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## Qualitative Research and Trials

The contribution qualitative research can make to improving intervention and trial design, evaluation and implementation is well recognised (O’Cathain et al, 2013).

Qualitative methods are often used alongside quantitative methods within a process evaluation to explore trial processes, intervention components and mechanisms in relation to context. Many different qualitative methodologies are used. Here we consider the application of one qualitative methodology, case study design, as it is being used within the OPAL trial.

## The OPAL Trial

The OPAL trial tests a complex intervention for women with urinary incontinence (UI) (OPAL ISRCTN 57746448).

The aim is to determine the effectiveness and cost-effectiveness of basic pelvic floor muscle training (PFMT) compared to biofeedback-mediated intensive PFMT for the treatment of stress or mixed (stress and urgency) female UI. Women with stress or mixed UI (n=600) were randomised to either basic PFMT or biofeedback intensified PFMT (Fig. 1). The primary outcome is severity of UI at 24 months (measured using the ICIQ-UI score).

The area in orange in Fig. 1 is the process evaluation which aims to identify and investigate the possible mediating factors that impact upon the effectiveness of the intervention (including intervention fidelity), how these mediating factors influence effectiveness, and whether the factors differ between randomised groups.

The area shaded in grey in Fig. 1 is the two-tailed qualitative case study which aims to: investigate women’s experiences of intervention in both trial arms, identify the barriers and facilitators which impact short- and long-term adherence, explain the process through which they influence adherence, and identify whether these differ between randomised groups.

The process evaluation and case study are integral to the research with a view to adding value to the trial (O’Cathain et al, 2014). Specifically, both the longitudinal qualitative case study and mixed methods process evaluation have been developed in order to **explain** trial outcomes as well as providing analysis that will support a better understanding of trial research and the intervention processes.

