

SWEET Newsletter



July 2025



Here's what has happened in the last month and what's to come!

Welcome to the July 2025 SWEET newsletter!

We are pleased to share with you the latest study news.

As of 28th July 2025 we have randomised **1464 participants** which means the initial trial target has been met! 🎉 We would like to thank all of our site study staff and their participants. Your hard work has allowed us to consistently beat our recruitment targets.

As you are aware we are permitted to over recruit to approximately 10%, therefore...

The last date to register patients to the SWEET trial will be 29th August 2025. Once patients have converted, we anticipate that we will have achieved the 10% additional randomised patients.

As recruitment is approaching its end we will now be focusing on follow up rates. The trial team will be sending weekly reminders to site staff to prompt posting out the relevant follow up questionnaire. We would love to see a great return rate! 😊

Please note the trial team will send three separate follow up reminders, at -4 weeks, 0 weeks and +2 weeks unless the questionnaire is received at the trial office prior to those time points. We encourage sites to send the questionnaires at -4 weeks to ensure patient has the optimum time frame to complete and return to the trial office within the desired window.

Finally, please continue to check if you have any Baseline/Follow Up Questionnaires that haven't yet been sent to us and send them back ASAP! **Please don't forget to include the TNO and initials.**

Thank you again for all your hard work.

Enjoy this edition of the study newsletter!

The Sweet team

In this newsletter you can expect:

Recruitment Update

Follow Up Spotlight

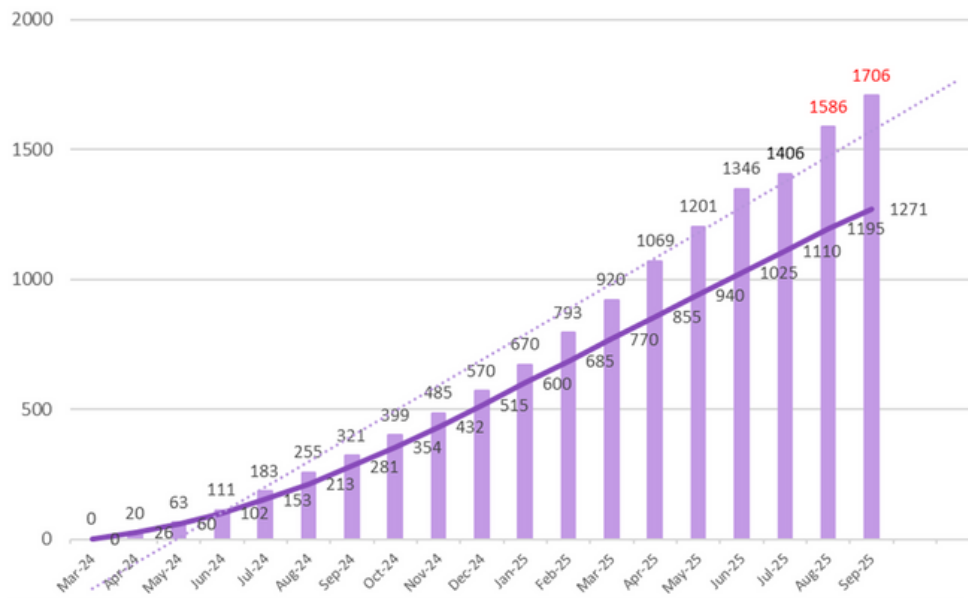
Event News

Withdrawals

Amendments

BCN Video Calls & IT Support

SWEET: Recruitment target Vs Actual



Recruitment Update

- We now have 66 sites across the UK open to recruitment with 1464 participants randomised by mid-July 2025- **Initial target met!**
- The trial will be over recruiting by approx 10% (1606) which has been approved by the funder (please note an amendment is not required)
- We project that 1606 participants will be randomised by 08th Sept 2025.
- 1620 Registrations = 1606 Randomisations
- **Last date to register patients 29th August 2025**
- Where possible please try and reduce time to randomisation so we can best monitor conversion over the next 4 weeks



Follow Up Spotlight

6 month & 12 month Follow Up is now well underway! Thank you for sending out the follow up questionnaires and completing the follow up CRF.

