Stroke Managed Clinical Network Manager.

Mrs Brennan has identified one of stroke community group in Scotland as being suitable to recruit stroke survivor people and has advised the nurse specialist NHS Lanarkshire about the research. She has also identified one of stroke rehabilitation Unit in hospital in scotland as being appropriated to recruit professionals and has advised the rehabilitation professional team about the research.

12. Who will be responsible for obtaining informed consent at this site? What expertise and training do these persons have in obtaining consent for research purposes?

| Name | Expertise/training |
|-----------------|--|
| Ms Sandra Neves | As part of her doctoral training, the chief investigator has been made aware of the importance of research ethics and embedded this in the design of her research. The process of gaining informed consent and the legislation governing this was outlined by the Glasgow School of Art ethics co-ordinator as part of training and, as part of obtaining institutional approval for this study, has been discussed in detail. We can meet to go through informed consent at some point prior to the study taking place. |

15-1. Is there an independent contact point where potential participants can seek general advice about taking part in research?

N/A

15-2. Is there a contact point where potential participants can seek further details about this specific research project?

They can contact Professor Macdonald (Director of Studies) by email and/or phone.

16. Are there any changes that should be made to the generic content of the information sheet to reflect site-specific

issues in the conduct of the study? A substantial amendment may need to be discussed with the Chief Investigator and submitted to the main REC.

No

Please provide a copy on headed paper of the participant information sheet and consent form that will be used locally. Unless indicated above, this must be the same generic version submitted to/approved by the main REC for the study while including relevant local information about the site, investigator and contact points for participants (see guidance notes).

17. What local arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? (e.g. translation, use of interpreters etc.)

This study will provide different ways of presenting information using, verbal, written and visual such as diagrams and illustrations to facilitate communication.

18. What local arrangements will be made to inform the GP or other health care professionals responsible for the care of the participants?

N/A

19. What arrangements (e.g. facilities, staffing, psychosocial support, emergency procedures) will be in place at the site, where appropriate, to minimise the risks to participants and staff and deal with the consequences of any harm?

Activity will be within Stroke Unit at NHS Lanarkshire Hospital and all of the local risk assessments will be in place.

The research presents little risk of harm or distress to participants. The participant information sheet clearly signposts to mechanisms that participants can complain to if they feel the research has not been carried out with due care or has caused greater distress than anticipated. The researcher will make herself aware of all policies and guidelines (Health and Safety, fire drills etc) at the site to help ensure the physical safety of herself and participants throughout the duration of the study.

20. What are the arrangements for the supervision of the conduct of the research at this site? Please give the name and contact details of any supervisor not already listed in the application.

Professor Macdonald will ensure the researcher executes the research with all due care and diligence. Mrs Katrina Brennan will oversee all activity in relation to this research in line with NHS Lanarkshire R & D Policies.

21. What external funding will be provided for the research at this site?

- Funded by commercial sponsor
- Other funding
- No external funding

How will the costs of the research be covered?

23. Authorisations required prior to R&D approval

This section deals with authorisations by managers within the NHS organisation. It should be signed in accordance with the guidance provided by the NHS organisation. This may include authorisation by clinical supervisors, line managers, service managers, support department managers, pharmacy, data protection officers or finance managers, depending on the nature of the research. Managers completing this section should confirm in the text what the authorisation means, in accordance with the guidance provided by the NHS organisation.

This section may also be used by university employers or research support staff to provide authorisation to NHS organisations, in accordance with guidance from the university.

1. Type of authorisation:

| |
|--|
| Title Forename/Initials Surname |
| Post Qualifications Organisation Work Address |
| PostCode Work E-mail Work Telephone Mobile Fax |
| Signature: |
| Date: |

Declaration by Principal Investigator or Local Collaborator

1. The information in this form is accurate to the best of my knowledge and I take full responsibility for it.
2. I undertake to abide by the ethical principles underpinning the World Medical Association's Declaration of Helsinki and relevant good practice guidelines in the conduct of research.
3. If the research is approved by the main REC and NHS organisation, I undertake to adhere to the study protocol, the terms of the application of which the main REC has given a favourable opinion and the conditions requested by the NHS organisation, and to inform the NHS organisation within local timelines of any subsequent amendments to the protocol.
4. If the research is approved, I undertake to abide by the principles of the Research Governance Framework for Health and Social Care.
5. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to the conduct of research.
6. I undertake to disclose any conflicts of interest that may arise during the course of this research, and take responsibility for ensuring that all staff involved in the research are aware of their responsibilities to disclose conflicts of interest.
7. I understand and agree that study files, documents, research records and data may be subject to inspection by the NHS organisation, the sponsor or an independent body for monitoring, audit and inspection purposes.
8. I take responsibility for ensuring that staff involved in the research at this site hold appropriate contracts for the duration of the research, are familiar with the Research Governance Framework, the NHS organisation's Data Protection Policy and all other relevant policies and guidelines, and are appropriately trained and experienced.
9. I undertake to complete any progress and/or final reports as requested by the NHS organisation and understand that continuation of permission to conduct research within the NHS organisation is dependent on satisfactory completion of such reports.
10. I undertake to maintain a project file for this research in accordance with the NHS organisation's policy.
11. I take responsibility for ensuring that all serious adverse events are handled within the NHS organisation's policy for reporting and handling of adverse events.

12. I understand that information relating to this research, including the contact details on this application, will be held by the R&D office and may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.
13. I understand that the information contained in this application, any supporting documentation and all correspondence with the R&D office and/or the REC system relating to the application will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.

Signature of Principal Investigator
or Local Collaborator:

Sandra Neves

Print Name:

Ms Sandra Neves

Date:

30/07/2012

APPLICATION TO NHS R&D OFFICE


All studies except clinical trials of investigational medicinal products

Short Title of Study: Using people-centred design methods to co-design a new stroke mealtime

Name of Principal Investigator or Local Collaborator: Mrs Katrina Brennan

Sponsor: The Glasgow School of Art

Please complete this checklist and send it with your application to each relevant R&D office

- Please send a disk containing one file for each document. Application form files should be saved in both pdf and XML format.
- Where signed documents are required, please send either a hard copy, a faxed copy or a scanned electronic file. Check that the submission code appears on each page of the application form before sending. It is acceptable to send hard copies of signature pages separately, as long as the submission code at the top of the page is the same as on the electronic version.
- All letters must be dated. All other accompanying documents must bear version numbers and dates.
- All documents listed below that are applicable to the application must be submitted for the application to be valid.
- When sending hard copies, please do NOT staple documents as they may need to be photocopied.
- This button  allows you to add extra documents of the same type. Include subtitles if appropriate, e.g. "Information sheet for relative".

| Document | Subtitle | Enclosed | Office Use |
|--|--|----------|------------|
| R&D Form (signed/authorised) | NHS R&D Form | Yes | |
| NHS/HSC Site-Specific Information (SSI) Form (signed/authorised) | | No | |
| Summary CV for Chief Investigator (CI) | Sandra M P Neves | Yes | |
| Summary CV for Principal Investigator (PI) | | No | |
| Summary CV for local researchers and research nurses | | No | |
| Summary CV for student | | No | |
| Research protocol or project proposal | Using people-centred design methods to co-design a new mealtime experience in rehabilitation | Yes | |
| Participant information sheet (PIS) - local version | Stroke Survivors | Yes | |
| Participant information sheet (PIS) - local version | Rehabilitation Professionals | Yes | |
| Participant consent form - local version | Stroke Survivors (Interview) | Yes | |
| Participant consent form - local version | Stroke Survivors (Workshop) | Yes | |
| Participant consent form - local version | Rehabilitation Professionals (Workshop) | Yes | |

| | | | |
|--|---|-----|--|
| Letters of invitation to participant - local version | | No | |
| GP/consultant information sheets or letters - local version | | No | |
| Evidence of Sponsor insurance or indemnity (non-NHS Sponsors only) | Glasgow School of Art: Professional Indemnity Cover 2012-13 | Yes | |
| Letter from statistician | | No | |
| Letter from funder | | No | |
| Referee's report or other scientific critique report | | No | |
| Summary, synopsis or diagram (flowchart) of protocol in non-technical language | | No | |
| Interview schedules or topic guides for participants | Topic Guide Interview Sheet (Stroke Survivors) | Yes | |
| Interview schedules or topic guides for participants | Workshop Design Overview Sheet (Stroke Survivors) | Yes | |
| Interview schedules or topic guides for participants | Workshop Design Overview Sheet (Rehabilitation Professionals) | Yes | |
| Validated questionnaire | | No | |
| Non-validated questionnaire | | No | |
| Copies of advertisement materials for research participants | | No | |
| Instructions for use of medical device | | No | |
| Documents required prior to final NHS permission (may be submitted after the initial application) | | | |
| Letter from sponsor | | No | |
| REC favourable opinion letter and all correspondence | | No | |
| Confirmation of REC favourable opinion for any substantial amendments and all correspondence | | No | |
| Confirmation of any other regulatory approvals (e.g. NIGB) and all correspondence | | No | |

West of Scotland REC
Ethics Department
Ground Floor, The Tennent Institute
Western Infirmary
38 Church Street
GLASGOW G11 6NT

30.07.12

Sponsor Declaration Letter

AH/KN

To Whom It May Concern;

I confirm that Glasgow School of Art will act as Sponsor for the study entitled *using people-centred design methods to co-design a new stroke mealtime experience in rehabilitation* and will use all best endeavours to comply with the requirements of the role. This study is being run by Ms Sandra Neves as part of her doctoral degree training under the supervision of Professor Alastair Macdonald, School of Design.

Yours sincerely,



Dr Ken Neil
Acting Head of Research & Graduate School

PROF. SEONA REID CBE
BA HonDLitt HonDArt FRSA
Director

167 Renfrew Street
Glasgow
United Kingdom
G3 6RQ

t +44(0)141 353 4500
f +44(0)141 353 4746
info@gsa.ac.uk
www.gsa.ac.uk

To Whom It May Concern

8th July 2012

Dear Sir/Madam

Glasgow School of Art: Professional Indemnity Cover 2012-13

This is to confirm that the School will have Professional Indemnity insurance in place from 2012/13 onwards.

The School is presently tendering its insurance arrangements from 2012/13 onwards through the Advanced Procurement for Universities and Colleges (APUC) procedure, and will consider tender applications shortly. Included in the tender specification is Professional Indemnity cover with a Limit of Liability of £2,000,000.

When the tender outcome is known and contracts awarded, I shall be happy to provide details of the School's broker and individual policies.

Yours sincerely



John Martin
Assistant Company Secretary
j.martin@gsa.ac.uk

PROF. SEONA REID CBE
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Director

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www.gsa.ac.uk



Sandra Neves
 167 Renfrew Street
 Glasgow, G3 6RQ
 Tel: 0141 353 4442

STUDY TITLE

Exploring lived experiences during mealtimes in rehabilitation

Topic Guide Interview Sheet (Stroke Survivors)

Style: Interviews will be conducted face to face in a semi-structured style. The interviewer will probe the responses given by the interviewee.

Data capture: All interviews will be recorded using a digital voice recorder and subsequently fully transcribed per verbatim.

Introduction

I would like to thank you for agreeing to participate in this interview. This interview is to gather your views and opinions of your experience of mealtimes during your stroke rehabilitation. There are no right or wrong answers and I would like you to be open and honest about your experience of mealtimes during your stay in hospital after your stroke. Please feel free to expand on any question that I ask you and if there are any questions that I do not ask that you think are particularly relevant to your involvement in the study then please let me know.

