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A pilot study of an occupational therapy-led group intervention for women with anxiety and stress-related disorders in an Irish primary care context

Submission date
28/11/2016

Recruitment status
No longer recruiting

Registration date
30/11/2016

Overall study status
Completed

Last Edited
11/08/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Anxiety and stress-related conditions are extremely common, especially among women. The majority of individuals with anxiety disorders are seen in primary care by a general practitioner (GP), although many do not seek treatment at all. It is known that anxiety and stress reduce women's ability to enjoy participation in the activities of daily life, such as work, hobbies, managing the home and taking care of family. Helping people to take part in daily life activities is the core function of an occupational therapist, but the evidence for the effectiveness of occupational therapy with individuals with anxiety disorders is limited. In Ireland, the multidisciplinary staff are sometimes not available on primary care teams to provide focused treatment to those with mental health issues such as anxiety and stress. However, occupational therapists are core members of primary care teams and, while they are qualified to work with individuals with mental health difficulties, primary care occupational therapists mainly work only with those with physical/sensory conditions. A review of the literature identified the Redesigning Daily Occupations programme; a group programme that has been designed and researched by occupational therapists. It has shown to bring about good outcomes for women with anxiety and stress related conditions in Sweden in terms of return to work following sick leave, improved quality of life and better self-esteem. It is unknown whether this programme would result in similar positive results for women with stress and anxiety in Ireland. This initial (pilot) study will look at the effectiveness of this program in women who are under the care of a GP for anxiety or stress. In addition, the study will look at whether a conducting a larger study looking at this programme would be feasible.

Who can participate?
Women who are under the care of a GP for anxiety or stress.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in the Redesigning Daily Occupations programme. This is a 10-week programme which is designed

to help people examine their daily patterns of activities, and identify their own stressors. It helps individuals to problem-solve and set goals to make life changes. The programme involves one group session every week for 10 weeks and is led by an occupational therapist. Those in the second group continue to see their GPs are they would normally for the duration of the study. At the start of the study, after the 10 week programme and three months later, participants in both groups complete a number of questionnaires to measure their anxiety levels and quality of life. In addition, participants, the GPs who referred them to the programme and the occupational therapists who took led the group sessions are interviewed three months after their programme ends for their views, in order to see if a larger study would be feasible.

What are the possible benefits and risks of participating?
Women who take part in the 10-week programme may find that it improves stress levels and quality of life, as the programme did show some such positive results for women in Sweden. There are few risks involved in this study. Women who take part in the groups may find that talking about their stress is emotionally draining.

Where is the study run from?
Galway City East Primary Care Centre (Ireland)

When is the study starting and how long is it expected to run for?
April 2016 to July 2019

Who is funding the study?
National University of Ireland, Galway (Ireland). The study is also supported by the Health Research Board Primary Care Clinical Trials Network (Ireland

Who is the main contact?
Ms Jackie Fox

Contact information

Type(s)
Scientific

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Protocol serial number
1

Study information

Scientific Title
A feasibility study and pilot randomised controlled trial of the Redesigning Daily Occupations (ReDO) intervention for women with anxiety and stress-related disorders in an Irish primary care context

Study objectives
The proposed study has the overall aim of exploring the feasibility of the Redesigning Daily Occupations (ReDO) programme with women with anxiety and stress-related disorders in an Irish primary care context.

The following are the specific objectives to meet the aim of the study:
Objective 1: To explore the trends towards effectiveness of the ReDO programme for women with anxiety and stress-related disorders in an Irish primary care context
1. Determine if the ReDO programme shows the potential to reduce symptoms of anxiety and stress, improve participation in valued occupations and reduce the impact of anxiety/stress on daily functioning.

Objective 2: To explore the feasibility of implementing the ReDO programme in an Irish primary care context. To do this, multiple perspectives will be gathered and considered
1. Explore womens' perspectives of the future feasibility of the ReDO programme in Ireland, specifically;
1.1. Acceptability of the intervention
1.2. Intent to continue use of the techniques learned
1.3. Acceptability of the research process e.g. being randomised
1.4. Perceived effectiveness and satisfaction with the ReDO programme
2. Explore occupational therapist perspectives of the future feasibility of the ReDO programme in Ireland, specifically;
2.1. Experiences with running the programme
2.2. Intent to continue use of the programme
2.3. Factors affecting implementation ease or difficulty
2.4. Perceived fit with the organisational culture and current practice
3. Explore general practitioner perspectives which will determine the future feasibility of the ReDO programme in Ireland, specifically;
3.1. Experiences referring to the programme
3.2. Perceived fit with the organisational culture and current practice
3.3. Perceived demand for the programme

Objective 3: To collect data which would determine the future feasibility of an RCT of the ReDO programme in primary care in Ireland, specifically;
1. Recruitment rates
2. Retention rates
3. Approximate cost and resources needed
4. Appropriateness of outcome measures

5. Appropriateness of inclusion/exclusion criteria
6. Appropriateness of the randomisation and stratification procedure

Ethics approval required
Old ethics approval format

Ethics approval(s)
Irish College of General Practitioners Research Ethics Committee, 15/03/2017

Study design
Mixed methods feasibility study which includes a pilot randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anxiety or stress-related disorders

Interventions
Recruited participants will be asked to complete 5 outcome measures at three time points – before the pilot RCT, after the pilot RCT and in a further 3 months' time. These outcome measures should take no more than 30-40 minutes to complete in total. They are then randomised to one of two groups.

