PODCAST
Prevention of Decline in Cognition After Stroke Trial

PODCAST UK TELECONFERENCE WORKSHOP MINUTES

11 August 2011, 12.30pm

UoN attendees: Sandeep Ankolekar (SA), Sally Utton (SU), Lynn Stokes (LS)

Apologies: Philip Bath (PB)

UK attendees (19): Maggie Ball (C10 Chesterfield), Ahmed Barkat (C12, Newcastle), Shagufta Khan/Mel Dickens (Leicester), Vicki Laughlin/Tracey Marsden/Jayne Hardicre (Salford Royal), Donna Hayward (C05, Yeovil), Lorna Holford (Doncaster), Anna Orpen/Catherine Ovington (C03, Bournemouth), Paula Sharratt (C08, Airedale), Inez Wynter (C11, Mansfield), Kirsty Harkness (Sheffield), Rachel Jolly (C02, Whitehaven), Kath Chapman (James Cook, Middlesborough), Lynn Johnston (C13, Bradford), Ali James (C06, Truro), Michael Keeling (York), Barbara Longland, Gary Ford (Centre 012, Newcastle, SRN Director).

1. Welcome and status
Sally Utton welcomed everyone to the call.

2. Recruitment. Update from Lynn Stokes
There are now 14 centres and 10 patients have been recruited.

3. Personal experience of ward nurse at Centre 01 - Judith Clarke

- JC said that screening from clinic has been very successful as the patients are a few months on from the initial event, and while they are waiting to be seen they are often happy to talk about the trial.
  JC also said that former trial patients have been very successful because if they are interested in trials they are usually interested in hearing about another trial, especially if they had a good experience with the first trial. JC has recruited former ENOS and TARDIS patients into PODCAST.
- On the acute ward JC said they are often busy with the acute trials but at weekends she visits the rehab wards and follows up patients that have previously been highlighted for Podcast.
- JC said most of the patients she has talked to have been very interested in the trial, and some have been disappointed if unable to participate.
- JC warned of the need to ensure patients remain eligible. A patient at Nottingham, was brought in to be randomised, who was out of time. This patient had been in TARDIS, then it was Christmas, and it resulted in the patient being a few days out of time.

- JC said it was important to warn patients that they may fail the telephone screening as they can be cognitively too well or not well enough.
- From meeting the patients on the ward and contacting them JC said she has built up a good relationship and rapport. JC contacts the patients prior to the Baseline appointment to ask them if they have had their bloods taken and checks if they know enough about the trial to answer the main consent questions. JC also reminds them to bring their informants.
- JC feels the Baseline appointment is long but the built in breaks have helped and practising the Addenbrookes, prior to the appointment, with the other research nurses has helped. The scoring needs to be practised. The monitoring appointments ie intensive BP 1 mth, 2 mth, 3 mth, intensive lipid 3 mth, etc only take about 20 minutes.

4. From Screening to Baseline: a reminder

(A flowchart is soon to be made available.)

- Co-recruitment: If a patient is in another trial they cannot be randomised until the patient has completed another trial's primary outcome. However they can be consented for telephone screening once the patient has completed the treatment phase of another trial eg day 8 onwards for ENOS and day 35 onwards for TARDIS.
- If a patient is seen at 8-26 weeks post-stroke eg at clinic, it is possible to actually consent and telephone screen face-to-face on the same day.
- If a patient has been approached re PODCAST on the ward, verbally expressing an interest, and is discharged unexpectedly it is possible to document this verbal interest in the medical notes. However you will still need consent for telephone screening to be undertaken prior to the telephone screening so you could perhaps catch them at a follow-up clinic or visit them at home if this is feasible (unfortunately no payment can be made for home visits).
- Important to make a professional judgement on who will be eligible in the future when you consent the patient on the ward. It is good idea to compile a long list of 'potentials.'
- If a participant is successfully telephone screened, send to the patient the PIS / IIS / SSIS / blood form (requesting fasting UE, lipids and glucose) at patient's GP. To the patient's GP send GP letter screening and GP Briefing letter.
- 1 week later contact the patient and remind them re bloods and about reading the PIS (as the main consent asks them about 'intensive' and 'guideline' it is important the patient is aware of these groups), answer any questions.
- A day or two before the Baseline contact the patient and arrange transport, go through the pre-inclusion checks (Baseline form) to ensure patient is still eligible, remind them their informant needs to attend the Baseline visit, remind them to bring along their meds or prescription sheet.
- Before the Baseline appointment, obtain the blood results, scan results, look through the medical notes and complete as much of the paper Baseline form as possible.