Participant ID number.....

Date/Time.....

Overview of the Interview

| | |
|------------------|---|
| Question | What insights about mealtime experiences during hospital rehabilitation can stroke survivors reveal? |
| Rationale | This topic guide is designed to enable stroke survivors to express their lived experiences about their mealtimes during rehabilitation in hospital. |

Description

A group of 6 participants will be individually interviewed by the researcher (facilitator) of the study. The interview will be structured using the conceptual framework (fig 1) which considers four inter-related aspects of the mealtime experience:

- 1) Sensorial
- 2) Emotional
- 3) Physical
- 4) Social

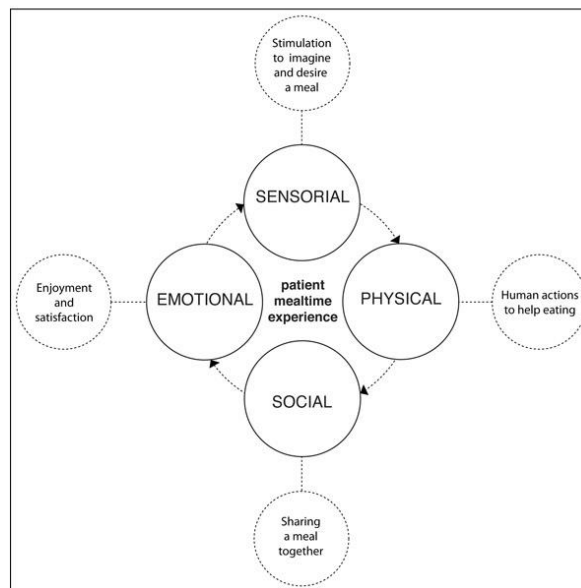


Fig 1: Conceptual framework

Interview Script
ABOUT YOUR STROKE

1. Can you remember how long you were in hospital?
2. Did you experience any difficulties during hospital mealtimes?
 - Can you give me an example?

3. Did you receive care assistance to help you eat?

- Can you explain why you needed care assistance?

4. Did this change over time during your stay?**MEALTIMES**

My understanding of the mealtimes for stroke patients in rehabilitation in hospital is shown in the diagram (fig 2). *(Show diagram to participant)*

5. Could you describe briefly to me how you experienced the sequence of events during a typical mealtime?***Before you received your meal***

My understanding of the type of environment you ate your food in is shown in the picture. *(Show picture to participant)*

6. Is this how you experienced the ward environment at mealtimes? If not, how would you describe this?**7. Was it an attractive or unattractive place to eat?**

- What kinds of smells were there?
- What were the sounds did you heard?
- What were you seeing and/or looking at while you ate your meal?

8. How did these sensory aspects affect you at mealtimes?**9. Can you provide an example of an environment attractive or conducive to eating in – perhaps that you did not have there but wish you had been in?*****When you received your food***

My understanding of the type of food you receive in the hospital is shown in this picture. *(Show picture to participant)*

10. Is this how you remember seeing the food? If not could you describe it?**11. How did you find the visual appearance of the food at your mealtimes? Can you explain your reply thinking?**

- What was the shape like?
- What was the colour like?
- How was it arranged on the plate?

- What kind of thoughts did you have when you looked at the food for the first time?
- Did you express your food likes and dislikes at mealtimes to anyone?
- Did the care assistance and/or ward staff take into account your likes and dislikes about food?

12. How did these visual aspects of food stimulate your appetite and interest in eating?

During the mealtime

13. In what ways did the care assistant help you eat at the mealtimes?

- Can you give me an example?

14. Was there any form of social interaction with patients during mealtimes?

- Can you give me an example?

After you ate the meal

15. What kind of thoughts did you have at this stage?

Overall

16. What in your opinion, are the positive aspects you experienced at mealtime during your hospital stay?

17. What in your opinion, are the aspects that you experienced at mealtime during your hospital stay?

OTHERS

18. Is there anything else you would like to mention that you thought about whilst we have been talking?

Thank you

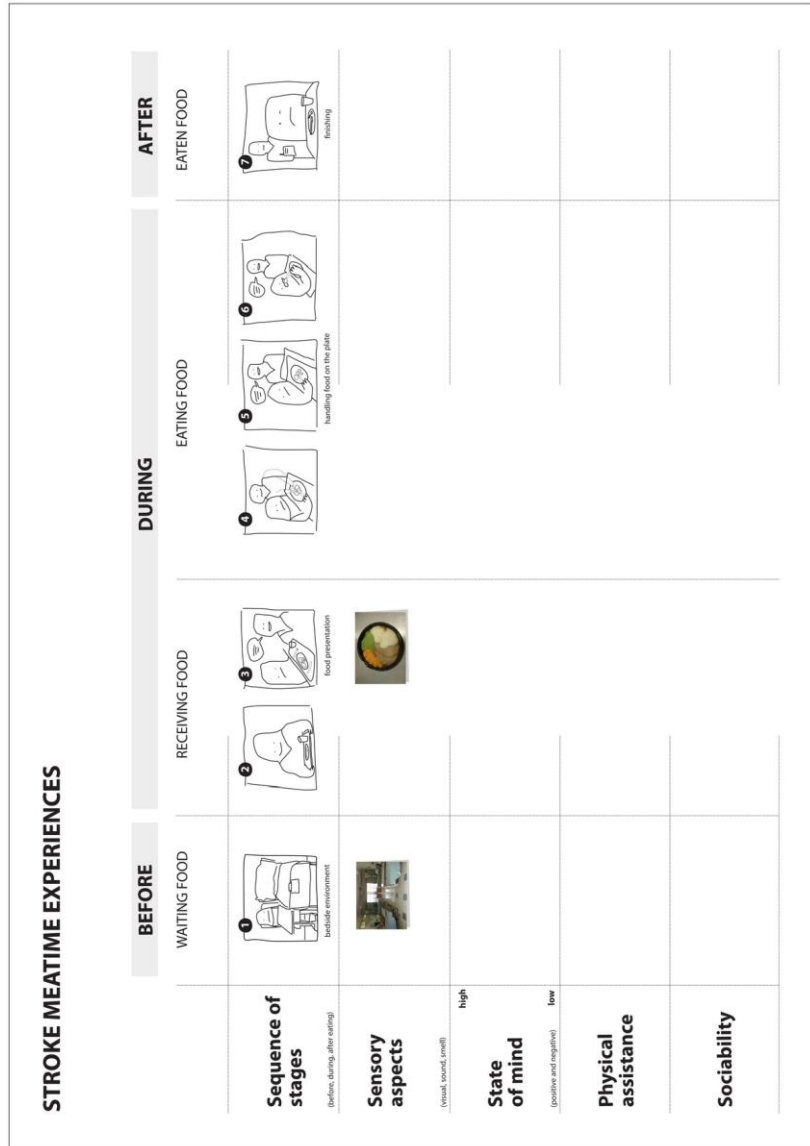


Fig. 2 Example of the diagram on view throughout the interview



Sandra Neves
 167 Renfrew Street
 Glasgow, G3 6RQ
 Tel: 0141 353 4442

STUDY TITLE

Mapping ideas to redesign the mealtime experience in rehabilitation

Workshop Design Overview Sheet (Stroke Survivors)

Style: Workshop design will be conducted with a group of six participants in a meeting room. The participants will co-design a new mealtime experience through design methods.

Data capture: The workshop activities will be recorded using a digital audio/video recorder and subsequently some parts transcribed per verbatim.

Introduction

I would like to thank all of you for agreeing to participate in this workshop. This workshop is to gather your knowledge through the sharing of ideas about how the mealtime experience could be improved during stroke rehabilitation for future patients. There are no right or wrong ideas and I would like all of you to be open and honest to share your ideas and thoughts about what can be done. Please feel free to ask any question that you think are particularly relevant to involve in the study.

Workshop 1
 Date/Time.....

Overview of Activity

Question What ways of improving the mealtime experience for stroke patients during rehabilitation in hospital would stroke survivors propose?

Rationale This activity is designed to help stroke survivors in sharing their knowledge among those who experienced mealtimes in rehabilitation. It will be important for participants to form a shared focus to think about what can be done to improve the stroke mealtime experience.

Description A group of 6 participants will work with the researcher (facilitator) of the study in each session. Following a brainstorming session the group will develop their ideas using a version of the conceptual framework introduced in Activity 1 as a mealtime experience map.

Activity script

Introduction

15 minutes

The researcher briefly introduces the activity and the stroke mealtime event in rehabilitation.

Presentation of the stroke mealtime event

The researcher will prepare a short overview (15 min PowerPoint) of how the stroke mealtime event could be improved in the future with less focus on the functional model and more focus on the sensorial and emotional models. This presentation will be prepared in advance and printouts of the slides will be provided to give the participants an opportunity to take notes.

Activity 1

Sharing ideas

5 minutes

The researcher will brief the group for the next part of the activity.

40 minutes

The group of participants will be asked to imagine the ideal mealtime experience which they would suggest for future patients during rehabilitation in hospital.

The activity will be structured using the conceptual framework (fig 1) which considers four inter-related aspects of the mealtime experience:

- 1) Sensorial
- 2) Emotional
- 3) Physical
- 4) Social.

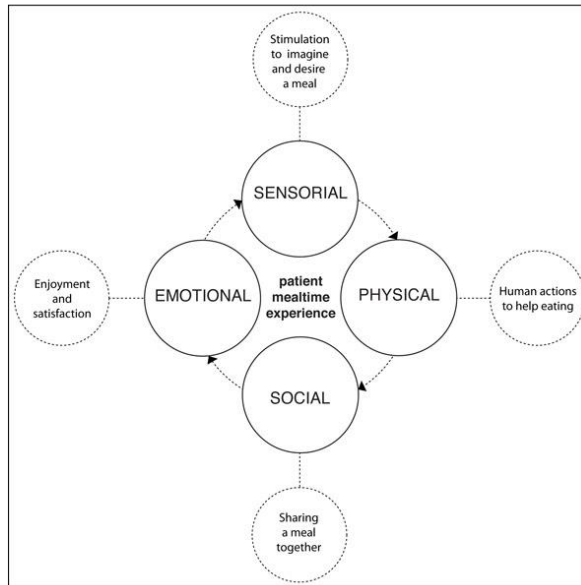


Fig 1: Conceptual framework

The participants will be given a large board for each aspect of the framework (sensorial, emotional, physical and social) on which they can place post-its annotated with their ideas (see fig 2)

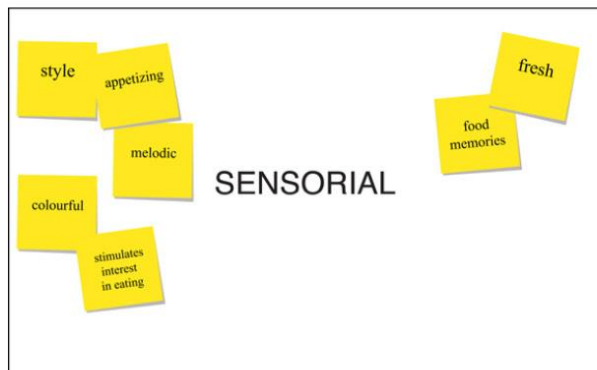


Fig 2: Example of brainstorm board with post-its

To encourage participants' thoughts during the brainstorming activity the researcher will ask a series of questions to help stimulate responses, for example:

What should the ideal mealtime experience be like?
 How would one best stimulate the patient's desire for the meal?
 What should food look like and how should it be presented to the patient?
 What kind of physical assistance should be provided?
 What kind of social rituals should be encouraged?
 What additional aspects should the mealtime provide?

