CADET NEWSLETTER

ISSUE 8: February 2024 (version 1, 26 February 2024)

Newsletter

CONTENTS

1. WELCOME MESSAGE FROM THE CHIEF INVESTIGATOR

Welcome to our February Newsletter.

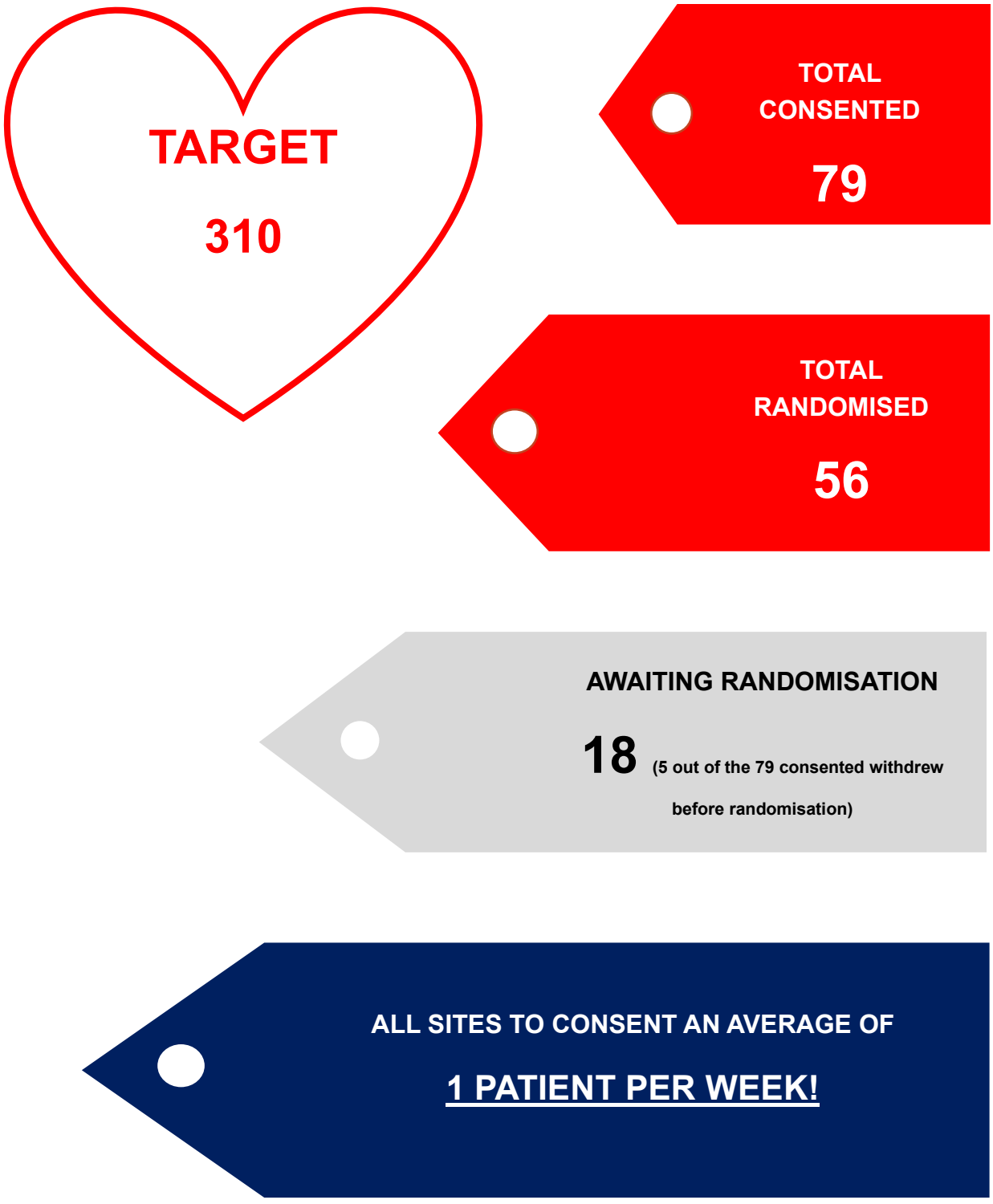
This newsletter will provide updates on recruitment, logs, useful guidance documents, important reminders, cadet in the news, repeat of Baseline visits, e-consent updates, and helpful answers to screening questions.

