

Draft Interview Schedule: Participant Interviews (First Stage)

Introduction to the project

1. I'd like to start by finding out a little bit about you (sets context).

Please could you tell me about your life:

Where do you live? Who do you live with?

Are you employed, unemployed or retired? If unemployed or retired, what was your previous occupation?

2. I would now like to move on to discuss your health.

Could you tell me a little about your health:

How long ago were you first diagnosed with MS? Which type of MS do you have and has this always been the case (i.e. it might have progressed into another type)? What impact does this have on you physically (mobility issues, visual, bowel/bladder, fatigue, numbness) and emotionally (cognitive issues, depression, mood swings)?

How do you manage your symptoms (e.g. gentle exercise, sleep patterns, diet, medication, bladder/bowel strengthening exercises)? Have you ever used any non-abdominal form of massage? If so, did this elevate your symptoms and how was this treatment administered (self, carer, nurse)? If not, why not, and would they consider having any non-abdominal massages post-AMBER?

Do you go to any support groups (charities, community groups, friends) relating to MS?

If any experience with bowel problems: You mentioned earlier that you had problems with your bowel – could you expand on this, explaining the difficulties you face and the impact this has on your life?

3. I would like to explore your previous knowledge of abdominal massage

Before you signed up to the AMBER trial, what did you know about abdominal massage as a form of treatment for bowel problems and have you ever used it before the AMBER trial?

If little knowledge and experience, then what are your thoughts on it as a way of managing bowel problems? Is this preferable over alternative forms of treatment (e.g. laxatives)?

If knowledge but no experience, then why did you never use it as a form of treatment – perhaps alternative methods were used?

If knowledge and experience, how has AMBER differed from previous massages? Did you find the other abdominal massages worked and, if so, what encouraged you to sign up for AMBER?

4. Now I would like to find out a bit about your experience of taking part in AMBER.

Let's start from the beginning. How did you find the process of recruitment? How did you feel about the treatment before attending your baseline appointment? Did anyone (e.g. relative, friend) attend the baseline appointment with you? Was everything clearly explained to you at the baseline appointment? Is there any way this could be improved?

How was the AMBER training administered and by whom? How do you feel the training went – was everything clearly explained and did you feel you had a clear understanding by the end of it? Is there any way this could be improved?

Will you be administering the massage yourself at home or will someone else? If yourself, how confident were you after the baseline appointment – has this changed at all? If someone else, did they attend the massage training? If yes, do they feel confident after the training? Did they have any suggestions for improvement?

5.I now would like to look at expectations of AMBER when agreeing to take part in the trial.

Why did you sign up for the AMBER study (i.e. expectations about outcomes)? Was anything different to what you expected? Did these outcomes change at any point during the study (baseline appointment, training, after that)?

6.Could we now discuss how you have been getting on with the abdominal massage.

[Based on response to question 4 about who is administering it]: how often have you/they been do this? Do you/they do this at a set time or whenever is convenient? How long does the massage and setting up/winding down take? Is this similar to your other forms of symptom management (i.e. has it been incorporated into a daily routine or is it burdensome)?

Have you altered the massage at all to suit your needs (e.g. using fists to combat fatigue)? Do you feel you/they have a good grasp of the technique? How motivated are you to carry out the massage? Do you have any support when doing the massage or to chat to people about the massage (e.g. local support groups, carer)?

7.May we now discuss whether you have experienced any benefits of doing the massage?

Have you seen an improvement in your bowel functions? If so, in what way (passing stools more frequently and easily)? If not, why do you think this is the case (e.g. massage not administered correctly, diet, medication, any other factors)?

Have there been any other unexpected benefits (e.g. decreased use of laxatives, more confidence, other physical symptoms)? What impact has this had on your life (e.g. able to go out more, able to eat more, able to engage in another activity like exercise without feeling bloated)?

8.Have you experienced any problems in doing the massage?

[Based on response to question 7 about their success so far with the massage] Have you/they encountered any problems when carrying out the massage? If so, what was the main issue (e.g. pressure to apply, fatigue (if themselves), timing of steps, confusion about massage)? Did you/they devise any solutions to deal with this?