Please remember:

- To send the cover letter & a return envelope with the **Follow Up** questionnaire.
- Ensure you complete the patient **TNO, initials and follow-up timepoint**- please tick the right box on the front!
- Regardless of questionnaires status please complete the **Participant Status section** of the follow up CRF (the other questions are for WCTU use) using the records available to you.

Thankyou!



Event News: Site Drop In

Join us for our upcoming study site drop in session. These sessions comprise of a few updates from the study team followed by open discussion. We encourage your team to come along and raise any queries and or experiences you have. Here are the details:

- Date: 12 August 2025
- Time: 12:00-12:30
- Location: Microsoft Teams
- Meeting ID: 314 957 200 738
- Passcode: Qb7zrG

If you are unable to attend a session please decline the occurrence and not the series.

Withdrawals

We have received an influx of emails regarding non-adhering patients and withdrawals. **Please note that non-adherers do not need to withdraw!** Withdrawal of non adhering patients could lead to a bias in results. We would like to maintain as many participants in the study as possible.



There are 4 levels of withdrawal to consider- Please discuss this with the patient and clarify which options apply as they may not wish to withdraw from the trial completely. Where possible only withdraw from the specific options applicable to the patient.

•Does the participant wish to be withdrawn from the HT&Me intervention only?

Participant will continue to complete questionnaires and will continue to be followed up per the protocol schedule.

- Does the participant wish to withdraw from questionnaire completion?

In this case, the participant will no longer complete questionnaires but will continue to be followed up as per the protocol.

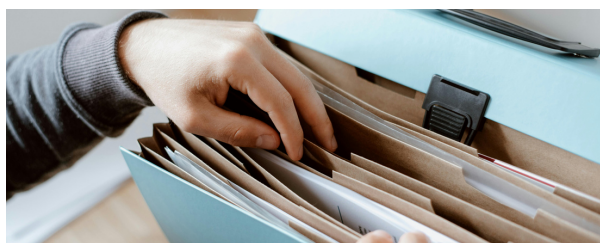
Does the participant wish to withdraw their consent to be contacted for follow up information?

Follow-up information should still be reported from hospital records, where possible, using CRF 6. This can continue without further contact with the patient

•Does the participant wish to withdraw completely from the study?

Encompasses all previous options. No further data will be collected; all data collected to date will be retained and analysed.

If a participant is fully withdrawn, this means we cannot calculate long term adherence using data linkage...so please consider this with the patient.



