

## The CHOICE Trial Newsletter

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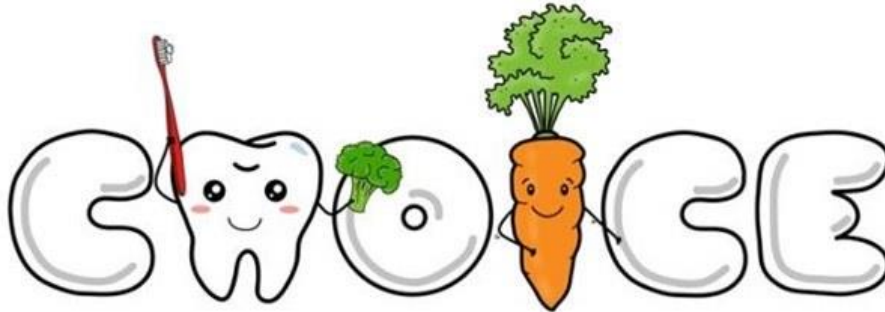
**KIPPAX DESIGN**

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*The CHOICE Trial Newsletter*

*Summer 2024 Edition*

## In This Edition...



Welcome to the fourth edition of the CHOICE Newsletter! Here you will find the following updates to trial progress:

- **CHOICE Progress Summary - Key Milestones**
- **Amendments**
- **Site Setup/Training**
- **CHOICE Facilitators**
- **Sites and Recruitment**
- **The Associate PI Scheme**
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*1 - The CHOICE team at Queens University Belfast*

## Trial Progress - Key Milestones



- **100th participant recruited!** There are now 101 participants recruited, a massive milestone for the trial. Well done to everyone on all your hard work. We are hoping to grow this number quickly in the coming weeks and months so keep up all the fantastic work!
- *Sites can now be recruited from the whole of the U.K.!* Previously, sites could only be recruited from four regions of the U.K. (Northern Ireland, Cheshire and Merseyside, East of England and Yorkshire and The Humber). We have now opened recruitment up to anywhere in the U.K., this will hopefully help boost recruitment figures fast. We are really looking forward to working with more practices and adding to our fantastic team.
- The Study Within A Trial (SWAT) has been approved to continue alongside the main study. This is great news as we are almost at our SWAT target of 18 sites. We hope to reach this in the coming months and get more letters sent out when schools begin again in September. If your practice is interested in signing up to the SWAT please contact **Marc Edwards-** [marc.edwards@gub.ac.uk](mailto:marc.edwards@gub.ac.uk) or **Nicola Carlin-** [n.carlin@gub.ac.uk](mailto:n.carlin@gub.ac.uk).

## Amendments



We have taken your feedback on board and some changes have now been made to hopefully make the recruitment process easier. These important changes are:

- The window between randomisation and the intervention visit has been increased from 6 to 12 weeks.
- Trial information can now be sent out to potential participants ahead of the participants' appointment at the clinic.
- The intervention can now be carried-out remotely (e.g., phone call, Teams).
- Consent can be completed on paper and uploaded to REDCap later (e-consent is still available).

**All relevant documents have been updated with these changes and will have been sent out to your practice.**

## Changing Habits To Prevent Child Caries

- The trial has now been formally listed on The International Standard Randomised Controlled Trial Registry, which is recognised by the World Health Organisation and provides the unique identification number necessary for future publication. See <https://doi.org/10.1186/ISRCTN87811904>
- Regular Trial Management Committee meetings have been held to update the team on trial progress and plan for upcoming activities.
- **We now have merch!** Thank you to the fantastic team at LCTC for arranging a range of CHOICE merch items including: pens, notebooks, travel mugs and tote bags. Each practice will receive these items in the coming weeks!

## Site Setup/Training



**Twenty one sites** have now been successfully opened for recruitment across the U.K., each with its own team of enthusiastic dental nurses and dental practitioners.

*Sites can now be recruited from the whole of the U.K. and we have began site set up in new regions: West and East Midlands!*

Additional site trainings are set to take place in the coming weeks, led by Pauline, Cynthia and Marc. We welcome the fantastic additions to the trial.