If not, did you believe there would be any problems (e.g. see those above) before undertaking the treatment and, if so, what were related to? Why do you think this has problem has not arisen (e.g. good grasp/adaption of technique, found the right amount of pressure, etc.)?

Would you recommend that intervention staff at other sites adopt this lesson in their training?

9.We hope that if AMBER works well for patients, that we might roll this out more widely to help others. Based on your experience so far, is there anything that we could do better?

You have summarised your experience with AMBER so far, is there anything that could be done differently to improve it (e.g. information leaflets provided, training with intervention team, DVD and other training materials, providing more support during the process – telephone calls with nurses in particular, provisions for visual problems and other disabilities)?

Do you think there is anything in particular that could improve the experience for patients who are of a similar age group, as well as the same gender and employment status, as yourself? [Captures demographic details – perhaps there will be different requirements for younger employed females, for instance, compared to older, retired males]

10. Lastly, is there anything that we could do to encourage more MS patients to take part in AMBER?

Earlier we discussed why you were motivated to sign up for AMBER – do you think those reasons would encourage other people with MS to do the same? If not, why not? Do you think there is a way to tackle this issue (e.g. be clearer about what the study involves, provide more incentives to take part)?

[If they stated they keep in touch with other MS patients in their answer to question two] Did you tell your friends/group members about your participation in AMBER? If so, what were their thoughts about it? Did you try to encourage them to sign up? If not/they declined, why was this the case (do not meet criteria, not enough support in place, unsure about study)?

What about motivation during the study: did you feel engaged and motivated throughout the process? If not, why not (e.g. not enough support, difficulties with massage, etc.)? If this was the case, why did you refrain from dropping out? What would you suggest to encourage completion from other MS patients?

For those interviewed who have ‘dropped out’/not completed:

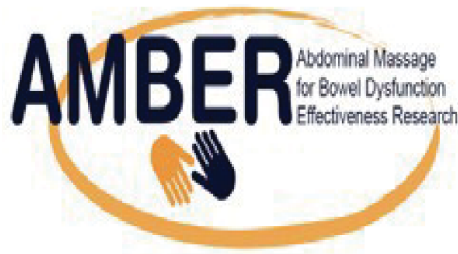
Ask questions 1-5 (modifying as appropriate to their responses) then follow with:

11. I understand that you withdrew early from the study. We would like to learn from you what might have put you off and what we might be able to do better.

Could you please explain why you dropped out the study (e.g. personal reasons, lack of time, problems with study)? If personal/unrelated to study, is there anything AMBER could have done to help you with this? Have you got adequate support in place to deal with this issue? [This is where a recommendation to a support centre for advice might come in]

If directly related to the study, follow up on why they did not feel motivated and engaged with the process: What would have helped with your motivation? How could the level of support provided been improved? What would you recommend to avoid making the same mistakes with future patients of AMBER?

Thank you for your time – we value your input.



Interview Schedule: Participant Interviews (Second Stage)

Pre-amble to the second stage: it will assess what was said in the first stage to see if anything has changed and also to get an overview of their experience with AMBER now they have reached the 24 week stage.

1. I would like to start by looking at your expectations of AMBER when agreeing to take part in the trial.

Why did you sign up for the AMBER study (i.e. expectations about outcomes)? [Add details from first stage about extent of bowel problems.]

Did these outcomes change at any point during the study (baseline appointment, training, 6 weeks, after that)? You said in the first stage of interviewing that you felt the massage was working/not working [delete as appropriate and add details based on perceived impact discussed in first stage of interviewing.] – has this stance changed? How frequently do you visit the toilet now? Did you ever previously have accidents with your bowel, because of urgency in needing to go?

Was anything about the trial different to what you expected?

2. Any problems mentioned last time

[Ask about any problems mentioned during the first stage]. Did any problems occur relating to paperwork or nurse telephone calls or other health problems?

3. In the first stage of interviewing, you shared your experiences of administering the massage:

Did any problems arise that might have impacted upon the effectiveness of the massage [Add details from first stage]

4. Continuing lifestyle changes:

Have you made any lifestyle changes since we first spoke (i.e. more exercise, changes to diet, laxatives, changes to medication)? [Add details from changes made during first stage of interviewing.]