Thank you for your continued great work on CaDeT.

Dr Cathy Murphy

Our next **3-weekly CADET catch-up with sites** will be held on **WEDNESDAY 6th March @11am-11:30am**

2. RECRUITMENT UPDATE FEBRUARY 2024



3. STUDY LOGS

A. Screening Logs

We will be requesting that you send your most updated screening logs to SCTU/ or Scottish Hub (GCU) by:

10 Mar 2024

B. Catheter Accountability Logs

We will also be requesting that you send your most updated accountability logs to SCTU/ or Scottish Hub (GCU) by:

10 Mar 2024

C. Delegation Logs

Please ensure that you keep your delegation log updated. Any changes to the Trial Research Team should be reflected on the Log. Please ensure that you send any updated logs to:

SCTU Trial Manager cadet@soton.ac.uk

Or (Scottish sites only)

GCU Trial Manager gcucadet@gcu.ac.uk

4. REMINDERS OF USEFUL GUIDANCE DOCUMENTS

- ✓ PROMPT SHEET
- ✓ TENALEA USER MANUAL
- ✓ E-CONSENT GUIDANCE
- ✓ TEXT ANYWHERE MANUAL

5. RECRUITMENT

Please continue to notify SCTU/ GCU of all **completed consent visits** and let us know the date that you have booked for the patient's **Baseline Visit**!

The PROMPT sheet is a helpful guide, all the documents that we need from you during recruitment are detailed here!

OPTITIP EXPIRY DATES

Please continue to log the Optitip expiry date on the catheter accountability log.

Please notify the Trial Manager if you have Optitip at the site with an **expiry date of less than 12 months, at the time of review.** As per CaDeT protocol (v3, 27 Sep 2023), all patients randomised to the Optitip must be given 12 months' worth of catheter

6. REPORTING REQUIREMENTS FOR ADVERSE EVENTS, AND SERIOUS ADVERSE EVENTS

As per protocol (version 3, 27 Sep 2023), all related Adverse Events (AE), and Serious Adverse Events (SAE) are to be recorded on the database RAVE.

In addition to reporting on RAVE, we need you to complete an **SAE reporting form** for **related Serious Adverse Events AND unrelated Serious Adverse Events ONLY** (we don't need you to complete this form for related *Adverse Events*, **Serious ones only**….)

See the table below.

MORE IMPORTANT REMINDERS

When you notify us of consented patients and their scheduled Baseline visits, please let us know if the patient is a frequent changer.

Please ensure that EVERY invited patient, who does not respond to the invite letter, is **called,** OR sent **the non-response to the invite reminder letter** within 3 weeks of posting the invite.

Please email cadet@soton.ac.uk for all Optitip order requests.

AE and SAE reporting		Record on the database?	Report to SCTU?
AE	Related to bladder/ catheter	Yes	No
	Unrelated	No	No
SAE	Related to bladder/ catheter	Yes	Yes
	Unrelated	No	Yes

7. CADET IN THE NEWS

> Southampton Clinical Trials Unit > News >

Care home resident Chris encourag others to take part in vital research

Published: 26 January 2024

Sue at Chris at Claxton House

A care
first pe
researc
people

Chris, 6
Norfolk
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The Ca
Southa
by the
Research (NIHR), is testing a new 'Optitip' catheter which researche
infections (UTIs) in people who have to use them, compared to the

Many patients using an indwelling catheter (which is left in place a
needed) experience problems that impact their lives. These include
quality of life.

People aged 18 years or over who use an indwelling catheter are ir
which randomly allocates participants to use either the new or old
Participants on the CaDeT trial are monitored regularly and receive
about how the catheter is affecting their health and life in general.

With the help of Sue, one of his carers, and a research nurse from t
team behind the trial by taking part. Chris said:

"I'd had the same catheter since the bladder had stopped working,
and I thought 'well, I'll have a go at it' as I felt that it could help a b

Sue, who has worked at Claxton House for three years, is keen to h
try to improve care. She said:

CaDeT in the News!