It proposes 10 minutes of activity for each of the 4 categories: sensorial, emotional, physical and social

The output of this session will be ideas to help stimulate thinking for part 2 of the activity.

10 minutes

The group will discuss the ideas they have generated.
 The researcher will summarise the key points for the group.

15 minutes

Coffee break

Activity 2

Mapping ideas

5 minutes

The researcher will brief the group for the second activity.

40 minutes

The group will be asked to further develop their ideas using a version of the conceptual framework introduced in Activity 1 this time structured as a mealtime experience map (fig 3), which illustrates the sequence of events – before, during and after the mealtime and outlines each of the 4 aspects of the mealtime experience. Again, 10 minutes will be allowed per aspect.

The output of part 2 will be a 'co-designed' new stroke mealtime experience for discussion.

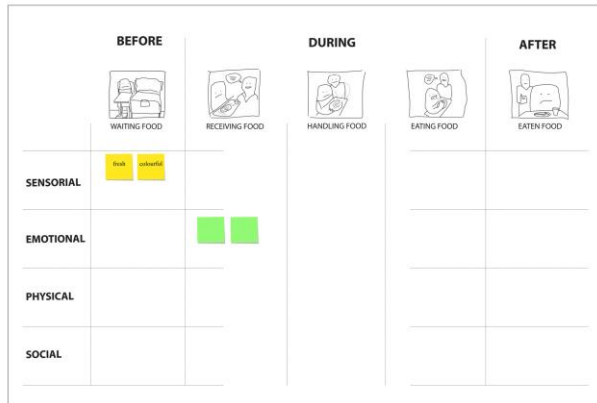


Fig 3: Example of the mealtime experience map

10 minutes

The group will discuss the mealtime experience map (10 minutes).

20 minutes

The researcher summarises the day pointing out some of the most popular and innovative ideas. She then ends the workshop by thanking all participants, and gives them the study information to receive a summary of the findings and get in touch if they have any additional thoughts following the workshop.

Total: 2h and 45 minutes



Sandra Neves
 167 Renfrew Street
 Glasgow, G3 6RQ
 Tel: 0141 353 4442

STUDY TITLE

Mapping ideas to redesign the mealtime experience in rehabilitation

Workshop Design Overview Sheet (Rehabilitation Professionals)

Style: Workshop design will be conducted with a group of four participants in a meeting room. The participants will co-design a new mealtime experience through design methods.

Data capture: The workshop activities will be recorded using a digital audio/video recorder and subsequently some parts transcribed per verbatim.

Introduction

I would like to thank all of you for agreeing to participate in this workshop. This workshop is to gather your knowledge through the sharing of ideas about how the mealtime experience could be improved during stroke rehabilitation for future patients. There are no right or wrong ideas and I would like all of you to be open and honest to share your ideas and thoughts about what can be done. Please feel free to ask any question that you think are particularly relevant to involve in the study.

Workshop 2
 Date/Time.....

Overview of Activity

Question What ways of improving the mealtime experience would rehabilitation professionals propose for stroke patients during rehabilitation in hospital?

Rationale This activity is designed to enable rehabilitation professionals to 'think differently' about their current practices and to consider how they might improve their patients' mealtime experiences and to imagine a quality mealtime experience for

the patient by reflecting on aspects of the mealtime they would not normally consider.

Description

A group of 4 participants will work with the researcher (facilitator) of the study in each session. Following a brainstorming session the group will develop their ideas using a version of the conceptual framework in Activity 2 as a mealtime experience map.

Activity Script

Introduction

15 minutes

The researcher briefly introduces the activity and the stroke mealtime event in rehabilitation.

Presentation of the stroke mealtime event

The researcher will prepare a short overview (15 min PowerPoint) of how the stroke mealtime event could be improved in the future with less focus on the functional model and more focus on the sensorial and emotional models. This presentation will be prepared in advance and printouts of the slides will be provided to give the participants an opportunity to take notes.

Activity 1

Feeling differently

5 minutes

The researcher will brief the group for the next part of the activity.

30 minutes

The group of participants will be asked to develop the patients' current mealtime experience. This activity will be structured by distributing a storyboard template (fig 1) which considers three stages of the mealtime experience: before, during and after.

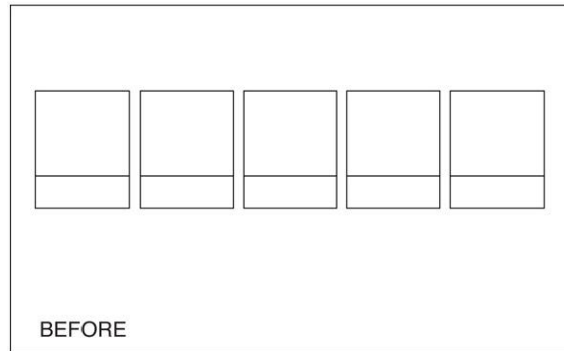


Fig 1: Example of storyboard template

To encourage participants' thoughts the researcher will ask them to role play a fictional character whose profile represents the characteristics of stroke patients. In this way participants consider the characteristics of stroke patients they represent, which enables them to think about the mealtime more from a patient perspective.

It proposes 10 minutes of activity for each of the 3 stages: before, during and after.

The output of this session will be to stimulate thinking for part 2 of the activity.

Activity 2

Sharing ideas

5 minutes

The researcher will brief the group for the second activity.

40 minutes

The group of participants will be asked to imagine the ideal mealtime experience which they would suggest for future patients during rehabilitation in hospital. The activity will be structured using the conceptual framework (fig 2) which considers four inter-related aspects of the mealtime experience:

- 1) Sensorial
- 2) Emotional
- 3) Physical
- 4) Social

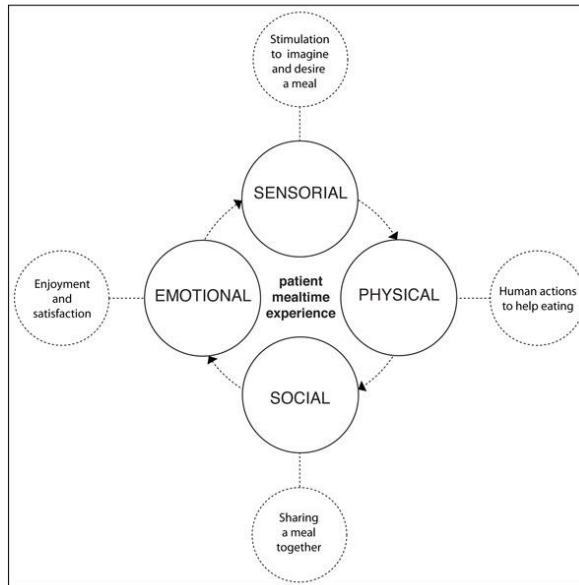


Fig 2: Conceptual framework

The participants will be given a large board for each aspect of the framework (sensorial, emotional, physical and social) on which they can place post-its annotated with their ideas (fig 3)

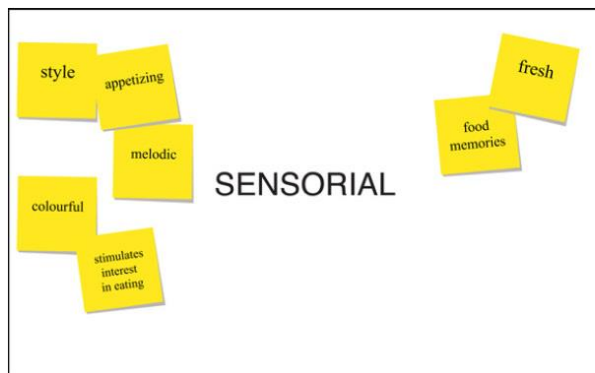


Fig 3: Example of brainstorm board with post-its

To encourage participants' thoughts during the brainstorming activity the researcher will ask a series of questions to help stimulate responses, for example:

What should the ideal mealtime experience be like?
 How would one best stimulate the patient's desire for the meal?
 What should food look like and how should it be presented to the patient?
 What kind of physical assistance should be provided?
 What kind of social rituals should be encouraged?
 What additional aspects should the mealtime provide?

It proposes 10 minutes of activity for each of the 4 categories: sensorial, emotional, physical and social

The output of this session will be ideas to help stimulate thinking for part 3 of the activity.

10 minutes

The group will discuss the ideas they have generated.
 The researcher will summarise the key points for the group.

15 minutes

Coffee break

Activity 3

Mapping ideas

5 minutes

The researcher will brief the group for the third activity.

40 minutes

The group will be asked to further develop their ideas using a version of the conceptual framework introduced in Activity 2 this time structured as a mealtime experience map (fig 4), which illustrates the sequence of events – before, during and after the mealtime and outlines each of the 4 aspects of the mealtime experience. Again, 10 minutes will be allowed per aspect.

The output of part 3 will be a 'co-designed' new stroke mealtime experience for discussion.

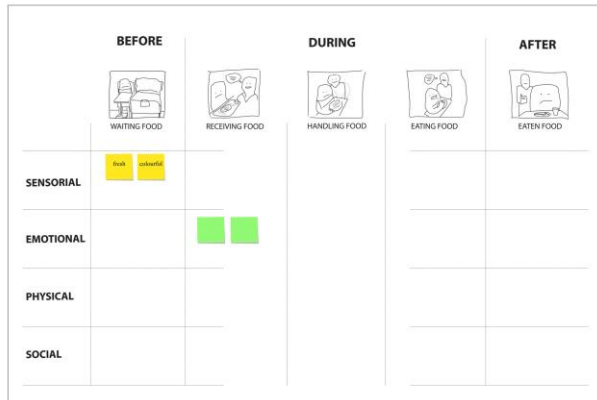


Fig 4: Example of the mealtime experience map

10 minutes

The group will discuss the mealtime experience map (10 minutes).

20 minutes

The researcher summarises the day pointing out some of the most popular and innovative ideas. She then ends the workshop by thanking all participants, and gives them the study information to receive a summary of the findings and get in touch if they have any additional thoughts following the workshop.

Total: 3h and 15 minutes



Sandra Neves
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Tel: 0141 353 4442

PROJECT TITLE

Using people-centred design methods to co-design a new stroke mealtime experience in rehabilitation

Context

Recent design involvement with healthcare has been influenced by participative and 'co-design' approaches, which considers patients and professionals as collaborators in the research process. This collaboration allows for a significant contribution by professionals and patients to explore a wide range of issues and capture their different lived experiences respectively. Design emotion and user-experience literature indicates that design can play a significant role in identifying peoples' emotions to create more positive experiences, for example, constructing 'user' profiles based on an individual's lifestyle and using narrative-based scenarios to describe imagined events and experiences. However, there has been no design involvement with the stroke survivors with the intention of improving hospital food services and mealtimes for these patients. In fact, the 'patient voice' is absent even in clinical studies. This study aims to explore the hypothesis that by involving stroke survivors and rehabilitation professionals in this research they can bring new insights that may contribute to the improvement of the mealtime experience for stroke rehabilitation patients.