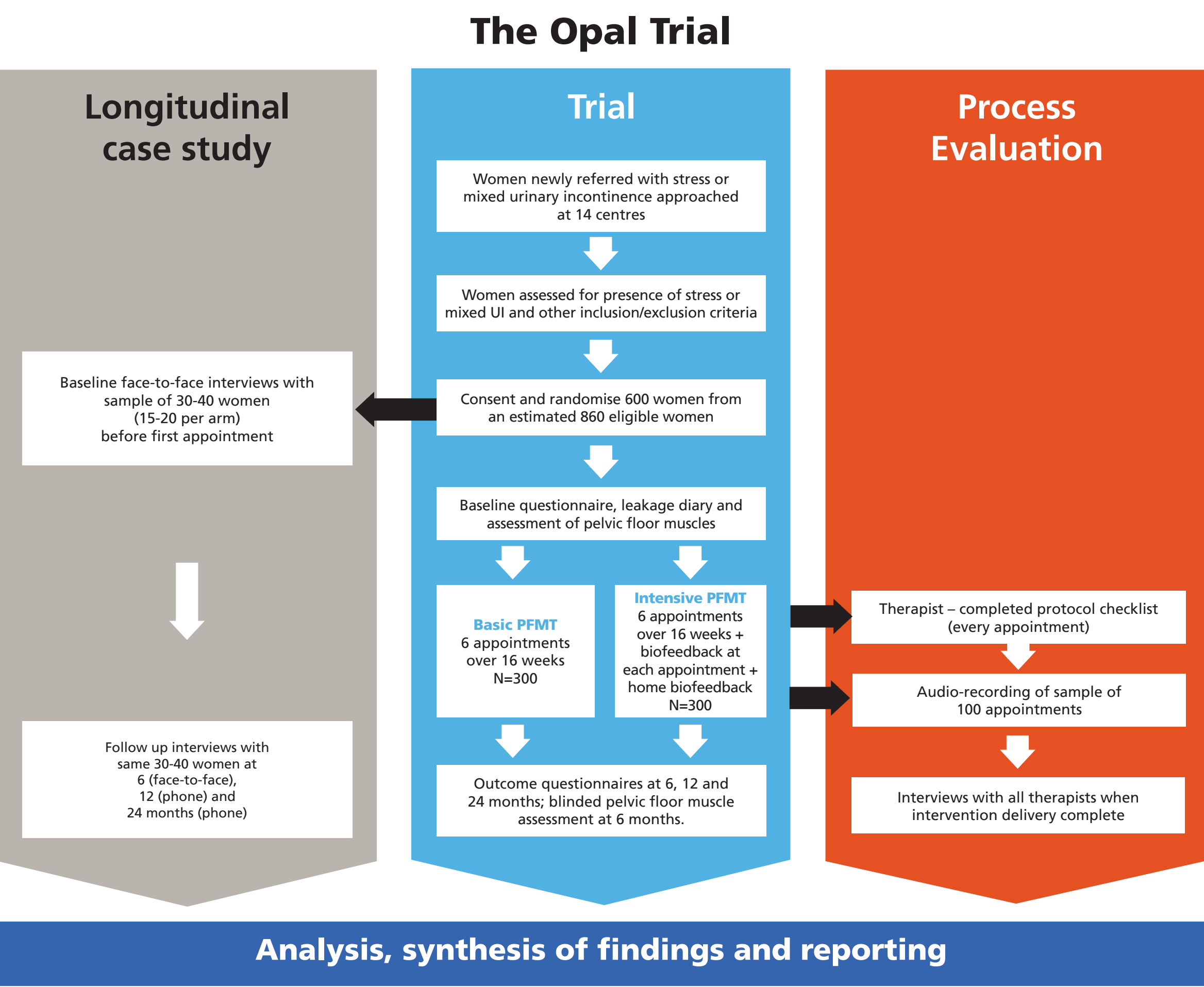


Figure 1: The OPAL Trial Flow Diagram.

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## Case Study Design

Case study methodology is advocated for exploring real life phenomena within a contemporary context (Yin 2014).

Case study design lends itself to investigations that aim to understand, in detail, how or why events occur. Hence the design is well suited to a study that aims to understand: 1) what factors influence short and longer term adherence; 2) how they influence adherence; and 3) what impact this has on outcome. Our study is also longitudinal, thus fitting well with a trial that aims to improve the primary outcome at two years through long term adherence.

Case studies come in many forms, such as individual or multiple case studies. There are varying approaches advocated by different researchers (Stake 1995, Thomas 2016, Yin 2015). Our design is heavily influenced by Yin. We are using a two-tailed case study design, which means multiple cases from each trial arm (n=20 cases in each arm) are sampled with a view to enabling comparison between the trial arms (Fig. 2) Mirroring the trial data collection, our case study is longitudinal with women interviewed four times (baseline, post-treatment, 12 months, and 24 months post-randomisation). Thus, the case is built and summarised over two years with four data points for each woman.

Analysis starts with a case summary for each case. Each case is then systematically compared to other cases within the tail (trial arm). Finally the tails (trial arms) are compared using some predefined and some iteratively developed theoretical propositions (hypotheses). The nature of the analysis encourages a move beyond description to explanation; for example, understanding why a specific contextual factor has a specific influence in a specific way on the primary outcome.