***Training for dental nurses can now be carried out online.*** Current training dates are; ***14th & 28th of August, and 9th of October (10am - 4pm).*** If any dental nurses in your practice need trained please let us know and we will arrange for them to join one of these sessions.

Online refresher trainings can also be arranged, if you feel you would benefit from brushing up on your skills, please contact Marc Edwards- [marc.edwards@gub.ac.uk](mailto:marc.edwards@gub.ac.uk)

*As a reminder, the REDCap system now has a test facility so you can practise before recruiting your first participants. REDCap is also now updated to allow research nurses to view recruitment figures and to show reasons for patients ineligibility. This is a great help in troubleshooting and a great opportunity to become familiar with the system.*

## CHOICE Facilitators

Dental nurses have been continuing to send in their practice CHOICE DR-BNI recordings and we have been extremely impressed by the quality.

We now have 45 dental nurses who have been approved and certified as CHOICE Trial Facilitators, currently on CHOICE, with many more to undertake training in the coming month!

*Congratulations everyone on your hard work in becoming facilitators!*

**As a reminder, there is a study drop-in session every Wednesday from 1:00 - 1:30pm on teams for all sites.**

This is a great opportunity to speak with the team if you have any questions or ideas regarding any aspect of the study.

Moving forward, we hope to use each of these sessions to focus on a specific topic area (e.g., 'using REDCap'). If you have any particular topic in mind please contact Nicola, our trial administrator [n.carlin@qub.ac.uk](mailto:n.carlin@qub.ac.uk) or [choice.study@liverpool.ac.uk](mailto:choice.study@liverpool.ac.uk). However, **all types of questions** will be welcome at each drop-in session so please come along so we can support you the best we can.

## Sites and Recruitment



**Recruitment hits 100!** A big shoutout to *Milne, Spencer and Harris* who have recruited our 100th participant, a great achievement for the trial!

**Congratulations everyone on all your hard work recruiting participants this far.**

We need to progress the number of recruits quickly to show NIHR that we can succeed with recruitment, so keep up all the fantastic work and don't hesitate to contact us with any queries you may have. The CHOICE team are here to support you in anyway we can.

Contact [n.carlin@qub.ac.uk](mailto:n.carlin@qub.ac.uk) or [choice.study@liverpool.ac.uk](mailto:choice.study@liverpool.ac.uk)

## Associate PI Scheme



The Associate PI Scheme is now up and running for the trial.

- The scheme is a six month, in-work training opportunity, allowing healthcare professionals to gain practical research experience.
- Once completed, you will gain Associate PI status and receive a NIHR and Royal College endorsed certificate to indicate the study, time period, and centre at which you were certified.
- This is a fantastic opportunity for dental staff to receive formal recognition for the work they're already doing as part of the CHOICE trial.
- We have had our first two applicants approved for the NIHR Associate PI Scheme which is a great achievement. Please contact us if you want support for this via Nicola [n.carlin@qub.ac.uk](mailto:n.carlin@qub.ac.uk).

If you are interested in joining the Associate PI Scheme, please speak to your regional research nurse. If you would like to know more about the scheme click [here](#).

Email: [associatepiscHEME@nihr.ac.uk](mailto:associatepiscHEME@nihr.ac.uk)

***Thanks to all the staff who have already signed up!***

## CHOICE Study Within A Trial (SWAT)

Continuing to run alongside the trial during the initial recruitment phase is the Study Within a Trial (SWAT), which is an optional recruitment-enhancing activity to engage non-dental attenders.

***The aim of the SWAT is to enhance recruitment to the CHOICE Trial in irregular dental-attending children and to explore the facilitators and barriers to recruitment of the target population.***

The activity is being run by the research team at Queen's University Belfast and involves dental nurses in the initial CHOICE sites opened for recruitment engaging with two local nursery or primary schools and arranging for 4-7 year-olds to receive letters to take home encouraging them to go to their local CHOICE dental practice for a check-up if they don't already have a dentist.

Primary caregivers who consent to take part in an interview will be asked about the things that helped them decide whether to take part in the CHOICE trial.



This is an exciting opportunity to investigate a potential method for increasing recruitment to a clinical trial and for engaging potentially high-risk children who might otherwise be missed by interventions.