The World Health Organisation (WHO) estimates that stroke affects 15 million people worldwide each year with Scotland and Portugal having the highest incidence. Stroke impacts on people's abilities to eat creating a number of physical, cognitive and psychological difficulties, which require rehabilitation. Currently, mealtimes are structured more on clinical models aimed primarily at restoring function, which follow a number of Stroke recommendations from the National Health Service (NHS) on how to plan stroke mealtimes in rehabilitation. However, research into the stroke mealtime reveals that this experience might result in, for example, low morale and nutritional problems (Ekberg et al., 2002; Kumlien and Axelsson 2002; Westergren et al., 2002 and Wright et al., 2005).

The research proposal

This research aims to co-design an improved mealtime experience with stroke survivors and rehabilitation professionals.

Stage 1

The researcher views survivors' voices as significant to express their lived experiences about mealtimes in the post-stroke phase. This research aims to

interview stroke survivors to collect their retrospective accounts of their mealtime experiences during their stroke rehabilitation in hospital. The semi-structured interviews will be conducted with six stroke survivors face-to-face using a topic guide which will allow their thoughts and feelings to be put into words. This will provide new data and insights into the experiences of stroke survivors through their responses. Participants will also be invited to participate in the next stage of this study.

Stage 2

The researcher also considers the stroke survivors as experts who can bring new ideas to improve mealtimes during rehabilitation following stroke based on their past experiences. As this research aims to use co-design approaches through workshop methods both stroke survivors and rehabilitation professionals will be asked to participate in separate workshops, as each of these two groups will have a different perspective on issues. These workshops will bring new knowledge through the sharing of ideas about how the stroke mealtime experience could be improved in the future with less focus on the functional model and more focus on the sensorial and emotional models.

This ethics application is concerned with collecting stroke survivors' past experiences through interviews (dataset 1), stroke survivors' ideas through Workshop 1 (dataset 4), and professionals' ideas through Workshop 2 (dataset 5) (see table 1).

This researcher believes that through design techniques and tools used in both workshops she will collect new insights, which will help in designing a new stroke mealtime experience for future stroke survivors.

Participant numbers

As the purpose of this study is to give voice to participants and represent their experiences and ideas, the researcher indicates the sample selected to this study reflects particular features, or specific groups within, the population under study. The sample selected is not intended, non-required to be statistically representative. The basis of selection is on the key characteristic of the specific population being studied (Ritchie and Lewis 2006). To achieve the aim, the researcher needs to collect information-rich accounts from both stroke survivors and rehabilitation professionals. This study selects the sample, which will best answer the research questions.

Stroke survivors

The researcher decided on a sample size, a minimum of six adults was deemed large enough to capture the types of sources of information, which the study need, which are their experiences and ideas. The sample will be from a range of experiences across a number of eating difficulties associated with impacts of stroke. Interviews will gather six participant's 'stories' accounts. A workshop will collect a map of participant's ideas.

Rehabilitation professionals

The researcher decided on a sample size of four professionals who represent a multidisciplinary team involved with stroke care - a nurse, a speech therapist, an occupational therapist and a dietitian - was deemed large enough to capture the types of sources of information which the study need which are their ideas. The sample will be from a range of expertise involved to plan the mealtime in rehabilitation. A workshop will collect a map of participants' ideas.

Analysis of data

This study is not intended, nor requires to be statistically representative. The methods of analysis will be appropriate for qualitative research by which the data will be analysis through a framework analysis which provides a step-by-step guide to assist the researcher to manager, conceptualise and describe the data (Green and Thorogood, 2004). The study aims to bring a descriptive proposal for a co-designed new mealtime experience.

Research ethics

All participants will provide consent to take part in the research study. They will also be informed that this study is to generate ideas in how to improve the stroke mealtime experience.

Ethical approval will be approved by IRAS, local NHS Research & Development Office, The Glasgow School of Art ethics co-ordinator's and academic supervisor's reviews. This ethical approval relates to an exploration of the stroke mealtime experience conducted with stroke survivors and healthcare professionals to bring a response/answer to the research study hypothesis. This study will have the support and approval of the Stroke Manager of rehabilitation services in Scotland where the study will be conducted.

Table 1 Datasets

| | 'Voice' | Ideas |
|-------------------------------------|---|------------------------|
| Stroke Survivors | Interviews (data 1) | Workshop 1 (data 4) |
| Rehabilitation Professionals | Literature review (data 2) Interviews (data 3) | Workshop 2 (data 5) |



Sandra Neves
167 Renfrew Street
Glasgow, G3 6RQ
Tel: 0141 353 4442

STUDY TITLE

Exploring lived experiences during mealtimes in rehabilitation
and
Mapping ideas to redesign the mealtime experience in
rehabilitation

Participant Information Sheet (Stroke Survivors)

Invitation

Sandra (the researcher) is inviting you to take part in this research study. Before you decide whether to take part, it is important for you to understand why the study is being done and what it involves. Please take some time to read the following information and discuss it with family or friends if you wish.

What is the purpose of this study?

The purpose of this study is to find out what are the mealtime experiences during patients' rehabilitation in hospital. This forms part of a PhD study. To allow Sandra to carry out this study she has been awarded a research grant for four years which will support her PhD Thesis.

Why have you been chosen?

You have been chosen to take part in this study as you have recently been in rehabilitation care in hospital with stroke and your experience and views are important. I hope to recruit into the study 6 stroke survivors in total who are in post-acute stroke rehabilitation in hospital.

Do I have to take part?

It is up to you to decide whether or not take part in the study. This information sheet is yours to keep what ever you decide. If you decide to take part in the study and then change your mind, you can withdraw at any time without giving a reason and

the support you receive will not be affected. **You do not have to make any decisions about the study today.**

Who is organizing the study?

The study has been funded by The Portuguese Foundation for Science and Technology. The sponsor of the study is the School of Design at the Glasgow School of Art.

The study has been approved by IRAS, local NHS Research & Development Office, GSA ethics co-ordinator's and academic supervisor's reviews.

What happens next?

The NHS Lanarkshire nurse specialist has given you this information sheet on the researcher's (Sandra's) behalf and you will inform the nurse specialist if you permit him/her to pass on your contact details to Sandra. If you have given permission she will contact you over the next three or four days to give you time to consider whether you wish to take part in the study. When Sandra contacts you, she will discuss the study with you and answer any questions you may have. If you are considering taking part in the study Sandra will arrange to meet you at your support group meeting. At that meeting she will speak with you about the study again and check that you are still willing to take part. If you agree she will then ask you to sign a standard consent form and you will be given a copy of this to keep.

What will taking part in the study mean for me?

Taking part in the study will mean that you and Sandra will meet twice, once for an interview and once for a workshop. The interview will last between thirty minutes and one hour depending on how much you have to say. The interview will take place towards the end of your support group meeting to discuss your experiences at mealtimes during your rehabilitation in hospital and will be audio recorded. The workshop will take place over 3 hours to discuss and share your ideas with Sandra and 5 other similar participants of how we could bring improvements to the mealtime experience in rehabilitation. The workshop will be audio and video recorded and will take place in your support group meeting. **The interviews and workshop will be arranged at a time that suits you within the support group site. The researcher will secure a space where you feel comfortable to participate in both interview and workshop.**

Will I benefit from taking part?

Sandra cannot promise that taking part in this study will be of direct benefit to you. But, by telling Sandra of your experience, your information and your ideas will be of immense value in understanding what the experiences and ideas of stroke survivors are. In turn, this might help to contribute to improving the mealtimes for people in stroke rehabilitation in the future.

Are there any risks involved in taking part?

It is unlikely that you will come to any harm as a result of taking part in the study, and no special arrangements have been put place for compensation. If you have concerns about the way you are approached or treated during the course of the study, please contact either Sandra or her supervisor Professor Alastair Macdonald at The Glasgow school of Art (0141 353 4715) or alternatively you can contact the National Health Service through the normal complaints mechanisms which will be available to you.

Will taking part influence my care / medical treatment?

Absolutely not. The study is independent of any care or medical treatment you are currently in receipt of. Whether or not you do decide to participate has no bearing on your treatment. If you do decide to participate, your information will be made available solely to the researcher (Sandra) for the purposes of her studies and will not be communicated to any medical professionals co-ordinating your care.

Will my taking part be kept confidential?

Any information which is collected about you, or that you provide during this study, will be kept strictly confidential. In any audio and video recorded material, your personal details will be removed so that you will only be identifiable by a project number and the researcher and her supervision team only will have access to your details. All information will be held securely for a period of 10 years, as required by Glasgow School of Art. However, any audio and video-recorded information from you will be destroyed once the project is completed.

What will happen to the results of the study?

When the results of the study have been analysed, a PhD thesis will be prepared to present at The Glasgow School of Art and also reports will be prepared for publication in journals and presentation at conferences. A summary of the results of the study will also be available to you if you wish; Sandra can discuss this at the final of your interview and workshop.

Thank you for taking the time to read this information.

If you like to find more about the study please feel free to contact me

Sandra Neves
PhD student at The Glasgow School of Art

Tel. 0141 353 4442
Email. s.neves1@student.gsa.ac.uk



Sandra Neves
167 Renfrew Street
Glasgow, G3 6RQ
Tel: 0141 353 4442

STUDY TITLE

Mapping ideas to redesign the mealtime experience in rehabilitation

Participant Information Sheet (Rehabilitation Professionals)

Invitation

Sandra (the researcher) is inviting you to take part in this research study. Before you decide whether to take part, it is important for you to understand why the study is being done and what it involves. Please take some time to read the following information and discuss it with Sandra.

What is the purpose of this study?

The purpose of this study is to find out what are the ideas to contribute into the improvements of the mealtime experiences during patients' rehabilitation in hospital. This forms part of a PhD study. To allow Sandra to carry out this study she has been awarded a research grant for four years, which will support her PhD Thesis.

Why have you been chosen?

You have been chosen to take part in this study as you represent one of the multidisciplinary team members involved with stroke care at mealtimes in rehabilitation in hospital and your experience and views are important. I hope to recruit 4 rehabilitation professionals.

Do I have to take part?

It is up to you to decide whether or not take part in the study. This information sheet is yours to keep what ever you decide. If you decide to take part in the study and then change your mind, you can withdraw at any time without giving a reason. **You do not have to make any decisions about the study today.**

Who is organizing the study?

The study has been funded by The Portuguese Foundation for Science and Technology. The sponsor of the study is the School of Design at the Glasgow School of Art.

The study has been approved by IRAS, local NHS Research & Development Office, GSA ethics co-ordinator and academic supervisors reviews.

What happens next?

The researcher has discussed the study with you and answered any questions. If you are considering taking part in the study, if you agree she will then ask you to sign a standard consent form and you will be given a copy of this to keep.

What will taking part in the study mean for me?

Taking part in the study will mean that you and Sandra will meet once for a workshop. The workshop will last 3 hours to discuss and share your ideas with Sandra and 3 more rehabilitation professionals about how to improve the mealtime in rehabilitation. The workshop will be audio and video recorded and will take place at The Glasgow School of Art campus. **The workshop will be arranged at a time that suits you.**

Will I benefit from taking part?

Sandra cannot promise that taking part in this study will be of direct benefit to you. But, by telling Sandra of your experience, your information and your ideas will help give design research a greater understanding of what the experiences and ideas of rehabilitation professionals are. In turn, this might help to contribute to improving the mealtimes for people in stroke rehabilitation in the future.

Are there any risks involved in taking part?

