

RESEARCH PARTICIPANTS' ADHERENCE AND UNDERSTANDING: QUALITATIVE INSIGHTS FROM A RANDOMISED CONTROLLED TRIAL OF CONSERVATIVE THERAPY FOR WOMEN WITH PELVIC ORGAN PROLAPSE

Hypothesis / aims of study

This qualitative research explored the issues of experiences of participation, understanding and adherence within a randomised controlled trial (RCT) of conservative therapy for women with pelvic organ prolapse (POP). It had three main aims. The first was descriptive, and aimed to provide an understanding about participants' perceptual and contextual realities of living with POP, and the impact of POP on their quality of life. The second was explorative, and comprised both an examination of the expectations of and reasons why women with POP volunteered to participate in this trial, and an understanding of their experiences once they were 'inside' the research 'gates'. The third was inductive, that is, to build knowledge and understanding, based on women's experiences about factors that influenced them to adhere to the research protocol in this RCT.

Study design, materials and methods

A phenomenological design based on seeking meaning and essence of individual experiences in the context of research trial participation was used in this study. Two sources of data were combined. The first source was in-depth, individual interviews with 15 women (8 from the pelvic floor muscle training (PFMT) group, and 7 from the lifestyle advice group. Interviews were conducted using semi-structured, open-ended questions, recorded and transcribed verbatim, and a pseudonym assigned for each participant. The second source was written responses from 37 women to an open question (the 'open' responses) in a survey in this trial. The data from the 'open' responses were anonymous.

A thematic analysis, informed by principles of grounded theory (1) was performed. This involved line by line coding, and constant comparison of the identified codes and categories within and between the two groups of participants (2). This comparative approach led to a comprehensive exploration of the construct of adherence and understanding of the participants.

Three methods of triangulation were used to enhance rigour and credibility of this research: a) method triangulation – gathering data using different approaches and from different trial sites; b) data source triangulation – combining of the data sources with the literature; and c) researcher triangulation – discussing and reviewing the transcripts and findings from the analytic process such as categories and theme notations, by two other researchers.

Results

Three broad and related themes emerged from the data: '*restrictions*'; reasons for '*signing in*'; and the '*inside experience*' of understanding and adherence as a participant. Women identified a range of ways that POP impacted on their lives, all of which were described as '*restrictions*'. The theme 'restriction' portrays how POP influenced and restricted several aspects of these women's lives. Women described being restricted by the burden of the condition, and a changed life situation. They described work and family-related demands which were expressed as "stressful", "very draining" and sometimes "took up [their] time 24/7". They also gave vivid descriptions of how these 'restrictions' contributed to feelings of anxiety, distress and poor quality of life as they "try to stay positive", or "ignore it in daily life". Some women tended to normalise their condition as part of "change of life", and felt that they have to "just put up with it", or "accept" the condition and "grow old gracefully".

These restrictions of participants, in turn, influenced their reasons for 'signing in' to the research and their interpretation and judgements made about how and why to adhere to the research protocol, once 'inside' the research as participants.

A unifying explanation for the reasons for the '*signing in*' theme was the concept of '*hope*'. Each of the women expressed some form of '*hope*' when they reflected on why they had signed up for the research. For a number of women, their 'self-interest hope' of gaining a health benefit was their main and for some the only reason for 'signing in'. For example Anne reported "I was probably hoping just to get access to some very specific expertise by the physios really, was interested in knowing what they were doing [for POP], ... I was hoping to avoid surgery if possible and when this was seen as a possible thing, then it certainly was attractive because it was a possibility". However, there were some women who had 'altruistic hope' and were concerned with helping other women and medical research more generally, as Julie reported "I thought you help out researchers - that was part of it". In making their decisions to 'sign in', there were yet other women with 'passive hope', who conformed passively to please their doctor, or weighed up potential benefits against possible risks and joined the trial because they felt there were no significant harm to them: May described "it was the gynaecologist who told me about it and put me on to it" and Vivian said "I thought there's nothing to lose [by joining in]". In the 'signing in' stage, although some women stated a combination of these hopes, most women were aligned with 'self-interest hope' and 'passive hope'. These variations in hope impacted on women's understanding and adherence as participants.

The overall finding of this research was one of '*variation*' in participants' understanding and response to the set research protocol. Women expressed diverse 'understandings' and interpretations of the effect of POP in their lives, in addition to varying interpretations of their role and participation within the trial. The variation in women's preconceived values which they brought 'into' the research also shaped their interpretation and rationalisation of the information, their adherence, and subsequently, their 'inside experience'.

Five factors that influenced women's level of adherence were identified in this research.

1. Levels of motivation
2. Health beliefs
3. Levels of understanding
4. Perceived impact of POP on their quality of life
5. The researcher-participant relationship

Interpretation of results

These findings point to the inherent variability or individuality of understanding and adherence within a small group of women enrolled in a large RCT. The findings provide some insights which researchers may take into consideration when planning how to maximise research outcomes through participant adherence to a study protocol.

Based on the factors that potentially influenced women's level of adherence, the research identified that the first four factors were 'invisible' and inherently unique elements of a participant. An 'iceberg' model was developed to conceptualise and illustrate these invisible or below the surface health beliefs, their levels of motivation or understanding that were 'untapped' in the RCT, but were strong drivers which determined participants' active engagement and adherence to the research protocol, and the visible elements or above surface variables of women (e.g. age, stage of POP) which were controlled by the RCT design to standardise the participants.

A key implication of these insights gained from this research is a need for a more individualised, participant-centred approach, rather than a structured approach as is currently practised in research. As a direct consequence of the findings of this research a participant-centred approach of research was developed. The underlying literature for the approach was drawn from the traditional clinical care of the patient-centred approach, as well as from other relevant psychosocial and health behavioural theories and models. The approach focuses on maintaining a therapeutic alliance based on further strengthening the researcher-participant relationship, and collaborating with an individual in goal-setting, within the controlled structure of an RCT.

Concluding message

This research proposes that there is scope for improvement in participant understanding and adherence to research protocol by reconceptualising the researcher-participant relationship, in particular, how the researchers communicate with their participants. The findings also identify that there is the potential to 'tap' the invisible elements that participants bring to the research agenda.

References

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<i>Specify source of funding or grant</i>	National Health and Medical Research Council, Australia
<i>Is this a clinical trial?</i>	Yes
<i>Is this study registered in a public clinical trials registry?</i>	Yes
<i>Specify Name of Public Registry, Registration Number</i>	Australian New Zealand Clinical Trials Registry (ANZCTR Number: 12608000113358)
<i>Is this a Randomised Controlled Trial (RCT)?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	School of Health Sciences HREC, The University of Melbourne, Australia
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes