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Title	Balancing perspectives on intervention feasibility: using stakeholder views in decision-making
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Publication Date	2019-03-20
Publication Information	Fox, Jackie, Erlandsson, Lena-Karin, & Shiel, Agnes. (2019). Balancing perspectives on intervention feasibility: using stakeholder views in decision-making. BMJ Open, 9(Suppl 1), A23-A24. doi: 10.1136/bmjopen-2019-QHRN.60
Publisher	BMJ Publishing Group
Link to publisher's version	http://dx.doi.org/10.1136/bmjopen-2019-QHRN.60
Item record	http://hdl.handle.net/10379/15043
DOI	http://dx.doi.org/10.1136/bmjopen-2019-QHRN.60

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Balancing perspectives on intervention feasibility: Using stakeholder views in decision-making

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• Highly prevalent in general practice and **Anxiety and Stress** primary care [1], particularly in women • Potential role in primary care for **Occupational** mild/moderate Therapy psychological distress • A 10-week group-based Redesigning intervention **Daily** Focus on improving **Occupations** balance in daily life [2]

Objectives:

- To understand the feasibility and acceptability of ReDOTM from the perspective of stakeholders
- To understand the study processes better
- To use this information in decision-making to plan future intervention evaluation/development

Methodology:

- A mixed-methods feasibility study incorporating a process and outcome evaluation
- Women with anxiety/stress recruited through their general practitioner
- 10-week programme (Redesigning Daily Occupations ReDOTM) facilitated by two primary care occupational therapists
- Quantitative outcomes measured pre-intervention, post-intervention and at 3-month follow-up
 - Level of difficulty functioning in daily activities (WHODAS 2.0 [4])
 - Psychological distress (Depression Anxiety & Stress Scale [5])
 - Mastery (Pearlin-Schooler Mastery Scale [6])
 - Occupational value (OVal-pd [7])
 - Perceived health (EQ-5D-5L [8])

Use of Qualitative Methods

- In-depth qualitative interviews carried out with all stakeholders to better understand feasibility/acceptability/outcomes/demand
 - 5 female participants of the ReDOTM group
 - 2 Occupational therapists (OTs) (group facilitators)
 - 9 General practitioners (GPs) (referrers and treating clinicians)
- Data analysis
 - Guided by principles of qualitative evaluation research [9]
 - Evaluation coding influenced by research questions, but allowed for emergence of unanticipated themes [10]



Inclusion Criteria

Feasibility

- Felt to be too restrictive by primary care GPs
- "I think it was that the actual exclusion criteria made it trickier" (GP)

• Pilot RCT planned in

• Recruitment slower

than expected – no

control group

women)

Jan-May 2018 (n = 5



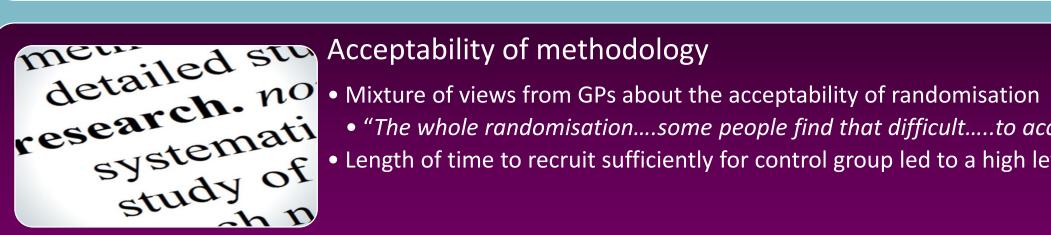
ReDOTM programme and session duration

- 10-week length felt to restrict recruitment by GPs but was very acceptable to participants and OTs
- "It's a pity we hadn't another ten weeks!" (Participant)
- "It was a lot. Two hours long" (GP)
- "She {patient} said there was no way she could touch that" (GP)



Response to the intervention – qualitative and quantitative outcomes

- Trends towards improvement on the outcome measures
- Personal and family-level positive changes reported by participants
- "The thing that clicked for me was realising that you can put yourself first every now and again" (Participant)
- "I'm more relaxed. I just focus on the activity that I'm doing" (Participant)



- Length of time to recruit sufficiently for control group led to a high level of dropout



pelvic organ prolapse. Trials. 2013; 14:1-13

Perception of equipoise

[1] Jackson JL, Passamonti M, Kroenke K. Outcome and impact of mental disorders in primary care at 5 years. Psychosom Med. 2007; 69:270-6

[9] Patton MQ. Qualitative research & evaluation methods: Integrating theory and practice. 4th Edition ed. Thousand Oaks, California: SAGE Publications; 2015.

- ReDOTM intervention viewed by GPs and OTs as already effective (lack of equipoise)
- "It was a nice option for us to have. To say to people, you know? Because there is a real lack of services" (GP)
- Research study viewed as an opportunity to receive services in an under-resourced area

Conclusions and Decision-making

Stakeholder perspectives can be used to;

- Assess feasibility
- Generate solutions
- Assist in making decisions about ongoing research that considers both the needs of a future trial and real-world considerations [11]

The Redesigning Daily Occupations programme was acceptable, well-received and showed potential for improving outcomes. However, recruitment was difficult and inclusion criteria were restrictive.



Ongoing Research

9 women were referred for a second round of ReDOTM (Feb-May 2019)

Changes to methodology

- Recruitment via GPs and self-referral
 - Resulted in quicker recruitment rate
- Wider inclusion criteria
 - Resulted in broader range of women taking up the intervention
- Change from an RCT design to a pre-test post-test design
 - Resulted in greater retention of participants prior to programme

Acknowledgments

- The HRB Primary Care Clinical Trials Network at NUI Galway, Ireland
- The HSE PCCC Occupational Therapy Services
- The ReDOTM participants
- The general practitioners involved
- Prof. A. Shiel & Prof. L.K. Erlandsson
- [3] Moore G, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process Evaluation of Complex Interventions: Medical Research Council Guidance. London: MRC Population Science Research Network; 2014 [4] Ustun TB, Kostanjsek N, Chatterji S, Rehm J. Measuring Health and Disability: Manual for WHO Disability Assessment Schedule. Geneva, Switzerland: WHO Press; 2010 [5] Lovibond SH, Lovibond PF. Manual for the Depression Anxiety Stress Scales (2nd Ed.). Sydney: Psychology Foundation; 1995 [6] Pearlin LI, Schooler C. The structure of coping. Journal of health and Social Behavior. 1978:2-21 [7] Eklund M, Erlandsson LK, Persson D, Hagell P. Rasch analysis of an instrument for measuring occupational value: Implications for theory and practice. Scandinavian Journal of Occupational Therapy. 2009; 16:118-28 [8] Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Quality of life research. 2011; 20:1727-36

[2] Eklund M, Erlandsson LK. Return to work outcomes of the Redesigning Daily Occupations (ReDO) program for women with stress-related disorders – a comparative study. Women & Health. 2011; 51:676-92

[10] Saldana J. The Coding Manual for Qualitative Researchers. London, UK: SAGE Publications Ltd; 2009. [11] Bugge C, Williams B, Hagen S, Logan J, Glazener C, Pringle S, et al. A process for Decision-making after Pilot and Feasibility Trials (ADePT): development following a feasibility study of a complex intervention for