It is unlikely that you will come to any harm as a result of taking part in the study, and no special arrangements have been put place for compensation. If you have concerns about the way you are approached or treated during the course of the study, please contact either Sandra or her supervisor Professor Alastair Macdonald at The Glasgow school of Art (0141 353 4715) or alternatively you can contact the National Health Service through the normal complaints mechanisms which will be available to you. If any malpractice or neglect is identified whilst participating in the research it is professional practice to report this.

Will my taking part be kept confidential?

Any information which is collected about you, or that you provide during this study, will be kept strictly confidential. In any audio and video recorded material, your personal details will be removed so that you will only be identifiable by a project number and the researcher and her supervision team only will have access to your details. All information will be held securely for a period of 10 years, as required by Glasgow School of Art. However, any audio and video-recorded information from you will be destroyed once the project is completed.

What will happen to the results of the study?

When the results of the study have been analysed, a PhD thesis will be prepared to present at The Glasgow School of Art and also reports will be prepared for publication and presentation at conferences. A summary of the results of the study will also be available to you if you wish; Sandra can discuss this at the final of the workshop.

Thank you for taking the time to read this information.

If you like to find more about the study please feel free to contact me

Sandra Neves
PhD student at The Glasgow School of Art

Tel. 0141 353 4442
Email. s.neves1@student.gsa.ac.uk



Sandra Neves
167 Renfrew Street
Glasgow, G3 6RQ
Tel: 0141 353 4442

STUDY TITLE

Exploring lived experiences during mealtimes in rehabilitation

Consent Form for Stroke Survivors (Interview)

Please read the statements below. If you agree, please initial each box and sign at the bottom of the page.

1. I confirm that I have read and understand the study information sheet (dated .xxx) and I have had the opportunity to ask the researcher questions.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected.

3. I understand that relevant sections of data collected during the study may be looked at by individuals from the Glasgow School of Art, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

4. I understand that I will take part in one interview as part of the study and that the interview will be audio-recorded.

5. I understand that any information I provide will be treated in the strictest confidence. This information will be held securely for 10 years at the Glasgow School of Art and will only be available to the researcher. Information will be destroyed after this time.

6. I give permission for the information I provide to be used for research purposes (including, reports, publications and presentations) with strict preservation of anonymity.

7. I agree to take part in the above study.

Full name in BLOCK CAPITALS

Date

Signature

Researcher

Date

Signature



Sandra Neves
167 Renfrew Street
Glasgow, G3 6RQ
Tel: 0141 353 4442

STUDY TITLE

Mapping ideas to redesign the mealtime experience in rehabilitation

Consent Form for Stroke Survivors (Workshop)

Please read the statements below. If you agree, please initial each box and sign at the bottom of the page.

1. I confirm that I have read and understand the study information sheet (dated .xxx) and I have had the opportunity to ask the researcher questions.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected.

3. I understand that relevant sections of data collected during the study may be looked at by individuals from the Glasgow School of Art, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

4. I understand that I will take part in one workshop as part of the study and that the interview will be audio/video-recorded.

5. I understand that any information I provide will be treated in the strictest confidence. This information will be held securely for 10 years at the Glasgow School of Art Ethics and will only be available to the researcher. Information will be destroyed after this time.

6. I give permission for the information I provide to be used for research purposes (including, reports, publications and presentations) with strict preservation of anonymity.

7. I agree to take part in the above study.

Full name in BLOCK CAPITALS Date Signature

Researcher Date Signature



Sandra Neves
167 Renfrew Street
Glasgow, G3 6RQ
Tel: 0141 353 4442

STUDY TITLE

Mapping ideas to redesign the mealtime experience in rehabilitation

Consent Form for Rehabilitation Professionals (Workshop)

Please read the statements below. If you agree, please initial each box and sign at the bottom of the page.

1. I confirm that I have read and understand the study information sheet (dated .xxx) and I have had the opportunity to ask the researcher questions.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected.

3. I understand that relevant sections of data collected during the study may be looked at by individuals from the Glasgow School of Art, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

4. I understand that I will take part in one workshop as part of the study and that the workshop will be audio/video-recorded.

5. I understand that any information I provide will be treated in the strictest confidence. This information will be held securely for 10 years at the Glasgow School of Art and will only be available to the researcher. Information will be destroyed after this time.

6. I give permission for the information I provide to be used for research purposes (including, reports, publications and presentations) with strict preservation of anonymity.

7. I agree to take part in the above study.

Full name in BLOCK CAPITALS Date Signature

Researcher Date Signature

Appendix E: Phase 1 – Topic guide to interview healthcare professionals

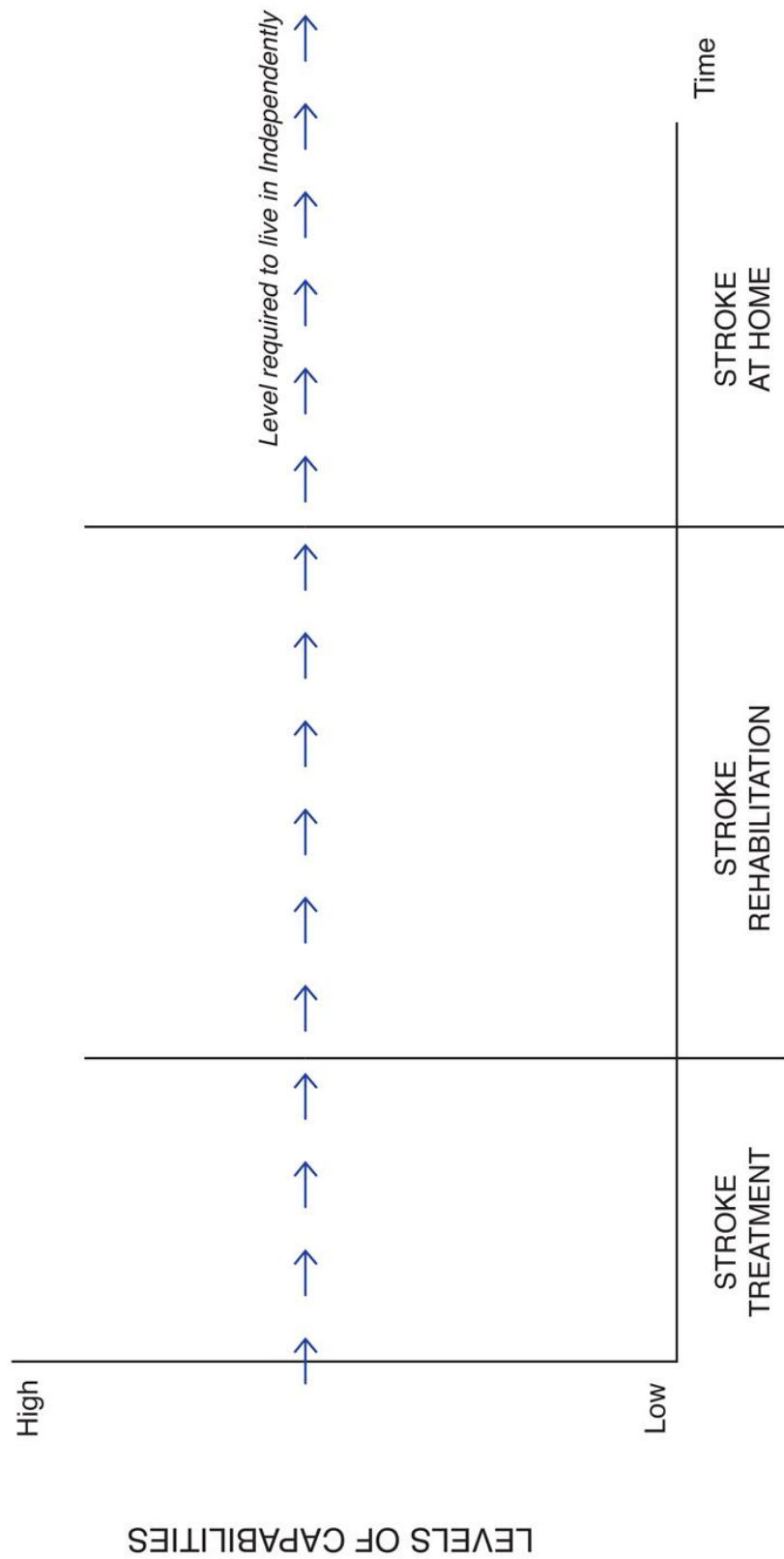
ABOUT YOUR ROLE

- 1) What is your role and specialism within stroke care and rehabilitation?**
- 2) What training and qualifications have you had?**
- 3) How many years have you been working in this area?**
- 4) Where do you see and work with stroke patients?**
- 5) Can you briefly describe a typical consultation(s) / session(s) with a stroke patient?**
- 6) What, in your opinion, are the main impacts of stroke on patients that you treat, for each of the following?**
 - What is the neurological impact?
 - What is the physical impact?
 - What is the social impact?
 - What is the psychological impact
 - How do you decide when people are ready to move on to another care stage?

ABOUT THE STROKE PATHWAY

My understanding of the stroke pathway is shown in the diagram.

- 7) Is this how you see the stroke pathway? If not, how would you draw this? Are there any stages missing?**



8) At what stage(s) in the stroke pathway do you see patients?

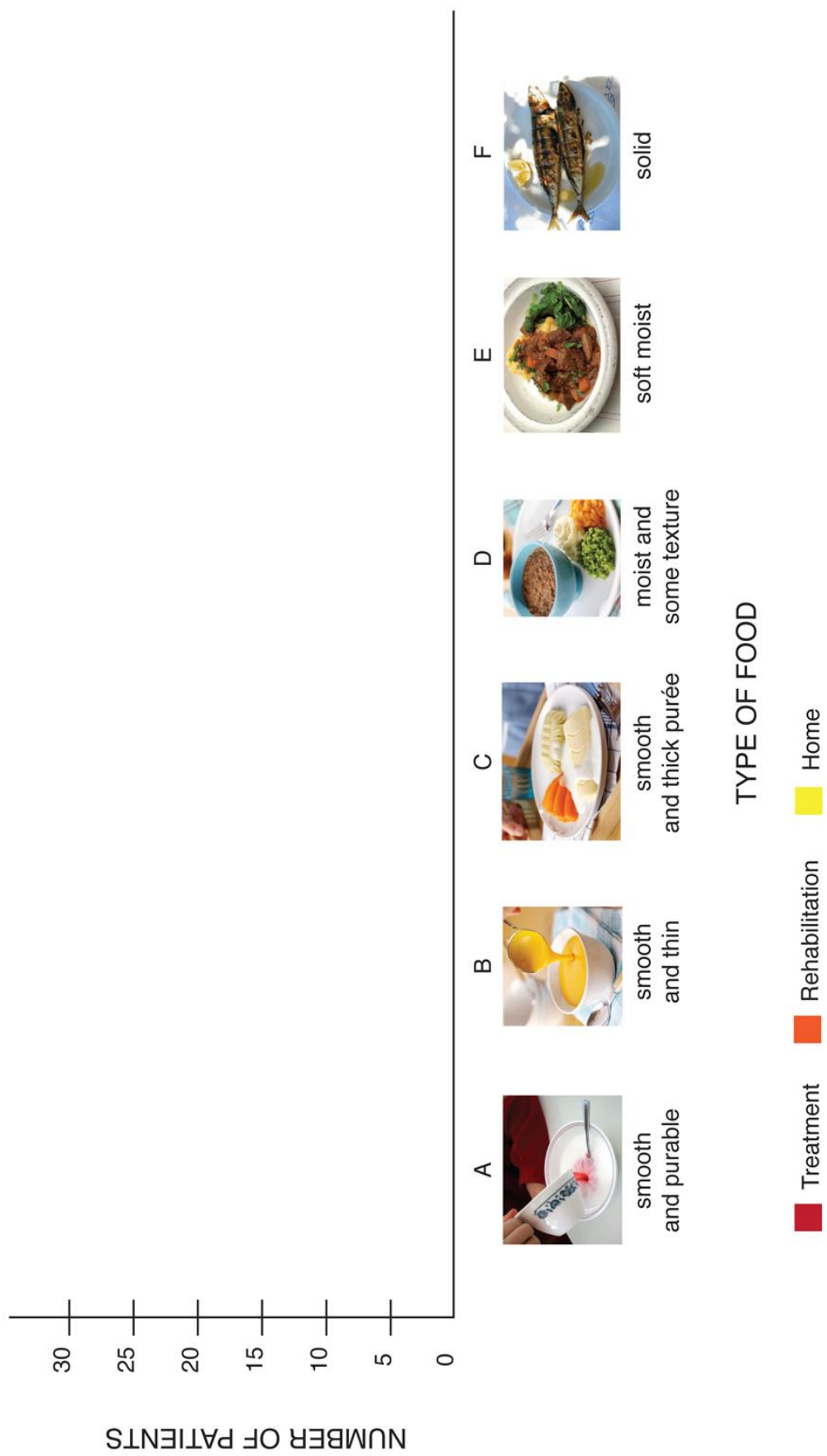
- 9) **What types of assessment are used to allow a patient to move from the stroke treatment to rehabilitation and from rehabilitation to home?**
- 10) **How do you define independence?**
- 11) **What level of competence do patients require?**