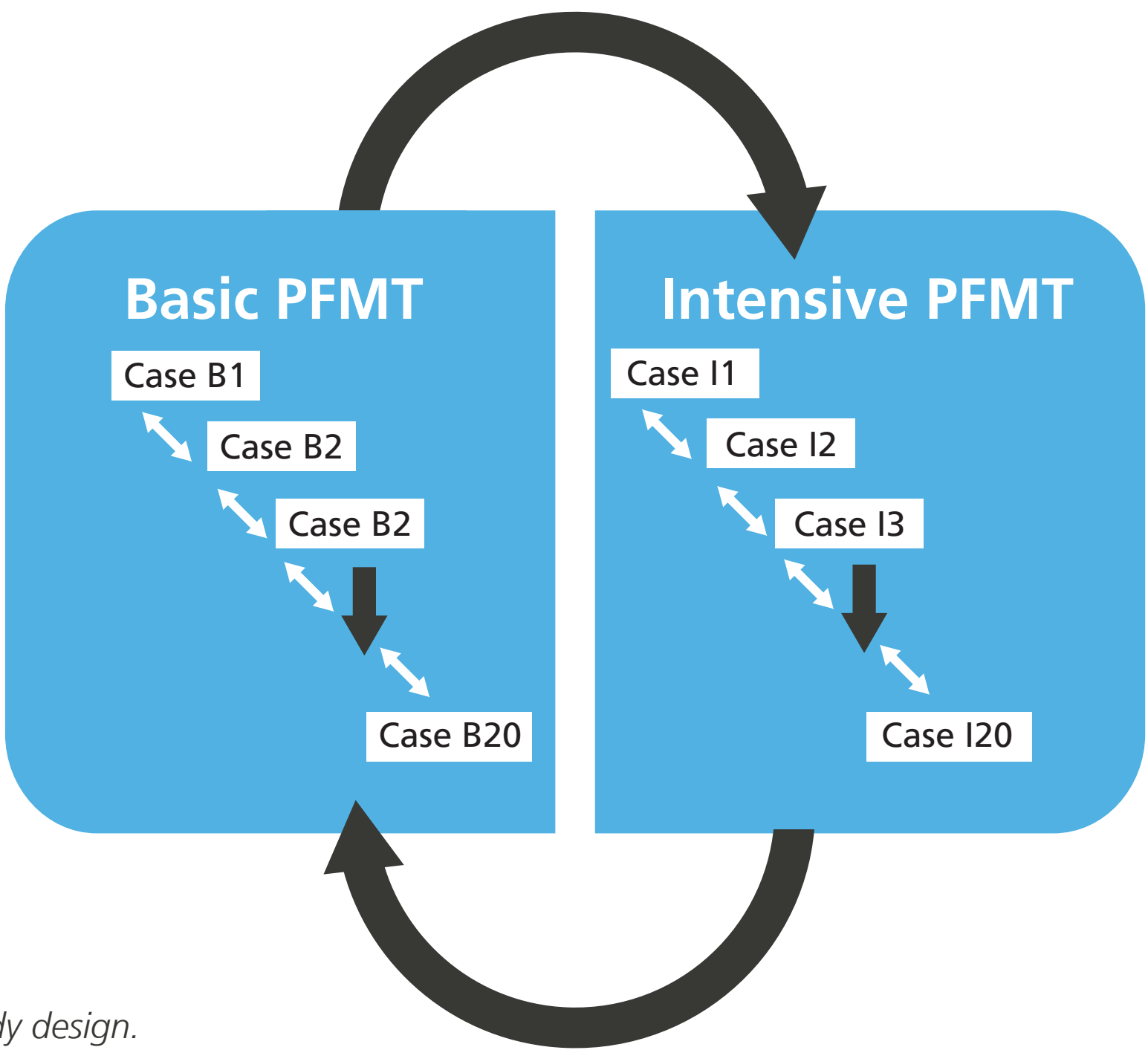


Figure 2: The two tailed case study design.

## Why is case study methodology useful for qualitative studies of complex intervention trials

- We know how important understanding context is to knowledge about how an intervention works (Wells et al, 2011). The depth of data generated from a methodological design that targets detailed understanding will allow explanations of how and why the intervention works or does not.
- A trial tests the effectiveness of an intervention in comparison to a control. Case study design can help uncover differences in the detail between intervention and control cases in a way that supports comparison and, importantly, explanation. Case study design addresses ‘why’ an intervention works (or does not) and the main trial investigates ‘if’ an intervention works or not.
- O’Cathain et al (2013) argue that qualitative studies associated to trials have several foci. Three of these are important for OPAL: the intervention being trialled; the trial processes and the outcomes. The case study design supports all of these purposes, for example, by helping to understand how the intervention is understood to be delivered in detail from the perspectives of the women who receive it and what impact women perceive the delivery has on their UI outcome over time.
- Trials often measure outcomes long after the intervention is delivered. This longitudinal element often means that the extrinsic contextual factors that may influence the outcome may continue to have influence or there may be new influences on the outcome that are important to understand. For OPAL our primary outcome is at two years, 18 months after the intervention delivery ends. Understanding how other factors may or may not influence the outcome is important, as is how this differs (or doesn’t) between the randomised groups. The complex interplay of how these factors affect an individual case (woman) is central to understanding how the intervention works or does not work.

## Lessons about case study research linked to trials for the opal trial (... so far)

- A longitudinal study is time consuming, the volume of data is large and it needs appropriate resource to gather and analyse the data. We are fortunate our funders have resourced this well.
- Attrition over time is higher than anticipated. While this mirrors the main trial it is higher for a qualitative study than we expected. The impact on the analysis is as yet unknown.
- In OPAL, the case study and process evaluation are linked but distinct. We have worked in ways that promote the links between the two. However, it is not always straight forward and remains a work in progress. We aim to triangulate the case study and evaluation analysis to further enhance our understanding of adherence in the longer term.