

STARFISH

Newsletter

Summer 2025

In This Edition:



A STARFISH Patient Story:

The NIHR have produced a video about the experience of one of our STARFISH patients. You can find the video [here](#) and the story also been shared by the NIHR [here](#).

There is also an interview with BBC Cambridgeshire is [currently available online](#). The section on STARFISH starts at 1:10:00.



Study Updates & Milestones

- Open sites
- Screened and recruited patients
- Best month for screening and recruitment
- Top screening site
- Top recruiting site

HearX Home Hearing Tests rollout

Training & Engagement

- STARFISH departmental slides for team training
- Q&A sessions

Patient Video

- STARFISH patient video

Primary Care

- Sudden Hearing Loss and STARFISH for GPs
- Primary Care Site participation
- General Q&A information

Associate PI Scheme

- aPI registrations
- More info on the NIHR aPI scheme

Hints & Tips

- WhatsApp group = better communication
- CRF completion
- Questionnaire Booklets
- Week 12 form and patient payments

Study Updates & Milestones

We would like to say a continuing ‘Thank You!’ to all the site team members for your support and hard work enabling us to open **61** sites to date, along with a further **10** in set-up and **12** that have shown an expression of interest.

Patients screened: over **1200**

Patients recruited: **181**

March 2024: Best recruitment month (**18**)

March 2025: Best screening month (**103**)

Congratulations to **UCLH** for being the top screening site with **265** patients.

Congratulations to **Addenbrooke's** for being the top recruiting site with **17** patients.

Screening Reminder

Please remember we require all patients that have been screened to be entered onto the Screening Log, even if ineligible.

HearX Home Hearing Tests rollout

Participants can now complete weekly (or more frequently if they wish) hearing tests at home using a smartphone or computer. The tests, rolled out in June, have been included in STARFISH based on patient feedback, allowing individuals to track their hearing recovery. It also gives us a means to record the trajectory of recovery, as previous evidence has suggested this may be initially steep. The test is an ear-specific digits in noise (DIN) test developed working with HearX, with the aim of assessing functional performance.

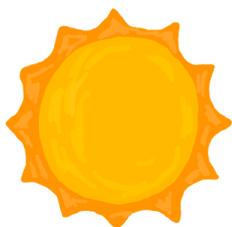
The tests have already been used by some of our STARFISH patients, 'Thank You' to the sites that have organised this. We would encourage all sites to discuss this with any newly randomised patients, when issuing the Participants Packs.

Training & Engagement

The 1:1 meetings held with engaged sites in January and February this year were found to be very valuable in recognising the differing pathways on how the patients enter the trial (either GP referral, after being seen at A&E or from patients actively seeking out the trial themselves). It also highlighted the need of greater in-house team awareness of the trial, hence we would greatly encourage adding as many staff members to the Delegation Log as possible, as this has proved better recruitment numbers at sites.

Please see the link below to the STARFISH Departmental Slides which can be used for internal training of new team members.

<https://entintegrate.co.uk/wp-content/uploads/2024/10/STARFISH-Departmental-Presentation.pdf>



Site Q&A Sessions

Site initiations continue to be in the format of a pre-recorded video presentation slides followed by live virtual Q&A sessions with the Chief Investigators and trials office team, hosted on Zoom. This is mandatory for the PI and Associate PI, although we recommend that anyone involved in research activities for the trial attends too.

Site staff can access the pre-recorded presentation online via [YouTube](#) or the [trial website](#) at their convenience.

You will be asked to self-certify that you have watched the pre-recorded video as evidence of trial training prior to joining a Q&A session.

We also ask that you to register for the Q&A session you will be attending; please do not share the Zoom meeting link details team colleagues, as the registration details will provide us with a record of attendees for report writing purposes.

The live Q&A sessions are held regularly, so you can attend a session that suits you; we would encourage you to join together as a team where you can.

- 1st Monday of the month – 10:00-10:30

To see all forthcoming session dates, please register [here](#).

- 3rd Tuesday of the month – 10:30-11:00

To see all forthcoming session dates, please register [here](#).

We also welcome members of site staff that may be struggling to screen or recruit patients, to re-attend a Q&A session to discuss steps that other sites may have taken to overcome any barriers they have experienced.

Sudden Hearing Loss and STARFISH for GPs

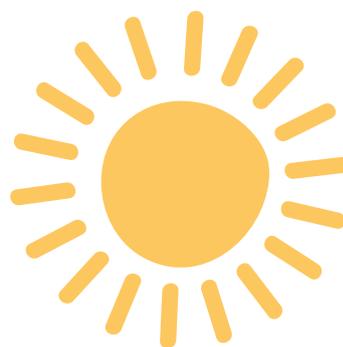
We were able to write an article recently to raise awareness of hearing loss with GPs. You can find this in the March 2025 InnovAiT journal (**Pages 155 - 159**):

https://europe.nxtbook.com/nxteu/sageuk/innovait_202503/index.php?startid=158&/p/154=#/p/154

Primary Care Engagement

The current total of Primary Care sites set-up in each Research Development Network (RDN) are as follows:

- East Midlands: 75
- East of England: 27
- North East and North Cumbria: TBC
- North London: TBC
- North West: 16
- South Central: 0
- South East: 0
- South London: TBC
- South West Central: 0
- South West Peninsula: 44
- West Midlands: 0
- Yorkshire and Humber: 0



Service Support Costs (SSCs) for Primary Care

Practices are now paid study support costs for participating, however SSCs may vary with each RDN. The EoE have agreed the following SSCs for each primary care site:

- £100 for site set up and installation of the pop-up
- £20 per participant recruited into the study via a referral from the site

(There are no research costs available to Primary Care referring sites for this study.)

IT Pop-up for GP medical records

Our IT specialists have created a pop-up which will alert the GP practice staff if a participant is potentially eligible for the study. You can find a pop-up for both EMIS and SystemOne (along with instructions for installation and editing) on the EoE Primary Care website [here](#).

It is important to note that the pop-up includes information on which hospitals/recruiting sites are receiving participants for STARFISH. The pop-up is set up for EoE sites, therefore the list of hospitals/recruiting sites must be updated in the pop-up for each RDN before use.

Full instructions are provided on how to edit the pop-up.

Approvals for Primary Care Sites

The Primary Care sites are referring sites, **not PIC sites**, therefore there are no approvals for Primary Care PICs. The standard pathway for an onset of sudden hearing loss is referral to A&E or ENT, therefore the Primary Care sites will be following routine procedure. If the patient meets the criteria for the study, the pop-up will advise the HCP that the standard pathway for this condition would be referral to A&E or ENT, along with a list of which hospitals are recruiting to the STARFISH study.

There will be no recruitment allocated to Primary Care sites and no database searches undertaken.

Explore our resources and training materials by clicking here:

- [How to assess SSNHL in primary care \(2 min\)](#)
- [Tuning fork tests in SSNHL \(55 sec\)](#)

Let's continue to raise awareness and improve outcomes together — thank you for helping us make STARFISH a success!



Associate PI Scheme

We would like to remind you that the NIHR CRN Associate PI Scheme (Portfolio CPMS ID: 53517) is still open for registrations for the STARFISH trial.

The scheme is open to any healthcare professional willing to make a significant contribution to the conduct and delivery of a study at a local level over a period of at least six months and for STARFISH **this opportunity is ideally suited to an ENT Specialist Trainee, though an Audiologist or nurse could also take on the role too.**

Participating healthcare professionals receive formal recognition of engagement in NIHR Portfolio research studies through the certification of Associate PI status, endorsed by the NIHR and Royal Colleges.

We currently have the highest number of registrations for any ENT trial (currently 100+ registrations). As confirmed by the NIHR aPI scheme team, 'STARFISH has completely revolutionised the number of trainees applying for the scheme with a far higher number registering for an ENT trial than has been previously seen.' Due to this success we have been able to recruit PIs at sites that are not usually research active and support them to deliver the trial. We hope this will encourage participation of others at our STARFISH sites.

For more information visit: nhr.ac.uk/AssociatePIScheme

INTEGRATE are now recruiting new committees for 2025-2027! Positions are available for chair, secretary, and each of the three research committees, with the otology team continuing to support recruitment and associate PI involvement in the STARFISH trial. More information and the application form are available below:

Website: <https://entintegrate.co.uk/integrate-committee-applications-2025-2027>

Application form:

<https://docs.google.com/forms/d/e/1FAIpQLScW0OZPscfEmKV33LuiMFIZ7IJO6-IGzq9o9sErxt0Onz99g/viewform>



SUMMER

Hints & Tips

We have found that sites who are in a WhatsApp group together can stay in touch with members of staff about the STARFISH trial and any potential patients, hence aids recruitment.

CRF completion — common errors:

- Remember to complete ‘Section 3 - Patient approach’ at the end of the Screening Log for **ALL** screened patients.
- PIs remember to complete the ‘Form Completed By & Sign Off’ and ‘Principal Investigator’ sections of the Randomisation and Clinic Visit Forms. Both fields require PI sign off (located at the bottom of respective forms).
- Ensure that if a patient questionnaire booklet is not completed, it is marked as ‘No’ on the relevant Clinic Visit Form, this will stop you receiving repeat missing booklet reminders.
- Ensure that **ALL** Clinic Visit Forms are completed. If the visit did not occur still complete and add the reason why.
- **Please could all sites ensure that the Baseline Clinic Visit form is completed for all patients.**

N.B. if the Week 12 Clinic Visit Form is not completed this will impact on the patient payment being made.

CRF Returns

Thank you to all sites for your continued support in completing CRFs on the STARFISH database in a timely manner; the current return rate is over **92%**.



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