MEALTIMES

- 12) **How do these stroke conditions affect people at mealtimes?**
 - How is their particular condition assessed with relevance to eating and drinking?
 - What proportion of patients need assistance?
 - What kind of problems can patients have at mealtimes?
 - What are the reasons for a patient needing care assistance to eat?
 - Can you give me an example?
 - How do you try to minimise these problems?
 - What difficulties do patient have with eating?
 - What techniques and/or methods do you use to minimize swallowing / eating difficulties?
 - What causes them to lose appetite and interest in eating?

My understanding of the texture of food is shown in the graphic.

- 13) **Is this how you see the stroke texture of food? If not, how would you explain this? Is there any type of food missing?**



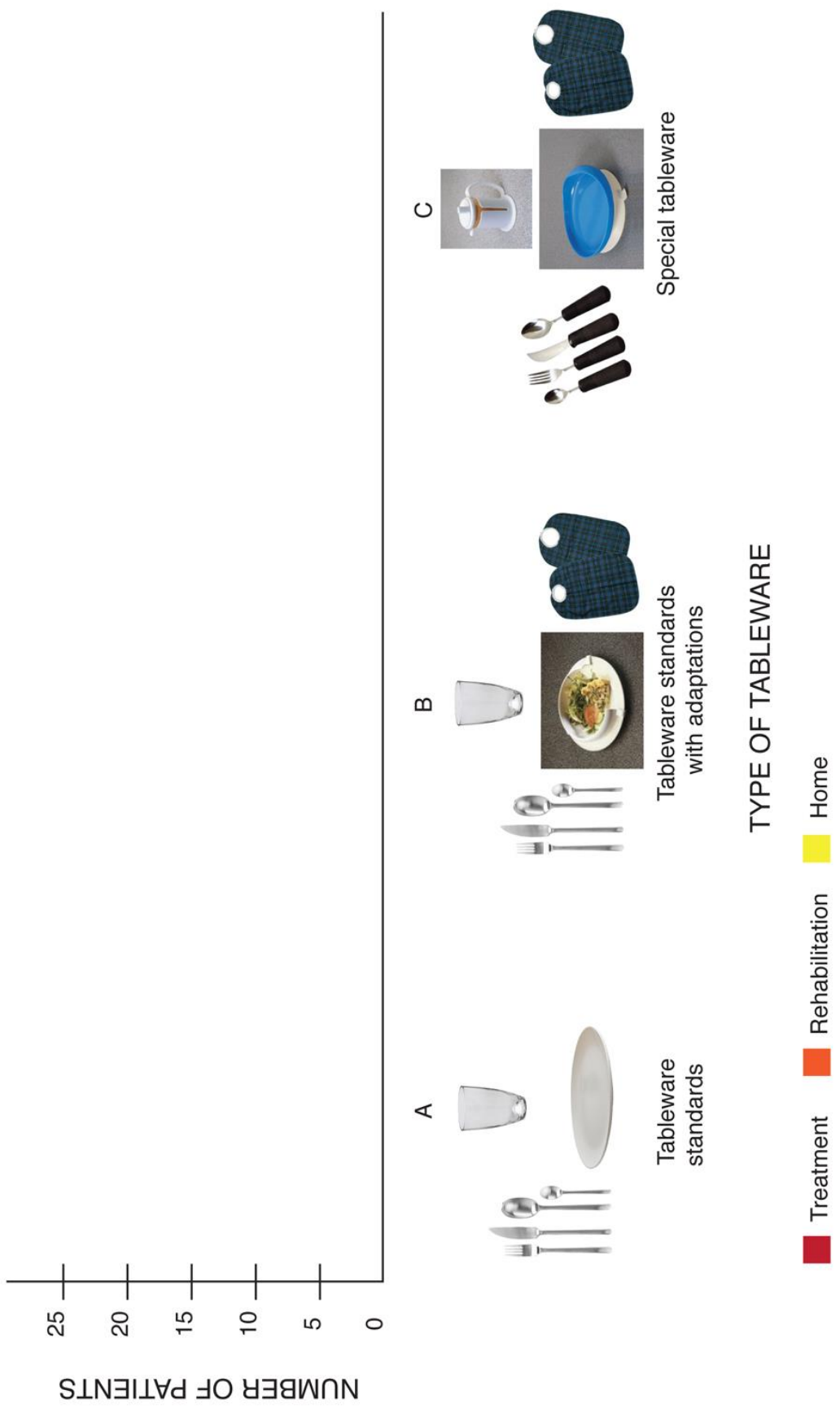
14) What type of food might patients eat?

- What is the number of patients who can eat solid food?
- How do you take into account patients' likes and dislikes about food?
- Do they express 'food memories' associated with certain food?

My understanding of the tableware standards is shown in the graphic.

15) Is this how you see the stroke tableware standards? If not, how would you show this?

Is there any type of product missing?



16) What type of design tableware/cutlery might patients use?

- How many patients use standard tableware to eat?
- How many patients need to use special tableware?
- Can you give me an example of tableware used by stroke patients?
- What do you think is the best way to help them to eat? Why?
- Do you know of any good examples of tableware – perhaps that you do not use but wish you could obtain?

17) How is rehabilitation important to help people eat?

- Who plans their meals?
- What guidelines are available in the kitchen to prepare meals for stroke patients?
- Are there certain strict procedures which staff who are preparing meals have to follow?
- How are social interactions stimulated at mealtimes?

OTHERS

18) Is there anything else you think important that we have not discussed?

19) It would be helpful to be able to observe stroke patients at mealtimes. Would this be possible and what would be the procedure I would have to observe?

Thank you

Appendix F: Phase 2 – Topic guide to interview patients

ABOUT YOUR STROKE

1. Can you remember how long you were in hospital?
2. What was the most annoying thing that you experienced during hospital mealtimes?
3. How did you deal with them?
4. Did you receive care assistance during hospital mealtimes?
5. Can you explain why you needed care assistance?
6. Did this change over time during your stay?

ABOUT YOUR MEALTIMES

My understanding of the mealtimes for patients in stroke rehabilitation in hospital is shown in the diagram. *(Show diagram to participant)*

positive

BEFORE

Waiting for Food



Receiving Food



DURING

Eating Food



AFTER

Eaten Food



negative

I would like to talk with you about your experience during a typical mealtime in hospital, for example an evening meal, throughout 3 stages: BEFORE, DURING and AFTER THE MEAL.

5. Can you tell me the differences between the events of waiting for food, receiving food, eating food and after eating at your mealtime?

- What happened at each of these stages?
- How long did each take?
- What good or bad things happened during each stage of the mealtime?

BEFORE THE MEAL

My understanding of the type of environment you ate your food in is shown in the picture. (*Show picture to participant*)

BEFORE

Waiting for Food



6. Is this similar to the ward environment you were in, in hospital? If not, how would you describe this?

- Where were you sitting to have your meal? Why?

7. In what ways was it an attractive or unattractive place to eat?

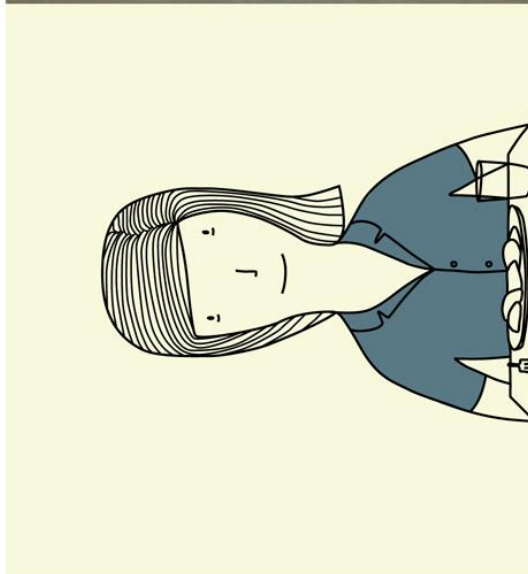
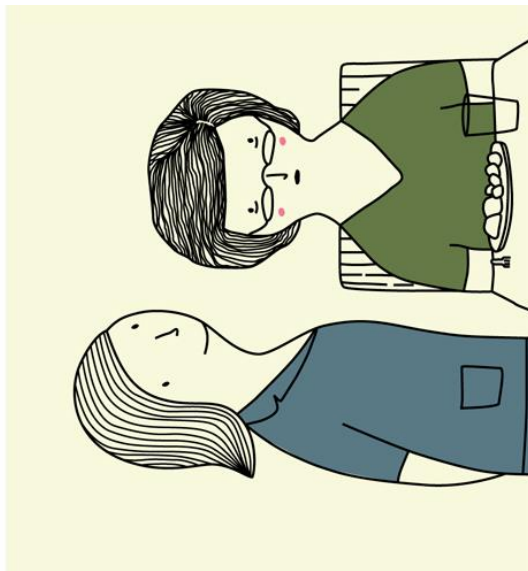
- Did smells affect your appetite?
- What kinds of smells were there?
- Were these smells consistent or inconsistent throughout each of these stages?
- Did ward noises affect your appetite?
- What the sounds did you heard?
- Were these sounds consistent or inconsistent throughout each of these stages?
- Did what you saw around you affect your appetite?
- What were you seeing and/or looking at while you were waiting for food?
- Were these sights consistent or inconsistent throughout each of these stages?
- Did you know what meal you were getting? If not why?
- Did you receive care assistance at this stage?
- Can you explain why you needed care assistance?
- Can you tell me how the care assistant and/or ward staff assisted you throughout each of these stages?
- Did social interactions affect your interest to eat?
- What kind of social interactions did you have there?
- Were these social interactions consistent or inconsistent throughout each of these stages?