***There are currently 17 sites participating in the SWAT and 9 have identified schools. A total of 1,484 letters have been sent out to these schools. Overall, there have been 15 New Starter Patients with letters.***

***We just need one more site to take part in the SWAT to reach our target of 18 sites!***

These are preliminary figures, if your practice has signed up and has any update please let us know. If your practice is interested in taking part, please contact **Marc Edwards-** [marc.edwards@qub.ac.uk](mailto:marc.edwards@qub.ac.uk) or **Nicola Carlin-** [n.carlin@qub.ac.uk](mailto:n.carlin@qub.ac.uk)

***A massive thank you to those taking part!***

## ENCOURAGE



Exciting additional research is being conducted as part of CHOICE to explore *how* the CHOICE trial works. Dr Fionnuala Lundy from Queen's University Belfast is the Primary Investigator on an efficacy and mechanism evaluation study called ENCOURAGE.

***Elucidating the mechanism of action of behavioural changes on Child tooth decay in the Randomised controlled CHOICE trial – a role for salivary lactic Acid? (ENCOURAGE).***

The study involves saliva samples being collected at the initial participant visit as well as 6 months after delivery of the CHOICE intervention and will investigate whether the acid levels in saliva change as a result of the behavioural changes that participants make. Let us know if you are keen to be involved in this sub-study.

## Website



We are delighted to have our fantastic CHOICE Participant Website, co-designed and hosted by our wonderful partners at Parenting Focus (previously Parenting N.I.).

On the website, CHOICE participants can find information about the study and we will post regular updates in the 'news section' regarding trial progress and reminders about follow-up questionnaires.

Link- <https://parentingfocus.org/choice-queens-university> Password- **CH01C3**

## Welcome To The Team!



Since the last update, the following people have joined the CHOICE team:

- **Claire MacAllister.** Claire is the Research Nurse in Northern Ireland and has already shown great expertise which will be invaluable when supporting our N.I. sites. We look forward to working with her.

## Research Dental Nurses

*Meet the fantastic Research Dental Nurses who will be supporting trial recruitment in each region.*



2 - Claire MacAllister, Northern Ireland



3 - Anna Nielsen, Yorkshire and The Humber



4 - Amy Rawsthorne, Cheshire and Merseyside



5 - Wendy Lodge, Essex and East Anglia

## The CHOICE Team



**6 - Professor Pauline Adair, Chief Investigator**



**7 - Dr Girvan Burnside, Statistical Lead/Co Chief Investigator**



**8 - Professor Cynthia Pine CBE, Dental Lead**



**9 - Dr Ikhlas El Karim, Clinical Lead for Northern Ireland**



**10 - Dr Peter Day, Clinical Lead for West Yorkshire**



**11 - Professor Nick Barker, Clinical Lead for Essex and East Anglia**



**12 - Professor Sondos Albadri, Co-Clinical Lead for Cheshire and Merseyside**



**13 - Professor Fadi Jarad, Co-Clinical Lead for Cheshire and Merseyside**



**14 - Catherine Spowart, Liverpool Clinical Trials Centre**



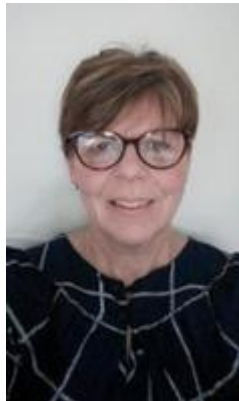
**15 - Professor Ciaran O'Neill, Lead for Health Economics**



**16 - Professor Sue Pavitt, PPI Advisor**



**17 - Professor Fionnuala Lundy, Lead for PPI, ENCOURAGE PI**



**18 - Muriel Bailey, Parenting NI**



**19 - Professor Aidan Feeney, Lead for Process Evaluation**





20 - Dr Marc Edwards, Postdoctoral Research Fellow



21 - Nicola Carlin, Trial Administrator

## Contact Us

If you would like to find out more about the trial or have any specific trial-related queries, please contact us:

[choice.study@liverpool.ac.uk](mailto:choice.study@liverpool.ac.uk)