5. Post 6 week AMBER experience?

Last time we spoke, you said you were going to carry on/stop [delete as appropriate] with the massage after the 6 week intervention period – did you do this? If so, please share your experiences on that (i.e. carrying out the massage, but not having to complete bowel diaries and receive weekly telephone calls)? Did this make any difference to your bowel problems? If not, why not and have your bowel problems worsened, improved or stayed the same during this period?

Have you received your 24 week pack? [Due to receive this on the [add date.]] If so, please indicate your thoughts about it. Will you continue to use abdominal massage following your completion of the trial? If so, how often and will you use any measures to track your progress (e.g. keep your own bowel diary)? If not, why and what other form of treatment are you going to use for your bowel problems - would you consider ever using abdominal massage?

Have you got any further questions or comments for the AMBER team?

Thank you for your time – we value your input.



Interview Schedule: Stakeholder Interviews

Introduction

1. I'd like to start by finding out a little bit about you. Please could you tell me about your role as [insert role]?

I'd like to find out more about the current projects you are involved with [add details based on background research and tailor questions around these.]

2. [Check how much she knows about AMBER beforehand] What do you think the potential might be for self-led abdominal massage to help MS patients with bowel problems? How does this compare to other forms of treatment for bowel problems?

-What kind of savings could be made by patients using self-led abdominal massage (i.e. in terms of not having to see a more expensive staff members like a GP or consultant, reducing nurse contact with patient and chances of hospitalisation)?

Some people with MS are not under the care of an MS service – impact on them?

3. If AMBER proves to be effective for managing bowel problems in MS patients, we would like to take this forward to implement the intervention within NHS contexts. Do you have any thoughts on what might help or hinder that?

Implementing message

-Could details for the massage be detailed in existing resources, such as guide to bowel problems or 'Making Sense of MS' booklet provided to newly diagnosed patients?

-Which stakeholders/NHS gatekeepers would need to be engaged/involved in the process?

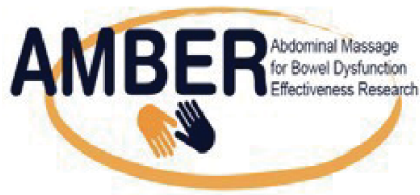
[Scottish MS Register, British Neurologists, third sector organisations?]

-Sustainability: would this be a long-term initiative?

-Would it be implemented in MS Trust educational training, e.g. 'MS Nurse Support Programme.'

4. Can you tell us anything about current or forthcoming policies related to the treatment of MS patients that might have a bearing on the rollout of AMBER in the future?

[Add details based on background research pertaining to neurology/continence services based on expertise of interviewee.]



Draft Interview Schedule: Health Care Professional Site Interviews (First Stage)

Introduction to the process evaluation

1. I'd like to start by finding out a little bit your background and your role in the organisation.

Explore their role and involvement with MS: Please could you tell me about your involvement in multiple sclerosis treatment/services? (Amend according to role of interviewee) How long have you been working in this specialist area and at [add name of site]? What does your role entail?

[Add details based on background research.]

Explore the size and location of facility

Could you tell me a bit more about the [add name of site]? Its mission statement is [add from website] – how does this impact your role and the way you treat patients? How is the shift towards consolidating specialist services and working with other specialist centres impacting upon the services offered to patients? Are there any new forms of training being offered to specialist staff?

[Add details about site]

2. How would you describe current difficulties facing the MS patients that come to your centre

Since MS patients can suffer from cognitive and visual difficulties, how does the [add name of site] accommodate patients with speech, visual and hearing problems?

[Add any information available about services.]

3. I'd like to find out about how recruitment of AMBER is going in your area.

Explore how many recruited to Intervention & Control and any barriers or facilitators to recruitment:

First of all, please could you tell me how many have been successfully recruited so far? Could you tell me more about your experience in recruiting these patients (i.e. how did they find out about the study, what convinced them to take part, was the process of sending out recruitment packs, screening and arranging a baseline appointment straightforward, was the information included in the recruitment packs helpful and relevant to the patients)? Did those interested in the study have any questions/concerns before their baseline appointment or wish any additional information to be included in the recruitment packs? Have there been any problems along the way and, if so, what was the cause?