Thank you to PI Julia, and her team at Norfolk Site, for supporting these patients and adding to their positive experience of being involved in Research!

Follow this link to access the full article: [Care home resident Chris encourages others to take part in vital research | Southampton Clinical Trials Unit | University of Southampton]

NHS
Norfolk Community Health and Care
NHS Trust

8. REPEATING BASELINE VISITS

When does a **Baseline visit** need to be repeated?

- The Baseline visit needs to be repeated if **more than 2 months have elapsed** since the Baseline visit before the next planned catheter change.
- Sites do not need to repeat the demographic information.
- Sites must also repeat the eligibility assessment.
- At the Baseline Visit, it is important to re-assess the questions regarding eligibility (i.e., has their UTI, antibiotic usage or living status changed since the previous baseline data was collected).

Updating the Baseline e CRF on RAVE

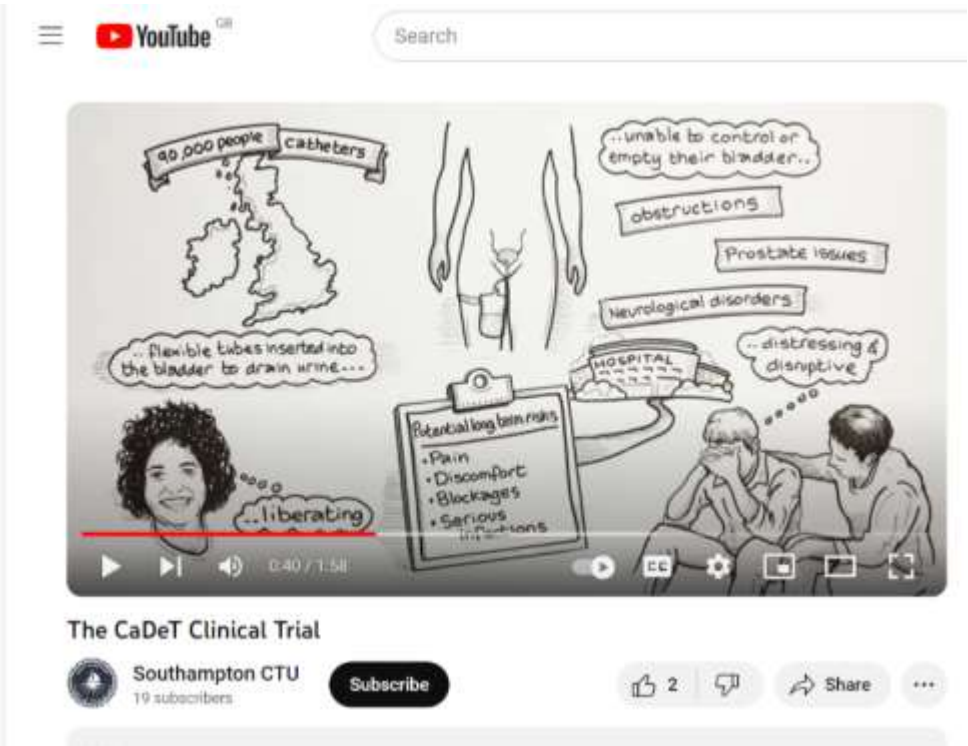
- When a Baseline visit has been repeated, the site must ensure that any information that has been changed, is updated on the electronic form on RAVE. Please be reminded to update the date of the Baseline completion on RAVE, and any information that has changed.

9. E-CONSENT

We have noticed that the most frequently used consent method at our cadet sites is face to face, or remotely (over the telephone/ MS Teams/ Zoom). Very few patients opted to complete the consent using the e-consent platform. Therefore, we decided not to update the e-consent platform with the new versions of the informed consent form. Please continue to consent patients face to face or over the telephone, please let us know if a patient has requested to complete their consent using the e-consent, so that we can advise accordingly to ensure that the patient completes the correct version of the informed consent form.

Please continue to share the **CADET INFOGRAPHIC** amongst your MDT (including community and district nursing teams).

