

Internal pilot
phase -
Qualitative
sub-study

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TODAY

- Brief intro to qualitative component
- We will provide crib sheet outlining the processes in detail so this is available to refer to whilst getting up and running

Also support of qualitative research fellow based at University of Birmingham

What is qualitative health research?

- Provides insight into people/patients' **perspectives, experiences and behaviours.**
- Focus on non-numerical, detailed and rich data e.g. spoken data.
- **interviews**, focus groups, observations e.g. **audio recordings of consultations.**

What do qualitative researchers explore during trials?

- Planned implementation vs the 'reality' – optimise trial processes e.g. recruitment
- The experience of trial pathways for **patients (and families)**, e.g. their satisfaction and **perceptions of treatment**.

Qualitative research in trials is evidence based.

- Example: ProtecT (Prostate cancer treatment RCT)
- Donovan et al. conducted in-depth interviews with men, and recorded recruitment conversations in the Prostate testing for cancer and Treatment (ProtecT) study.
- Lessons learnt **increased the recruitment rate to the trial by 30%.**

Aims for the GHD qualitative study

- To help explore the feasibility and acceptability of the trial to staff, children and carers (during the internal pilot phase)
- To explore children's and carer's perceptions – e.g. to retesting; trial participation; experience of allocated treatment

GHD Reversal Study - Qualitative data collection

- **Audio recordings of main trial recruitment discussions** between site staff, patients and/or their carers
- **Interviews with patients & carers who have consented to the trial** (within 2 weeks of randomisation, followed up at 6 months; both arms of RCT)
- **Interviews with patients and carers declining to consent**
- **Staff interviews**
- **ONLY DURING INTERNAL PILOT PHASE**



DON'T PANIC – vast majority of work undertaken by research fellow based at University of Birmingham (interview consent and conduct, analysis, feedback to sites etc.)

We will provide a simple CRIB SHEET to follow in relation to this part of the work

'ALL' we are asking you to do

- Consider having recruitment discussions with potential trial participants recorded – no obligation but we hope it will help staff who are recruiting to the trial (**all parties to the discussion need to consent for this to happen**)
- Consider consenting to take part in an interview (midway through internal pilot) – helps us understand your experience of implementing the trial
- Briefly mention the qualitative research to **ALL** potential trial participants and get consent for us to contact those that express an interest in taking part in an interview with the qualitative research fellow at UoB

Recording consultations

- **No judgement** will be made on site staffs' recruitment practice.
- We are not 'checking in' on sites, but attempting to uncover any challenges faced by recruiters that may undermine trial feasibility.
- Recordings and interviews help us to facilitate recruitment
- All data will be anonymised and **confidentiality will be maintained.**

In Summary

- The qualitative sub-study is **vital** to the success of the trial.
- It should be relatively **light touch** to facilitate – research fellow will help you
- We believe with good buy in from sites, **it will help you as well as us.**
- **We will provide a short but comprehensive crib sheet to help staff, and our research fellow will be in touch to help facilitate the qualitative research**

Thank you for listening!