[Patients can be recruited either in clinic or by sending out an “**AMBER Recruitment pack**” to patients who have been screened from notes or a clinic list. The nurse then sends out a recruitment pack to potential patients and, if interested, they return an ‘expression of interest’ form. The research nurse then telephones the patient to complete the CRF screening; thereafter a baseline appointment is arranged for the patient (either usual time or alternative appointment). The nurse sends out a bowel diary before their baseline appointment.]

4.If we focus now on delivering the intervention itself – what has been your experience of this so far

Explore: how have patients received the information and training; how do staff perceive the intervention:

What have patients reacted to the intervention treatment? Were there any difficulties during the process of administering the massage? Did patients have any questions/concerns about performing the massage themselves? Did patients find the materials provided (DVD, training manual, guide and leaflet) to be helpful and informative or were there any issues? Were there any particular questions about completing the bowel diaries and using the Bristol stool chart?

Now, I want to move onto talk about the experiences of those involved in delivering the intervention. What were your thoughts on the training and materials provided (i.e., was everything clearly explained, were there any problems, any suggestions for ways to improve the training and training materials)? How do you feel about completing the remainder of the intervention (i.e. six weekly telephone calls, 24 week follow-up)?

5.Have you faced any particular challenges in implementing AMBER

Explore challenges and local solutions (changes in staffing; resources; local policy/initiatives):

Does the [add name of site] currently have any treatment options to deal with bowel problems? If so, what does this involve and what challenges arose? If not, why is this the case (lack of funding, specialism in this area, other symptoms take priority)?

Overall, how do you feel about the process of implementing AMBER in the [add name of site] (i.e. challenges involved, what was successful)? With the current financial challenges faced and difficulty in recruiting trained nurses and other forms of clinical staff, are staffing conditions being met?

[Add background research findings.]

6.What do you think has worked particularly well for your centre in terms of implementing AMBER?

Explore local adaptations to the intervention; lessons learned that could be transferred to other teams:

What worked well during the process of implementing AMBER? Did you liaise with any other teams during the process (e.g GPs and community nurses about administering AMBER to those requiring long-term care in their homes)?

Are any additional resources required to successfully implement AMBER? What advice would you give other teams looking to implement AMBER?

7. Are there any other initiatives happening locally for MS patients that might have an impact on our results?

Explore: any local campaigns that might improve recruitment/take-up/completion, or make patients more receptive to self-management etc; other interventions/new treatments being rolled out as part of usual care that might have an impact on bowel problems?

Are there any developments relating to funding, service provision or any local initiatives (such as self-managing symptoms, dealing with bowel conditions) outside the organisation by groups [add names of local and regional groups] that are relevant to the treatment of MS patients? Are there any on-going initiatives, trials and proposed treatments in the [add name of site] or in the local community relating to bowel problems? If so, how would this impact on the administering of AMBER? Are there any charities or other organisations offering support to MS patients?

What kind of psychological and neuropsychological support is provided to patients with MS? Is funding being raised for specific initiatives and, if so, how (private treatment, training levies, fundraising)?

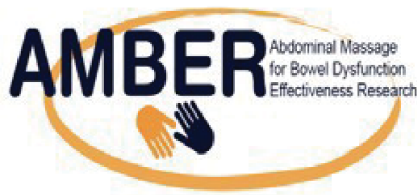
8. To finish, what are the general demographics of MS patients who come to your centre.

Explore: SES range of catchment (deprivation range; urban/rural; ethnicity; age range of patients; if fairly similar to other areas or anything different):

Which groups are most likely to fall into the category of 'did not attend for admission?' Do you think there is a way to change this?

[Add any details found during background research.]

With regards to the catchment area, what are the rates of deprivation, poverty and unemployment? Are these rural or urban places? What is the population of patients with regards to gender, age, ethnicity and unemployment status? Is this fairly similar to other catchment areas within NHS England/Scotland [delete as appropriate]?