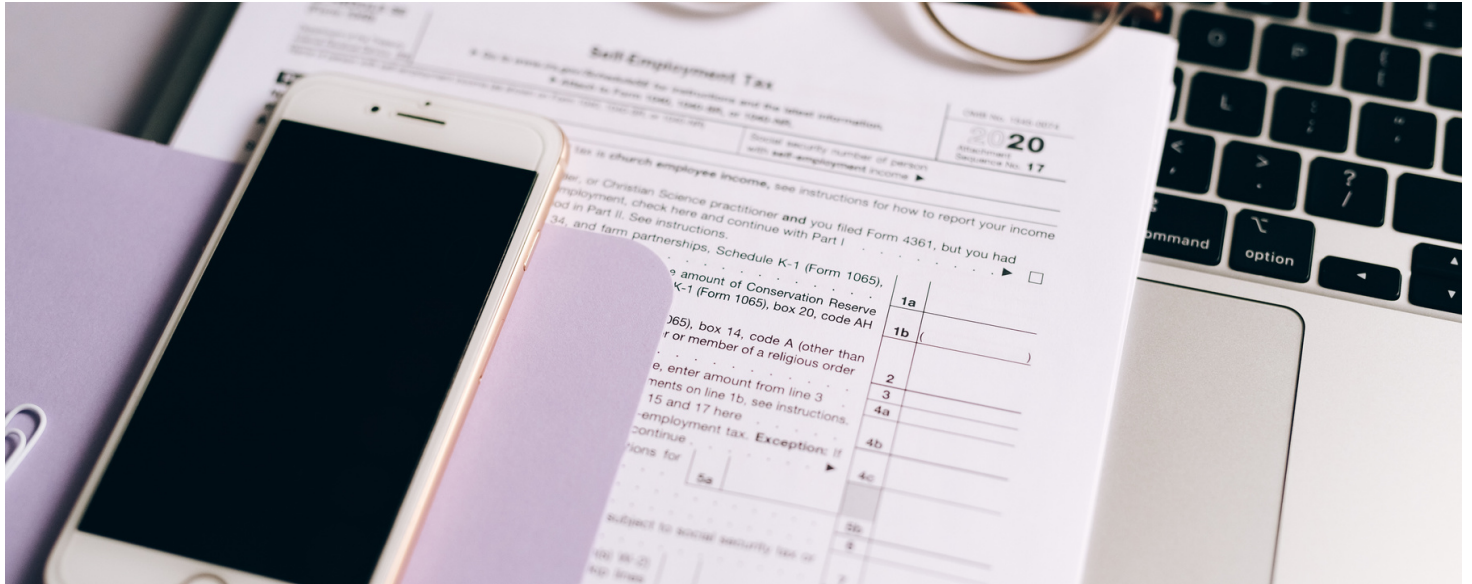
NSA20 & SA02

- NSA20 was sent to all sites on **27th June 2025**, if you have not done so already, please ensure you send confirmation of receipt to the SWEET resource account (SWEET@warwick.ac.uk). Please make sure the amendment details are saved in folder 4.2 of your ISF.
- SA02 will shortly be submitted to REC for review, once implemented our Trial Manager, Rae, will provide mandatory training to all site staff, this will likely be drop-in sessions across multiple days.



A Few Notes To Remember

- Please ensure patient contact details CRF is being completed promptly- really important!
- Ensure consultation checklist is being completed within 24 hours of consultation taking place- follow up text messaging service relies on this being completed promptly.
- Avoid sending trial related emails to personal inboxes- send to SWEET@warwick.ac.uk or htandmesupport@warwick.ac.uk
- Be mindful of sharing PID outside of the database
- All current ISF documents can be found on our website here:
<https://warwick.ac.uk/fac/sci/med/research/ctu/trials/sw eet/isf/>

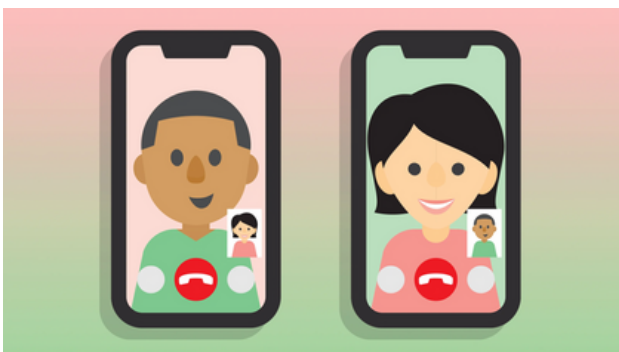


BCN Video Calls & IT Troubleshooting

The BCN nurses have reported a significant increase in the number of patients experiencing issues with technology- especially video calls for their HT&Me consultations. Some patients are reporting they have been told that consultations will all be managed via telephone calls.

It is preferred that **consultation 1 is carried out by video call** (Zoom or Teams), this is the most helpful and impactful way to share information so that the patient can get the most out of the consultation. We ask that a telephone call is the last resort!

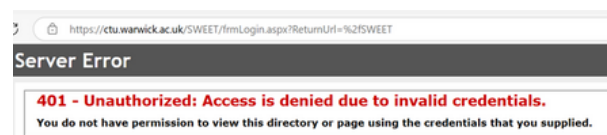
If patient prefers then it is ok to carry out consultation 2 by phone.



401 Error- We need IP addresses to ensure the database is being accessed by the correct people from a secure location. We ask sites to Google 'what's my IP address' and send the result.

Locked Database- You will be locked out of the database after 5 wrong attempts. Please use the 'forgotten password' link.

HT&Me Passwords- The username and passwords are **case sensitive**. Please be diligent when setting up the accounts to avoid patients having issues with logging in to their accounts.



Thank you for reading!

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