DURING THE MEAL

My understanding of the type of food you received at your mealtime in the hospital is shown in the picture. *(Show picture to participant)*

DURING

Receiving Food



8. Is this what the food looked like? If not could you describe it?

9. How did you find the visual appearance of the food at your mealtime? Can you explain your reply?

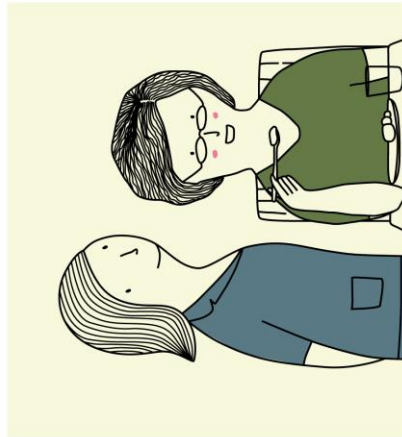
- What was the shape like?
- What was the colour like?
- How was it arranged on the plate?
- What did you think when you saw your food for the first time?
- Did you express your likes and dislikes about the appearance of food to anyone? Why?
- Did the care assistant and/or ward staff take into account your likes and dislikes about the appearance of food?

10. Did this appearance of food stimulate your appetite, or not? Why?

My understanding of the way you ate your food at your mealtime in the hospital is shown in the picture. (*Show picture to participant*)

DURING

Eating Food



11. Can you tell me about the care assistance during your meal?

- In what ways did the care assistant help you eat?
- Did these ways of care assistance affect your interest to eat?
- Can you give me an example?

12. Can you remember any form of social interactions during your meal?

- How did you find the social interaction between you and other patients during your meal?
- Can you give me an example?

AFTER THE MEAL

My understanding of the way you finished your mealtime in the hospital is shown in the picture.
(Show picture to participant)

AFTER

Eaten Food



14. Can you tell me what kind of thoughts came to mind after this mealtime in hospital?

- Did you see this mealtime as a good experience, or not? Why?

15. How did you see the best mealtime experience?

- What is the place like?
- What is the appearance of food like?

- What does this mealtime experience mean to you?

OVERALL

16. What in your opinion, are the positive aspects you experienced at mealtime during your hospital stay?

17. What in your opinion, are the negative aspects you experienced at mealtime during your hospital stay?

OTHERS

18. Is there anything else you would like to mention that you thought about whilst we have been talking?

Thank you for participating in my study and I very much welcome your input

Appendix G: Phase 1 – Sample coding and charting data in interview transcripts with healthcare professionals

Section 1: Developing a working analytical framework

| Theme | The main impacts of stroke | The stroke care pathway | The mealtime in hospital |
|------------|---|---|---|
| Sub-themes | Neurological (N) Physical (PH) Social (S) Psychological (PS) | Hospital (H) Day hospital (C) Home (HO) | Eating difficulties (ED) Team assessment (TA) Eating process (EP) |

Section 2: Coding data

| Coding | | HP2_SPEECH THERAPIST | Notes |
|--------|-----|---|--|
| N | 149 | Well obviously the neurological impact is why they have | |
| | 150 | swallowing difficulty to begin with because the majority | |
| | 151 | of patients don't have anything wrong with their swallow | |
| | 152 | beforehand it's interesting for me to, I find it interesting | |
| | 153 | to find out what the CT results is where the stroke has | |
| | 154 | occurred because obviously certain areas of the brain | |
| | 155 | will effect swallowing more than others and it's useful | |
| N | 156 | for me, I, to know that detail. The neurological impact is | |
| | 157 | great I mean it's massive but for some patients on the | |
| | 158 | swallow side of things it's quite minimal and it's enough | |
| EP | 159 | to be given advice on what to do, take little sips rather | Swallowing difficulties require modified meals |
| | 160 | than big drinks you know and general advice, but often | |
| | 161 | texture modification is required so it has a huge impact. | |
| | 162 | Well obviously patients become dehydrated, they can | |
| | 163 | lose weight, they have, it can affect their ability to rehab | |
| PS | 164 | if they don't if they're not nutritionally stable. I'm trying | Patient fatigue |
| | 165 | to think, their fatigue levels, they're already very | |
| | 166 | fatigued because they've had a stroke, they tire quickly | |
| | 167 | so they've no stamina, it's all these things. | |
| | 168 | Social impact, eating and drinking is a very social thing if | |
| | 169 | someone's on a textually modified diet it looks different | HP acknowledging the mealtime as a social aspect |
| S | 170 | from what other people are getting. / They don't | |
| | 171 | necessarily have a choice, where as other people are | |
| EP | 172 | given a choice / because the kitchen prepares food that | Lack of choice |
| | 173 | is suitable for them, it's not necessarily what the | |
| | 174 | individual necessarily likes and I'm sure that's going to | |
| | 175 | be a big part of what you're doing. | |

Section 3: Charting data

| The stroke care pathway | | | |
|-------------------------|---|--|--|
| | Hospital | Day hospital | Home |
| HP1 | <p>We're acute stroke ward (...) we see them from the very start (...) from within 4 hours of their stroke. (Line 86)</p> | | <p>We have a team who take the patient home as soon as they can transfer they go to discharge and treat them from their own home they've got physios, OT's, speech and language and nursing in that team. (Line 74)</p> |
| HP2 | <p>The patients who come into the hospital who are suspected of having a stroke have a differential diagnosis of stroke have a water swallow test, a water screening by the nursing staff and myself and colleagues train the nurses to provide the screen, screening assessment. (Line 48)</p> <p>At an earlier stage I would say assessment and rehab can often begin right away, we use the early mobilisation model (...) CT scan (...) diagnosis (...) the rehab phase starts right away as soon as you put someone on recommendations. (Line 217)</p> | | <p>Getting them home from here with the early supported discharge team the CARS team, that's the team of therapist that would go into the house and work with the patients (...) the intensity of therapy is much less. (Line 247)</p> |
| HP3 | <p>They come into the hospital and they get their initial medical treatment involved (...) very quickly in sort of early rehab early mobilisation (...) getting them up getting them out of bed. (Line 113)</p> | <p>They can then be referred onto rehabilitation teams for home but that's not always appropriate for everybody. They can also be referred to our day hospital. (Line 118)</p> | |
| HP4 | <p>Initially (...) you've got acute stroke Treatment(...) medically they've got to be stabilised (...)and then (...) they like to get them early mobilisation (...) acute can kind of overlap with rehabilitation. (Line 133, 137, 147)</p> | | <p>We also have early supported discharge (...) where they go home maybe slightly earlier but they continue their rehabilitation at home and physios and occupational therapists will go into the home and they'll basically rehab at home. (Line 192)</p> |

Appendix H: Phase 2 – Sample of coding and charting data in interview transcripts with patients

Section 1: Developing a working analytical framework

| Themes | Before (B) | During (D) | After (A) |
|------------------|------------|------------|-----------|
| Thematic colours | Sensorial | | |
| | Physical | | |
| | Social | | |
| | Emotional | | |

Section 2: Coding data

| Coding | | P3 | Notes |
|--------|---|--|---|
| D | 248 249 250 251 252 253 254 | See I very very rarely ate, I won't say it looked like that 'cause that looks quite nice, but that was nothing like what I ever had I only ever had like a baked potato. But, but the actual receiving of this there was never anyone there with you throughout your food, / so that's a big difference. They just used to give you it and then go away again. | |
| | 255 256 | How did you find the visual appearance of the food at your mealtimes? | |
| | 257 | Not very attractive, not very attractive. | |
| | 258 | So what do you mean by not being attractive? | |
| D | 259 260 261 262 263 | Cause like when you get food and I'm quite a fussy eater as it is but I tend to when I get food if it doesn't look appealing then it's not appealing and a lot of the time the food was very very unappealing. / It was as if it had just been slapped onto a plate. | Unattractive/ Unappealing food |
| | 264 | So what was the shape like? | |
| D | 265 266 | It wasn't the shape, it was just like a big bundle slatted on the middle of the plate. | |
| | 267 | And what was the colour like, do you remember? | |
| D | 268 269 270 271 | Not really as I say the only kind of meal I every really tended to have was a, I used to try the baked potato. The only thing about it was the actual potato itself could have been a lot softer in order for people to eat it, / I found it quite hard. | Food texture Patient difficulties |

Section 3: Charting data

| | Before | During | After |
|----|--|--|--|
| P1 | <p>The toilet was next door to my bed (...). Urine (Line 121)</p> <p>In bed (Line 113)</p> <p>I could not talk to the other patients. (Line 189)</p> | <p>Not appetising. It looked like a normal meal but not nice to look at. (Line 220)</p> <p>They fed me with a tea spoon. (Line 244)</p> <p>They would sit on a chair beside me. (Line 204)</p> <p>They did not talk while I was eating. (Line 206)</p> <p>I imagined I was eating. (Line 9)</p> <p>I could not eat like others. (Line 104)</p> | <p>The meal was recorded on a chart, what I eat. (Line 81)</p> <p>No interactions. (Line 266)</p> <p>None of them were better than the other. (Line 288)</p> |
| P2 | <p>I could smell the soup (...) They were consistent. (Line 91, 96)</p> <p>I mean you could tell if it was a Monday or a Tuesday cause of the meals. (Line 98)</p> <p>In bed (...) Because I couldn't get up. (Line 69)</p> <p>where I was everybody was in bed you couldn't move, you couldn't get up. (Line 240)</p> | <p>I wasn't eating, I didn't lie there thinking oh I wish I could have that. (Line 246)</p> | <p>Jealousy (...) Because the rest of them have had something to eat and I haven't, I never had any food at all. (Line 199)</p> |
| P3 | <p>It was quite bland (...) it didn't smell of roses (...) see they the disinfectant wipes and things like that (...) there's a really strong smell of that sometimes. (Line 154)</p> <p>We kind of usually they came in with, about fifteen, twenty minutes before (...) you would decide whatever you were wanting. (Line 54)</p> <p>There wasn't really (...) the other three women that were there but it never affected us eating (...) we used to have a little gab and that but that was it. (Line 234)</p> <p>You're always staring at the same people, you're always staring at the same four walls, it always seems to be the same food you're getting offered (...) it was always the same things you were getting offered. (Line 429, 435)</p> | <p>When I get food if it doesn't look appealing then it's not appealing and a lot of the time the food was very very unappealing. / It was as if it had just been slapped onto a plate. (Line 259)</p> <p>I had the left hand side but I still found that some of the meals were pretty difficult as in cutting (...) because I can't cut it or things like that. (Line 10, 17)</p> <p>I just used to struggle with a knife, like a fork. They just used to bring the food out to you, leave you with it. (Line 70)</p> <p>Being so young I think you don't really want to have to ask somebody to have to cut your food for you. So I think the most annoying thing was that you couldn't get some meals and you were probably thinking about it when you were seeing it, oh no I can't eat that. (Line 12)</p> | <p>They would just sort of start going back round again and collect everybody's trays. (Line 82)</p> <p>Time to go to sleep (Line 379)</p> <p>I was never satisfied by meals. (Line 381)</p> |
| P4 | <p>With my chair here and the toilet right there (...) In and out, in and out, in and out all day (...) It was just a smell of a toilet (...) it wasn't really a nasty smell (Line 299, 312)</p> <p>We were in our bed waiting, and when the trolley came round, and on the trolley there would be meals on it. (Line 100)</p> <p>Nobody, just talking (...) patients and nurses. (Line 381)</p> <p>There was a total lack of choice (...) the soup, it wasn't conventional and I don't like barley, that's what you got and I hate barley (...) I said what is this? The only thing you got. (Line 7)</p> | <p>See the roast potatoes you can't cut an inch, can't cut them with your knife see the skins in them solid. (Line 425)</p> <p>What really turned me was the so called mashed potatoes. (Line 442)</p> <p>I haven't got the strength in that hand and I tried to struggle with this hand I just couldn't, just had to get one of the nurses or whatever was serving the meals to help. (Line 252)</p> <p>You eat alone in your bed. (Line 129)</p> <p>I'd say to the nurse that meal was rotten. (Line 64)</p> <p>There was nobody really to complain to (...) They'd come round and say did you enjoy that meal or what? (Line 67)</p> | <p>The nurses just took (...) your dishes away, took your cups and saucers, cutlery and plates, they took them away. (Line 138)</p> <p>You were in bed you just stayed in bed. (Line 147)</p> <p>Sometimes I spoke, depends who the person, who's there some people weren't able. (Line 552)</p> <p>Thank god it's over and done with (...) Because the meals absolutely rotten, rubbish. (Line 677)</p> |
| P5 | <p>It's not an attractive place to eat is in the hospital. (Line 201)</p> <p>I was in the ward, four in a ward and just sitting there. (Line 31)</p> <p>I spoke to them (...) Just everyday things. (Line 84)</p> <p>Just four women in the ward, talking and the television. (Line 299)</p> | <p>It was different colours it depended what it was (...) I got em... cauliflower cheese (...) And I couldn't get enough of it, it was beautiful. (Line 323, 329)</p> <p>I couldn't hold the fork (...) my hand shook, so I had to use my right hand with the fork because the minute I lifted that up it was going like that and the dinner was falling off the fork, so I had to sort of dig in with the fork. (Line 154)</p> | <p>They just came and took it away (...) They just asked me if I'd enjoyed it. (Line 95)</p> <p>Just started talking away again to the other woman that was in the ward. (Line 174)</p> <p>I enjoyed it. (Line 380)</p> |