Draft Interview Schedule: Health Care Professional Site Interviews (Second Stage)

1. Recruitment

The [add name of site] has currently recruited [add number of participants at time of second stage interview]. Do you think the site will reach its target of [insert number] participants and, if so, do you think it will be able to recruit over this? What advice would you give to other teams in order to recruit successfully?

[Add details of recruitment and any problems faced during first stage of interviewing, including information discovered from interviews with other HCPs at this site.]

There has been [add number] potential withdrawal (check this). Why do you think the site has been so successful/struggled [delete as appropriate] with retention? Have there been any particular problems with patient recruitment and/or retention during the AMBER trial?

[Only ask to those actively involved in recruitment] In the last interview, you were the one been dealing with recruiting patients (e.g. sending out packs, arranging appointments, etc.) – did this continue during the trial or did another member of staff get involved in this?

2. Delivering intervention

Since we spoke last year, were there any difficulties during the process of administering the massage. If so, what impact do you think this would have had on the effectiveness of the massage? If not, did this improve patients' understandings of the pressure required? Did patients have any other questions/concerns about performing the massage themselves? Since you have been carrying out the follow-up calls, how have patients reacted to the intervention treatment?

[Any anecdotes or details mentioned during first stage.]

How has this compared to the reaction of those in the control group? Are you still planning to show the ones in the control group the massage at the end of the trial?

Did patients find the rest of the materials provided (DVD, training manual, guide and leaflet) to be helpful and informative? Have patients had any issues playing the DVD or accessing the videos online?

[Any information provided during first stage.]

Last time we spoke, you said some patients were a bit concerned about completing their bowel diaries properly. Did this continue or what were the reactions of the four other patients you have recruited since then?

How did you get on with the 24 week calls?

I will now move onto any larger changes that may have affected the delivery of the trial. Have there been any changes in staff involved in delivering AMBER in the past six months (e.g. staff leaving or joining the AMBER team)?

What impact, if any, have these changes had on the delivery of the AMBER trial?

Has there been any substantial funding or other changes to your organisation since we last spoke?

3. Problems mentioned during first stage

Mention any problems discussed during the first stage of interviewing – were these resolved?

Are there any other ways to improve the AMBER trial, particularly thinking in terms of an implementation study?

4. Implementing AMBER long-term

Considering your experience with AMBER, do you think it would be possible to implement this as a form of treatment in your centre in the long-term? If not, why not? If so, what additional resources would be needed (staffing, funding, liaisons with external stakeholders)?

Overall, based on your experience of delivering the trial how do you feel about the process of implementing AMBER in the Walton Centre (i.e. challenges involved, what was successful)?



SIX MONTH SITE TRACKING QUESTIONNAIRE

The purpose of this questionnaire is to collect some additional information from the sites involved in delivering the AMBER trial.

It should be completed by the Principal Investigator or their delegate.

Name of Organisation:

Name of Staff Member:

Date site recruited its first AMBER patient:

Date of questionnaire completion:

Have there been any new forms of treatment (including treatment for bowel symptoms) introduced to MS patients in your centre/department? YES/NO

If yes, please provide more details e.g. medication, physical therapy, symptom/pain management, any other issues):

How many other trials is your Unit involved in?

How many of these are specifically related to MS?

Are any of these trials related to bowel problems?

YES/NO

If yes, please provide more details:

During the last 6 months:

1. *Have there been any substantial funding or other changes to your organisation? YES/NO*

If yes, please provide more details:

What impact, if any, has this has on the delivery of the AMBER trial?

2. *Have there been any changes to care pathways in your organisation and the local area, which could affect MS patients? YES/NO*

If yes, please provide more details (e.g. the primary and secondary services patients can access, social care and community health services, etc.):

3. *Have there been any changes in staff involved in delivering AMBER in the past six months (e.g. staff leaving or joining the AMBER team)? YES/NO*

If yes, please provide more details:

What impact, if any, has this has on the delivery of the AMBER trial?

4. Have there been any particular problems with patient recruitment and/or retention during the AMBER trial? YES/NO

If yes, please provide more details:

Thanks very much for your time. Please return either by email to [REDACTED] or post to the AMBER Trial Office.