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

Implementing multiple randomisations using REDCap within a Sequential Multiple Assignment Randomised Trial (SMART)

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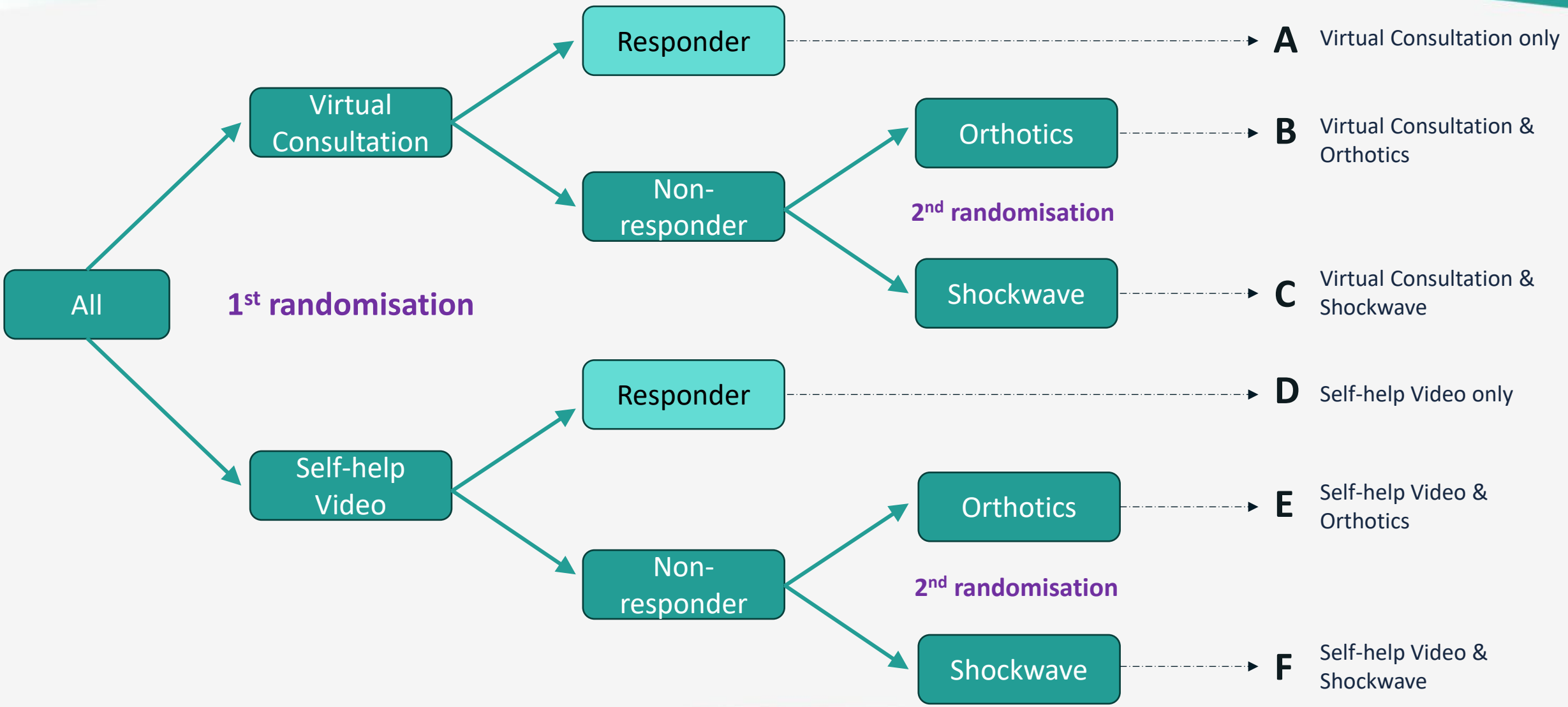
Ariennir gan
Lywodraeth Cymru
Funded by
Welsh Government

What is a SMART?