The PIS talks about this video, and explains how the patient can learn more about the trial by visiting: www.cadettrial.com



10. SCREENING Q&As

QUESTION	ANSWER
Can we include patients from 'intermediate care' beds that are based in care homes?	***Yes, patients that are in intermediate care beds in care homes would be eligible.*** *However, patients that are in community hospital-based intermediate care would not be eligible.*
Can we include people with open-ended Foley catheters	*Yes, patients using any Foley catheter (open or closed and including all Folysil variants) can be included* ***and they can stay on their usual open or closed catheter (including Folysils) should they be allocated to the control group.** **Please note that we recently have updated the decision to allow patients to stay on their usual Foley on 18 December 2023. If you have excluded patients due to them not wanting to use the standard Foley (if randomised to the Foley arm), please consider a re-approach to these patients.*
Can we include people with prophylactic antibiotics	*Yes, the use of prophylactic antibiotics would not exclude a patient.*
Can we include people with other signs/symptoms of UTI not in the definition (who have been prescribed ABx) e.g. strong smell of urine, bladder spasms, burning sensation?	*When screening for eligible participants, we're looking for people who have had a UTI in the last 12 months. This does not need to be microbiologically confirmed. Instead, patient-reported signs and symptoms can be used. This is in line with NICE guidance (Quality Standard 20 – Urinary tract infections in adults, Quality Statement 2 – Diagnosing urinary tract infections in adults with catheters). If a potential participant reports that they have had a UTI in the last 12 months (or if it is recorded in notes), this is sufficient for eligibility purposes.*
What is the definition of terminal diagnosis - timescale?	*If the individual is expected to live for 12 months or less from the time of randomisation.*

Do community nurses have to continue with bladder washouts if someone is given the Optitip? Or should they re-assess and see if they still need regular washouts? (in protocol it says to continue with previous routine, but won't this affect data if they're going out to do regular washouts if they don't need to?).	*They should continue with usual care, making decisions as they normally would (e.g., continue with washouts if they are needed).*
Can we include patients in hospital at home?	*Yes, as per protocol inclusion criterion 3 Community-dwelling (own home or residential care, including assisted living)*

QUESTION	ANSWER
How do you define unresolved urethral stricture? Is this when a catheter can't be placed easily or a special type of catheter needs to be used? I had one patient who had a stricture which seemed to be treated by having a catheter (if they removed the catheter, the stricture would return) – would they be included?	*Yes they could be included if they are anticipated to have a catheter that will be placed in the community for 12 months*
Does lifelong hormonal therapy for prostate cancer constitute ongoing interventional therapy?	*Can be included.*
Would a patient be eligible for the study, if they are taking Cranberry juice, D'mannose, or if they are on long-term antibiotics?	*Use of any of the above, would not exclude a patient, the use of prescribed concomitant medication is noted at the Baseline and follow-up.*
What happens if the catheter of a patient randomised to the Optitip catheter falls out or gets blocked and they are catheterised in A&E with the standard tipped catheter?	*As per protocol, medical records should be updated to indicate participation in the cadet trial. The patient will also have a trial card they keep with them, indicating their allocation (Foley participation Optitip). All patients should receive a box of Optitip to last them for 12 months, at randomisation, which is kept with them. In instances where the patient visits A&E the Optitip (if randomised to this) should be kept with the patient. If the Optitip is not available to use at A&E then the change back to the Foley catheter for that particular change will be*

	picked up in follow-ups and notes review. Their next changes should be back to their allocated treatment (Optitip) unless decided otherwise by the patient or research team.
For the purpose of this study is the catheter material of the standard Foley catheter relevant (Silicone or Latex)?	*The Optitip material is Silicone. Whilst the material type of current foley would not exclude, the patient must be aware that they have a 50:50 chance of being randomised to the Optitip, which uses the Silicone material.*

Newsletter

CaDeT

NIHR | National Institute for Health and Care Research

GCU Glasgow Caledonian University

University of Bristol

University of Southampton

University of Surrey

University of Stirling

University Hospital Southampton NHS NHS Foundation Trust

Acknowledgments to our Supporting Sites: Hertfordshire Community NHS Trust; Norfolk Community Health & Care NHS Trust; Shropshire Community Health NHS Trust; Bradford District Care; NHS Lanarkshire; NHS Fife; Hertfordshire Stevenage; Nottingham City Care; Central and North West London; Central London.