Appendix I: Phase 3 – Sample of coding and charting data in workshop transcript with patients

Section 1: Developing a working analytical framework

| Magical game | |
|------------------|-----------|
| Thematic colours | Sensorial |
| | Physical |
| | Social |
| | Emotional |

Section 2: Coding data

| Coding | | Magical game | Notes |
|--------|---|---|--|
| P1 | 616 | S: ok we wait a little bit more. I know P1's prepared to | Ambience (smells) (visual) |
| | 617 | tell us her story. | |
| | 618 | F: yeah, that's what I like. | |
| | 619 | S: ok so can we start... | |
| | 620 | S: yes | |
| | 621 | S: To tell our stories? | |
| | 622 | S: yes | |
| | 623 | S: P1 you would like to be the first, I can see you are... | |
| | 624 | P1_F: she's anxious. An Indian restaurant, the smell of | |
| | 625 | curry and different smells from the kitchen, tables all | |
| 626 | decorated with candles which are lit with different | | |
| 627 | colours and tables with placemats. | | |
| P2 | 628 | S: good thank you. How about you P2? | Ambinece (smells) Self-control |
| | 629 | P2: I'm going on somebody's boat, with the barbeque on | |
| | 630 | the back of the boat so you're getting the smell of the | |
| | 631 | smoked food and putting a couple of steaks on barbeque. | |
| | 632 | And then on the plate and inside the boat it's no very | |
| | 633 | comfortable but the plate on my lap and a glass of wine. | |
| | 634 | S: oh that sounds a good story too. | |
| | 635 | F: don't forget the wine. | |
| | 636 | P2: aye you've got to have some alcohol. | |

Section 3: Charting data

| P1 | P2 | P4 |
|--|--|---|
| <p>she's anxious. An Indian restaurant, the smell of curry and different smells from the kitchen, tables all decorated with candles which are lit with different colours and tables with placemats. (Line 624)</p> <p>A family sitting round the table and the meal brought in, in different dishes (...) of different food (...) choosing an appetising dish. (Line 554)</p> <p>socially ideally for her would be the Grandson's playing their games and I laughing at them and helping them when required. Typical grandmother (...) listening to them listening to their wee jokes. (Line 694, 698)</p> <p>She has said the satisfaction of feeling full and feeling drowsy. (Line 701)</p> | <p>I'm going on somebody's boat, with the barbeque on the back of the boat so you're getting the smell of the smoked food and putting a couple of steaks on barbeque. And then on the plate and inside the boat it's no very comfortable but the plate on my lap and a glass of wine. (Line 629)</p> <p>Al-a-carte. (Line 556)</p> <p>I was out one afternoon and I come in and I was hungry and I popped my head round in the dining room and there was a local Sheriff, Sir Steven Young and saw me and gestured that he wanted to talk to me. So I went and sat down at the table and I was starving and (clears throat) and he was just saying his daughter had been out drinking in different hotels in the Peninsula and he wasn't very happy about it and I was trying to tell him that I knew who she was and she hadn't been in here drinking because she was underage and that was all (...) to go to the pub and get a drink and a fag. (Line 667, 686)</p> <p>I was thinking hurry up and get across to the pub (...) I was thinking (...) I wanted to be more sociable after the meal (...) interact with the other people (...) have a drink and a fag (laughs). (Line 709, 722)</p> | <p>Aye, going to McDonalds with my Grand weans (...)</p> <p>Going to the McDonalds for the afternoon (...) you can smell the chicken and chips and that (...) the people going about and other people talking (...) it was quite good. (Line 658, 671)</p> <p>See what's happening and going on around you (...) you can pick up what you want to on yourself, have your meal by yourself. (Line 574)</p> <p>Well eh my daughter in law and son and the kids and sometimes my daughter. (Line 708)</p> <p>You get a good tuck in (...) quite happy (...) em... enjoyed being there. (Line 642, 651)</p> |

Appendix J: Phase 3 – Sample of coding and charting data in workshop transcripts with healthcare professionals

Section 1: Developing a working analytical framework

| What if? | | | |
|------------------|------------|------------|-----------|
| Themes | Before (B) | During (D) | After (A) |
| Thematic colours | Sensorial | | |
| | Physical | | |
| | Social | | |
| | Emotional | | |

Section 2: Coding data

| Coding | | What if? | Notes |
|--------|-----|--|--------------------------------|
| B | 100 | P6: Like the smells of the food, you know you get the | Ambience (smells) |
| | 101 | smells wafting through from the kitchen. | |
| B | 102 | P1: He's very enthusiastic isn't he, he's very enthusiastic | Empathy |
| | 103 | about what he's cooking. | |
| | 104 | <i>Tell me about enthusiastic, what do you mean by enthusiastic?</i> | |
| B | 106 | P1: He's very passionate about what he put's in his food, | Empathy |
| | 107 | he loves his spices and all things like that and he's very | |
| | 108 | passionate about his taste. Everything has to taste good | |
| | 109 | not just look good but taste. | |
| B | 110 | <i>And around of her what things could happen you see</i> | Ambience (visual) presentation |
| | 111 | <i>that Jamie Oliver could provide to....?</i> | |
| | 112 | P1: Something nice to look at. | |
| | 113 | <i>Ok</i> | |
| | 114 | P1: As in him | |
| | 115 | <i>(Laughter from the group)</i> | |
| | 116 | <i>Do you have an example to give me, what kind of things,</i> | |
| | 117 | <i>these nice things.</i> | |
| | 118 | P6: Not that you can put on tape | |
| | 119 | <i>(group laughter)</i> | |
| B | 120 | P5: I suppose good food, it doesn't make a difference | |
| | 121 | really when it's good quality. | |
| | 122 | Yeah | |
| | 123 | P6: I guess you've got that expectation because it's him | |

Section 3: Charting data

| Before | During | After |
|---|---|---|
| <p>P5: Like the smells of the food, you know you get the smells wafting through from the kitchen. (Line 100)</p> <p>P1: Something nice to look at. (Line 112)</p> <p>P5: I suppose good food, it doesn't make a difference really when it's good quality. (Line 120)</p> <p>P5: It's the interaction. (Line 142)</p> <p>P1: They take in what they person that they're cooking for, what they like. (Line 202)</p> <p>P5: You'd be hoping that he was going to come out and say hello to you. (Line 137)</p> <p>P1: He makes everything a joke, he makes things funny by the comments that he makes when he's doing the cooking. He involves people as well. (Line 149)</p> <p>P5: And yeah he can be quite amusing and he's so enthusiastic about the food that he talks about it's not as much about making jokes for him it's about "wow look at this" (Line 175)</p> <p>P5: He's very enthusiastic isn't he, he's very enthusiastic about what he's cooking. (Line 102)</p> <p>P1: He's very passionate about what he put's in his food, he loves his spices and all things like that and he's very passionate about his taste. Everything has to taste good not just look good but taste. (Line 106)</p> <p>P5: He's got a good sense of humour too though hasn't he. (Line 140)</p> <p>P1: It's his personality. (Line 147)</p> | <p>P1: It's to look nice for you, you don't want it just all shoved in a bundle in the middle of the plate, you want it presented well so that everything complements each other. (Line 248)</p> <p>P1: and they all have the same presentation so it's very pleasing to the eye, (Line 256)</p> <p>P6: It's that's thing that when you eat there is so much happens before you put that first bite in your mouth it's about the smells and it's about if something comes down and it's on your plate and it's just presented really nicely. It's laid out really well. (Line 258)</p> <p>P1: It would be like a nice environment, a comfortable environment. (Line 215)</p> <p>P6: A comfy chair, I hate it when you go to a restaurant and kind of half way through the meal you're like, back's killing you. (Line 219)</p> <p>P5: I think to be knowledgeable about what they're serving you, to be happy. (Line 246)</p> <p>P1: it's there personalities makes it pleasurable as well and the way they're dressed as well. (Line 280)</p> <p>P1: They all have the same passion though. (Line 255)</p> <p>P1: You enjoy it more. (Line 263)</p> <p>P3: You kind of go "oh wow." (Line 265)</p> | <p>P5: You can sit at the table. (Line 325)</p> <p>P6: You can sit and have a cup of tea or whatever afterwards you know at your leisure you know. (Line 326)</p> <p>P1: If they ask if you enjoyed it then, feedback. (Line 305)</p> <p>P2: I suppose you'd be chatting about "oh yours looked nice and how did you enjoy it." (Line 307)</p> <p>P1: "gis a bit" (Line 309)</p> <p>P1: Chat to Jamie about what he's doing at the weekend, a wee chocolate. (Line 328)</p> |

Appendix K: Phase 1 – Consent form for healthcare professionals

Project title: Enjoy your meal: design tools and strategies for stroke patients

Before you read this consent form please make sure you have read the enclosed 'Project information sheet: the initial meeting with stroke specialists' and asked the researcher any questions you may have.

This form is to ensure that everyone taking part in the research fully understands the following:

- 1) I confirm that I have read and understood the Project information sheet for this research and I have had the opportunity to discuss this project and ask (questions).
- 2) I understand that my participation is voluntary and that I am free to withdraw from the research at any point without giving any reasons.
- 3) I understand that I can withdraw all or part of what I say during the research. I'm free to do this without giving any reasons.
- 4) I understand that this research will be published in reports, journals or in other forms that will be widely available and that my contribution will remain anonymous.
- 5) I have been informed that what I say will be kept safe and secure in accordance with the Glasgow School of Art Ethics Policy.
- 6) I agree to my interview being recorded by a recorder.
- 7) I agree to take part in an interview for this research.

Name of volunteer Date Signature

Name of person taking consent Date Signature