- Sequential Multiple Assignment Randomised Trial
- Used to optimise treatment pathways
- Includes rules to tailor 2nd or 3rd line treatments based on
  - Individual characteristics
  - Response to earlier treatments
- Requires participants to be randomly assigned to different treatment groups at different stages of the process
  - Similar to a factorial design *except* the full pathway for an individual is not decided from the start

Example: HELPP Study

- HeEL Pain Pathways (HELPP)
  - Plantar fasciitis
- Feasibility study
- Funded by HCRW RfPPB
- NHS Sponsor (CAVUHB)
- Interventions are all standard care
  - Self-help video (remote)
  - Virtual consultation (remote)
  - Orthotics
  - Shockwave therapy (ESWT)


All
1st randomisation
Virtual Consultation
Self-help Video
Responder
Non-responder
Responder
Non-responder
2nd randomisation
2nd randomisation
Orthotics
Shockwave
Orthotics
Shockwave
A Virtual Consultation only
B Virtual Consultation & Orthotics
C Virtual Consultation & Shockwave
D Self-help Video only
E Self-help Video & Orthotics
F Self-help Video & Shockwave

The randomisation challenge

- REDCap® (Research Electronic Data Capture)
  - Secure, web-based application for building and managing research databases
  - Version 14.5.10
  - Randomisation module
- Allocation tables created outside of REDCap
  - www.sealedenvelope.com
  - HELPP randomisation is stratified based on duration of pain
    - LESS THAN 7 months and 1 week
    - MORE THAN 7 months and 1 week
- But only one randomisation module for each REDCap "project"

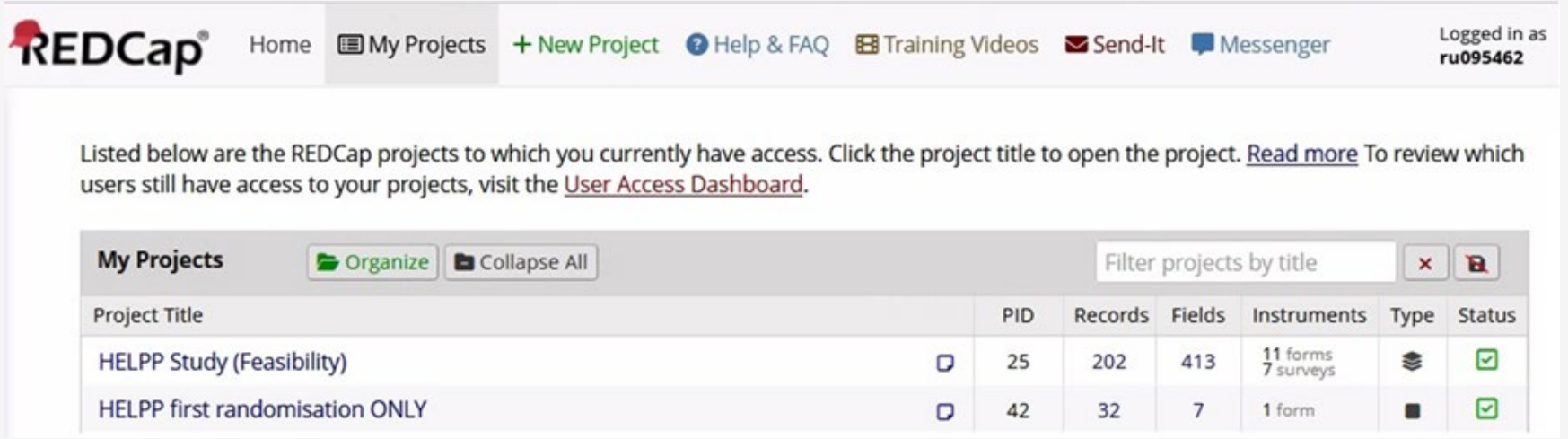
Workaround options (Lee et al. 2023)

1. Two REDCap projects (one for each randomisation)
2. Perform one randomisation using an external program and copy data in
3. Write Application Programming Interface (API) code for conducting one or both randomisations externally.

We chose **option 1** – two separate projects, both within REDCap.

Lee, C.A., Gamino, D., Lore, M. *et al*. Use of research electronic data capture (REDCap) in a sequential multiple assignment randomized trial (SMART): a practical example of automating double randomization. *BMC Med Res Methodol* **23**, 162 (2023). https://doi.org/10.1186/s12874-023-01986-6

HELPP - 2 REDCap projects



	1st Randomisation	2nd Randomisation
Timeliness	Not time crucial	During F2F clinical appointment
Carried out by	Central research team	Site staff
Module location	Separate REDCap project: HELPP first randomisation ONLY	Within main REDCap project: HELPP Study (Feasibility)

Microsoft Teams

Meeting with Ruth Poole (Cardiff and Vale UHB - CEDAR)

2025-06-16 13:30 UTC

Recorded by

Ruth Poole (Cardiff and Vale UHB - CEDAR)

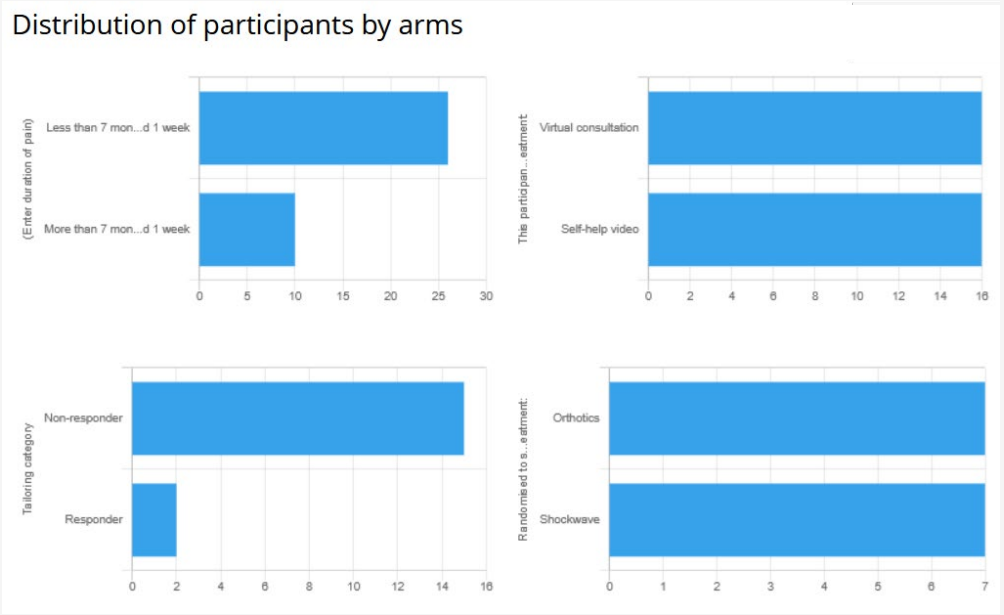
Organized by

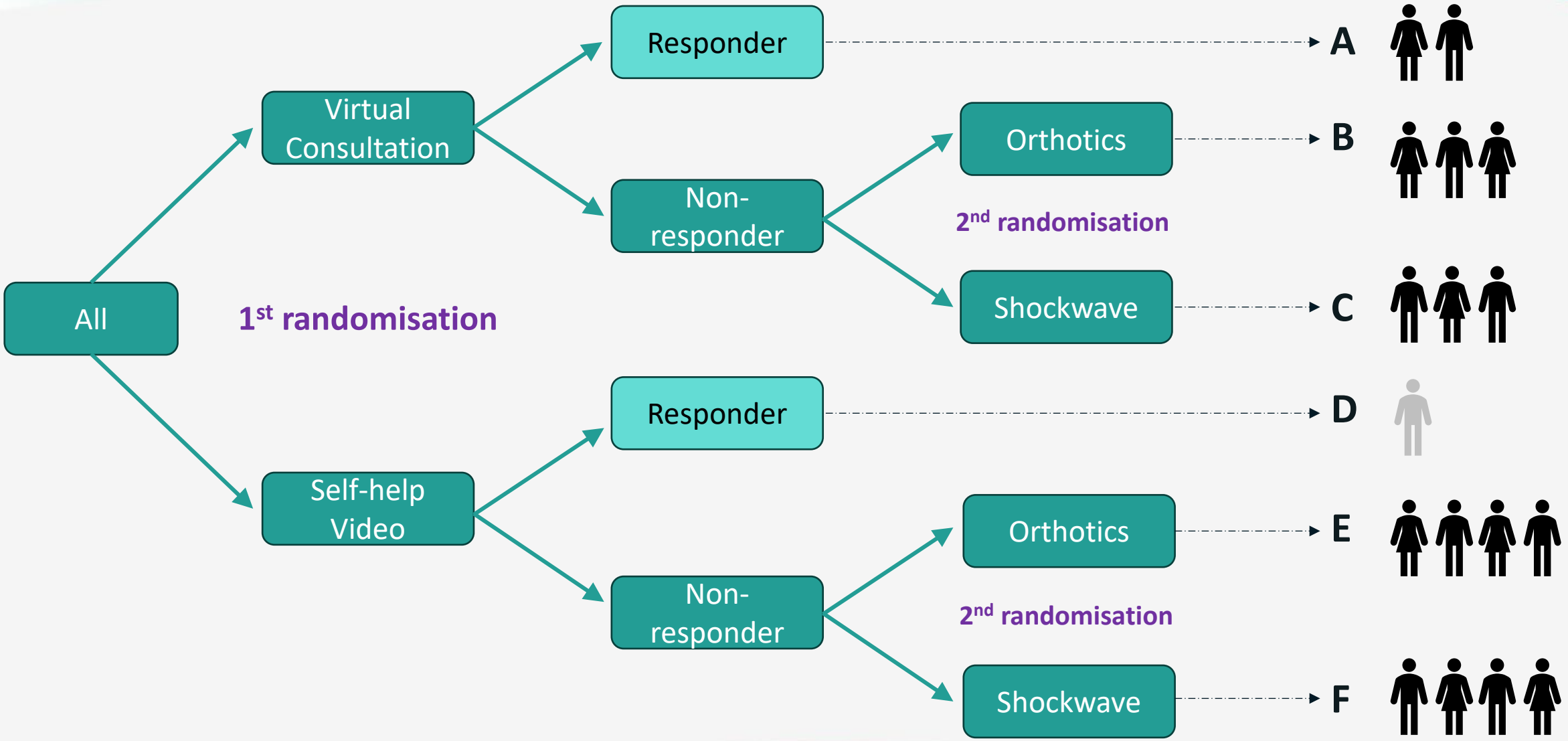
Ruth Poole (Cardiff and Vale UHB - CEDAR)

Results so far…

Progress through study	n=	Proportion
Recruited	**32**	**100%**
First randomisation	**32**	**100%**
- Virtual consultation	16	50%
- Self-help video	16	50%
Tailoring	**17**	**53%**
- Responder	2	6%
- Non-responder	15	47%
Second randomisation	**14**	**44%**
- Orthotics	7	22%
- Shockwave	7	22%

REDCap® Project Dashboard

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F

Summary

- A SMART study design compares combinations of treatments in sequence
- Automating multiple randomisations in REDCap is possible
  - But not within a single REDCap project
- There are risks to consider and mitigate when switching between projects or external tools
- We hope future versions of REDCap will allow multiple randomisation modules within a single project

References & Funding

Lee, C.A., Gamino, D., Lore, M. *et al.* Use of research electronic data capture (REDCap) in a sequential multiple assignment randomized trial (SMART): a practical example of automating double randomization. *BMC Med Res Methodol* **23**, 162 (2023). https://doi.org/10.1186/s12874-023-01986-6

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)

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