Canolfan ar gyfer Gwerthuso,
Asesu Dyfeisiau ac Ymchwil Gofal Iechyd
CEDAR
Centre for Healthcare Evaluation,
Device Assessment and Research

A comparison of paper versus electronic remote consent – lessons learned so far from the HELPP Study

Samuel Bird & Ruth Louise Pool
CEDAR (Cardiff and Vale University Health Board)
Samuel.bird2@wales.nhs.uk

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eConsent ≠ Remote consent

Remote Consent	eConsent
Collection of consent away from the site	Uses a tablet, smartphone, computer or other electronic device
May involve eConsent (but not always)	Can be remote or on site (or both)
Sometimes achieved by sending paper documents through the post	The 'electronic' part can be either or both: • Informing/educating participant e.g. video, podcast • Documenting consent using electronic signatures

Example: HELPP Study

- HeEL Pain Pathways
- Feasibility study
- Single-site, NHS Sponsor
- Interventions are all standard care
  - Self-help video (remote)
  - Virtual consultation (remote)
  - Orthotics
  - Shockwave therapy (ESWT)
- PROMs questionnaires
- Low risk, non-CTIMP

HELPP
HeEL Pain Pathways

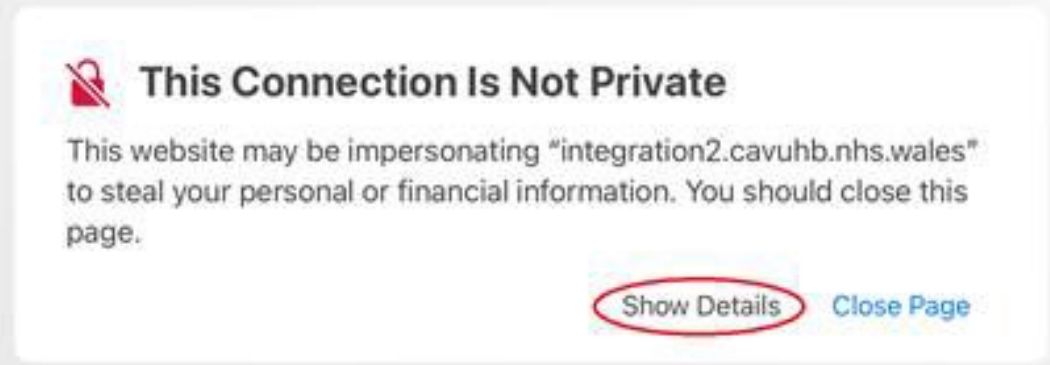
CTIMPs (high risk)	**Non-CTIMPs** (if negligible/minimal risk)
"There must usually be a discussion in real-time between the participant and the investigator" Researcher needs to document that they *witnessed* the patient signing the ICF (i.e. countersign).	Process "does not usually require the need for a two-way discussion" R&D agreed to have a separate electronic consent form that the researcher signed off after checking the participant ICF. No research activity started before that.
"eSignatures that involve the participant tracing their handwritten signature using a finger or a stylus or biometric eSignatures should be considered"	"any simple electronic signature is normally adequate"

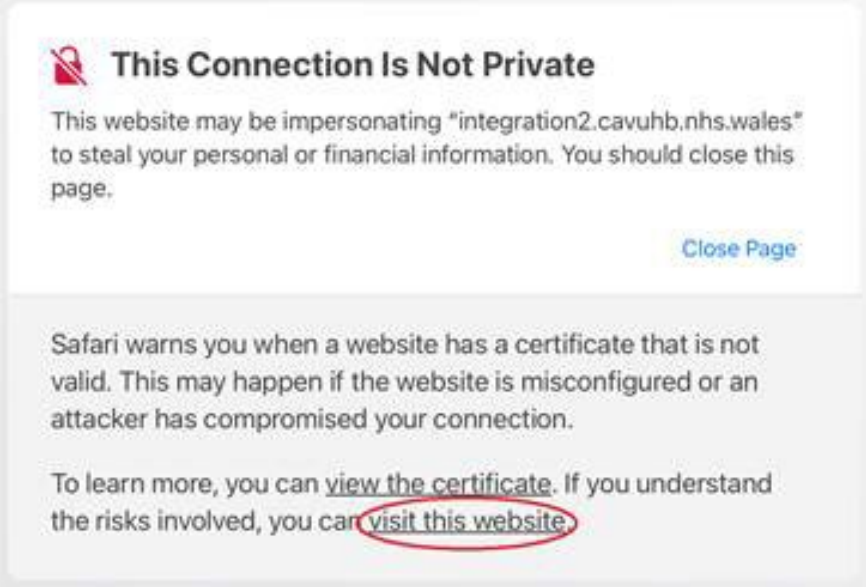
Consent methods in HELPP

Paper	Pre-screening call	Participant information sent **by post**	Screening call	Return signed ICF **by post**
Electronic	Pre-screening call	Participant information sent **by email**	Screening call	Sign & submit ICF **online**

Problems

- Paper ICFs delayed or lost in the post
- Patient access to REDCap forms from outside NHS Wales
  - Delays with installation of secure certificates for a public-facing server infrastructure

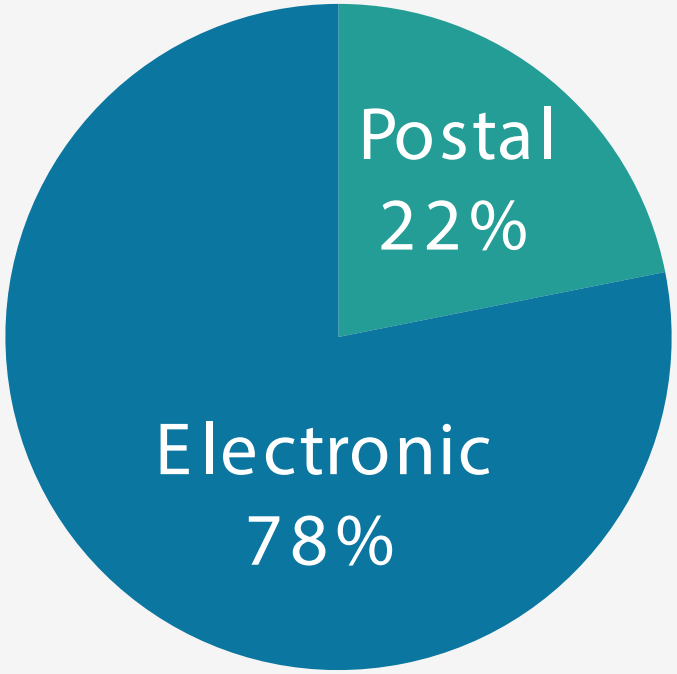




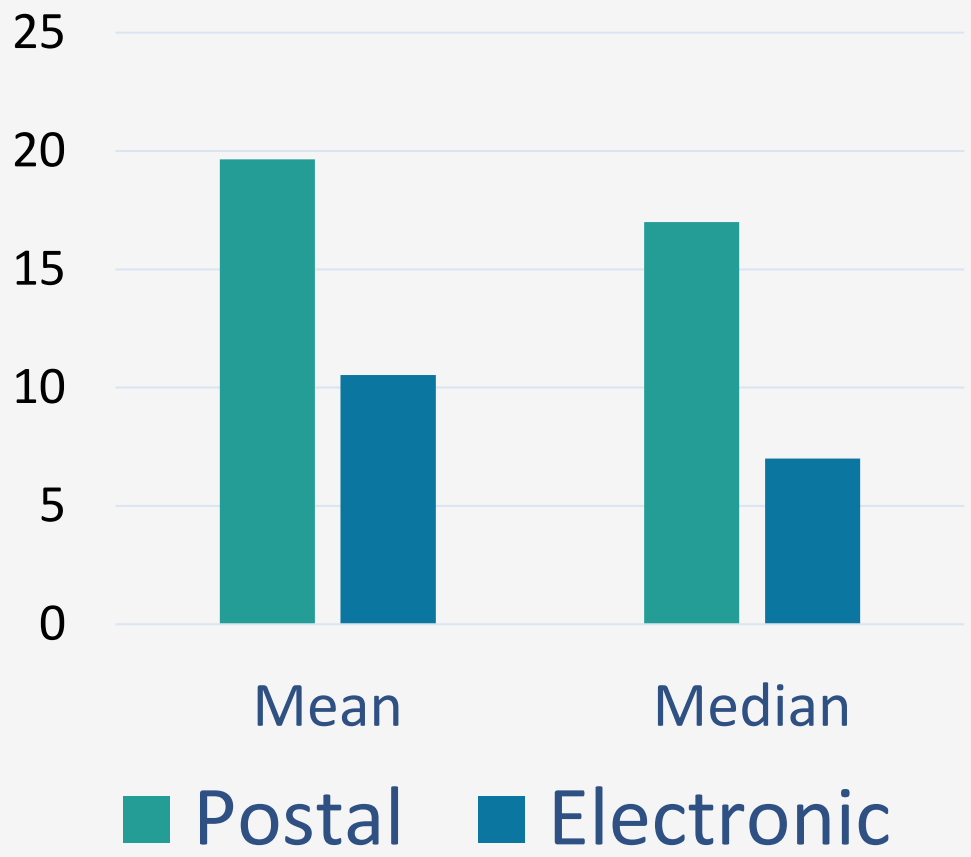
HELPP (Heel Pain Pathways) Study	
Full study title: Feasibility of developing personalised treatment pathways for relief of plantar heel pain using a sequential multiple assignment randomised trial (SMART) study design.	
I have been consulted about participation in this research project. I have had the opportunity to ask questions about the study and understand what is involved.	⊗ Yes
I confirm that I have read and understood the Participant Information Sheet version 2.0 (dated 21/06/2024) for the above study. I have had the opportunity to ask questions which have been answered fully.	⊗ Yes
I understand that I can withdraw from the study at any time, without giving any reason and without my medical care or legal rights being affected.	⊗ Yes
If I decide to withdraw or I am withdrawn from the	⊗ Yes

☐ I certify that all of my information in the document above is correct. I understand that clicking 'Submit' will electronically sign the form and that signing this form electronically is the equivalent of signing a physical document.

Findings (n=32)



Communication preferences of HELPP participants



Days between pre-screening and consent

Conclusion

Remote E-Consent can be completed more quickly and easily than postal consent, once initial teething problems have been overcome.

HELPP Trial Manager

eConsent is a more intuitive and smooth process to manage

That would be much easier for me!

Podiatry patient response to the offer of eConsent

References & Funding

Poole, R.L., Jones, N., & White, J. (2024, 30 September – 3 October). Protocol for a Sequential Multiple Assignment Randomised Trial (SMART) Feasibility Study to Develop Adaptive Intervention Pathways for Personalised Treatment of Heel Pain [Conference poster]. ICTMC 2024, Edinburgh, UK. https://osf.io/5frbz (abstract P-191)

HRA & MHRA Joint statement on seeking and documenting consent using electronic methods (eConsent) – September 2018 https://www.hra.nhs.uk/about-us/news-updates/hra-and-mhra-publish-joint-statement-seeking-and-documenting-consent-using-electronic-methods-econsent/

Norwich CTU "Implementing eConsent in REDCap and similar EDC systems" – May 2022 https://norwichctu.uea.ac.uk/econsent/

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https://cedar.nhs.wales/our-work/clinical-research/helpp/

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Questions?