- At the appointment you will need: stopwatch, Omron, internet access, Java applet for the STROOP, scales, height chart, medic for consent and randomisation (preferably PI but we will accept Specialist or Senior Registrar, if GCP trained), another member of staff (if available) and perhaps another room to do the informant's questions.
- Logistics: think about prescriptions and collections (if meds are prescribed).

5. Trial Medic Clarification and Discussion re Inclusion / Exclusion Criteria

- Dr Sandeep Ankolekar said that PODCAST is the only trial in the world looking at preventing dementia after stroke.
- If a patient scores 16 or less on the telephone MMSE they are excluded because the patient is already cognitively impaired so there is no justification for intervention.
- Cognition is affected by increasing age therefore if a patient has no cognitive problems at age 60 they are less likely to deteriorate during the trial period.
- MRS has to be 0-2 at randomisation because if a patient's mRs is higher then the trial interventions are unlikely to change that.
- Randomisation is at 3-7 months post-stroke to allow BP, lipid, cognitive etc stabilisation.
- BP needs to be at 125-170 systolic because if it is higher then it is highly likely they are going to require intensive management. Also it will be difficult to achieve BP differences between the intensive v guideline groups for such patients. It is the same if cholesterol is higher than 8mmol/L.
- Subarachnoid and secondary ICH are excluded as interventions are not effective against them.
- Anterior circulation affects brain regions mostly involved with cognition. Posterior circulation supplies the brain stem therefore less likely to affect cognition and dementia. But we have discussed the inclusion of posterior strokes.
- Cholinesterase inhibitor - this is uncommon, as it is for patients who are already demented, but it is used for patients who have Parkinsons without dementia, which will exclude them from PODCAST.
- Those patients with chronic renal failure and liver disease are excluded because of the medications we may have to prescribe ie higher doses than is common practice.
- The CT/MRI (within 10 days of the index stroke) is required because we would like evidence of stroke and exclusion of other pathologies. We do not require a repeat CT/MRI if there is no evidence seen on the scan as long as we have confirmation a stroke has been diagnosed.

6. Investigator Meeting Reminder

The meeting is to be held on 6th-7th September so please contact the PODCAST/ENOS office for a registration form.

7. Questions from Investigators

Question from Mel Dickens, Leicester – What is happening re their PCT permission?
Mel asked if there has been any update regarding their local PCT's approval of PODCAST. Trent CLRN to be contacted. Action Lynn Stokes.

Question from Inez Wynter, Mansfield – query from the PI
When this centre was started up the PI stated that he was already working to the intensive levels for lipid lowering so if a patient was randomised to guideline he would in fact be allowing higher cholesterol levels compared to his non-PODCAST patients. Inez has asked PI if he is willing to go ahead with PODCAST under these circumstances. Inez to feed back to LS when there is an update.

Question from Maggie Ball, Chesterfield - Are there 2 patient information sheets?
LS confirmed there is only one PIS but when the patient has telephone screened successfully it is a good idea to send them a further copy or to confirm they have their original. Sandeep also highlighted that pages 1 & 2 of the PIS are a brief summary of the trial and it is a good idea to give this short overview to the patient initially so they are not overwhelmed with information.

Prescriptions
The logistics of collecting prescriptions was discussed. Solutions from Nottingham includes using prescriptions that can be exchanged in the community or in the hospital because the hospital pharmacy can have waiting times of anything up to 2 hours. Nottingham research nurses also collect the meds, if prescribed for intensive patients, and then hand them to the patient the day after the Baseline appointment, when the patient returns to have their ambulatory BP equipment removed.

Question - Why are posterior strokes not eligible?
Kirsty Harkness (Sheffield) commented that most areas of the brain involved with cognition are supplied by the anterior circulation but there is some evidence that strokes involving the brain stem and cerebellum may also affect cognition. We acknowledge this and this particular exclusion will be fed back to the Chief Investigator / TSC.

Question from Paula Sharratt, Airedale - We have received CLRN letters asking why recruitment has not occurred within a month of site start-up. What should the response be?
Because of the possible 3 month delay if patients are only screened at time of index stroke then there will be a delay. Letters can be passed onto LS and gave a reminder that patients can also be recruited at f/u clinics so they will be 6 weeks + post index stroke.

Question from Lorna Holford, Doncaster – How can we maintain blinding when there is only one nurse at a centre?
Lorna asked how the research nurse can be blinded to a patient's randomisation when there is only one nurse at a centre. LS advised that DeNDRoN nurses can be used to help with the cognitive testing and nurses from centres local to each other can 'swap' patients. Unintentional unblinding may occur by looking at the sequence of patients monitoring appointments and also patients may contact the nurse mentioning their medications but this is unavoidable. [Patients need to be blinded to treatment as much as possible]. Follow-up by the co-ordinating centre at 12 months, 24 months etc will be truly blinded.

Date of Next Telecon Workshop: TBC