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”.

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