Redesigning Daily Occupations programme group: Participants will be asked to attend one group per week for 10 weeks. Each group will last approximately 2-2.5 hours. Interested participants will be informed of this time commitment from their first contact with the researcher. The Redesigning Daily Occupations programme was originally designed as a 16-week programme (Eklund & Erlandsson, 2011) for women with anxiety and stress-related conditions with a view to returning them to work following sick leave. The final 6 weeks of the programme therefore had a vocational rehabilitation focus. The programme has now been approved to be run as a 10-week programme without the vocational rehabilitation focus, and it is this version which will be tested for feasibility in this study. The programme consists of one 2.5 hour session a week for 10 weeks and two follow up sessions. In the first five weeks, the focus of the group sessions is on self-analysis. The concept of occupation (meaningful human activity) is introduced and participants look at their own lives and the activities they do every day. They examine the value of different activities in their lives and look at how activities are prioritised. One session examines how activities can be interrupted and overly-complex. Women are encouraged to identify their own daily hassles and stress-triggers, as well as activities that are important for their own self-care and relaxation. Throughout these weeks, the participants will also take part in some occupations as part of the group e.g. a relaxing walk or an art activity. In the second five weeks, the focus of the group sessions is on goal-setting and making changes. The group uses problem-solving and group support to encourage each person to set goals around lifestyle changes. There are specific sessions around healthy sleep and exercise. There is also material about coping with work-related stress (which would include home-making, if that is the main occupation). There is an emphasis on developing healthy patterns of self-care and rewarding

activities and an evening seminar to which the women can invite family members, friends or work colleagues, recognising that life changes are easier when those around the person are also involved.

Control group: Participants will be asked to continue to see their GP as and when they would normally do so. They should continue on any usual medication. For ethical reasons, they cannot be prevented from seeking out other support or therapies, which it is acknowledged may affect results.

Occupational therapists will be asked to participate in a short focus-group interview following the completion of the trial.

GPs will be asked to participate in a short interview following the trial. For the convenience of the GPs, it would be more appropriate to visit the GP surgery for a short interview, rather than gathering a focus-group together.

The participants will be asked to participate in a short focus-group interview following the completion of the 3 month follow-up.

Intervention Type
Behavioural

Primary outcome(s)
The following outcomes will be measured at three timepoints for both the control and intervention groups; before the programme, after the 10-week programme, and 3 months after the end of the programme:
1. Symptoms of anxiety, stress and depression will be measured using the Depression, Anxiety and Stress Scales
2. The impact of the health condition on daily life functioning will be measured on the WHO - Disability Assessment Schedule II
3. Perceived health will be measured on the EuroQol five dimensions questionnaire (EQ-5D) – only the self-perceived health scale will be completed
4. Occupational value – the participation of the individuals in daily life activities that are valued and have meaning will be measured on the Occupational Value Assessment
5. Individuals' feeling of control and mastery over everyday life situations will be measured using the Pearlin Mastery Scale

Key secondary outcome(s))
Feasibility will be explored using qualitative interviews and focus groups three months post-intervention.

Completion date
01/07/2019

Eligibility

Key inclusion criteria
Patient participants:
1. Women
2. Aged between 18 and 60
3. Have a primary diagnosis, or reason of complaint to their GP, of anxiety or a stress-related

disorder. This could include generalised anxiety disorder, social anxiety, panic disorder, adjustment disorder or acute stress reaction or stress-induced depression.
4. Have visited their GP on at least two occasions with concerns regarding stress or anxiety.
5. Self-identify as feeling that their life is out of balance, overburdened or lacking meaningful activity

Occupational therapists
Facilitate the groups

General practitioners:
Refer participants to the programme.

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
15

Key exclusion criteria
Patient participants:
1. Male
2. Under 18 or over 60
3. Are under the care of a Consultant Psychiatrist
4. Do not present with anxiety or a stress-related disorder or a stress-related reason to their GP
5. Are in acute crisis or struggling with a trauma e.g. bereavement or recent serious diagnosis
6. Have a drug or alcohol addiction
7. Have a cognitive impairment such that would prevent them being able to participate in group therapy
8. Do not have sufficient English to participate in a group programme

Date of first enrolment
01/06/2017

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Ireland

Study participating centre
Galway City East Primary Care Centre
Merlin Park Industrial Estate
Doughiska Road
Galway
Ireland
H91 FCV9

Sponsor information

Organisation
National University of Ireland, Galway

ROR
https://ror.org/03bea9k73

Funder(s)

Funder type
University/education

Funder Name
National University of Ireland, Galway

Alternative Name(s)
Coláiste na hOllscoile, Gaillimh, Ollscoil na hÉireann Gaillimh, Queen's College, Galway, University College, Galway, NUI Galway, National University of Ireland, Galway, National University of Ireland Galway, Ollscoil na Gaillimhe, National University of Ireland, Galway/NUI Galway, NUI Galway, OÉ Gaillimh

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Ireland

Funder Name
Health Research Board Primary Care Clinical Trials Network

Results and Publications

Individual participant data (IPD) sharing plan
It is not expected that this will be made available because this has not been applied for in the ethics application. Approval has not been sought for the data to be publicly available. The participant-level data (using pseudonyms) will be held in hard copy in a locked filing cabinet in the office of the principal investigator. A key to identify participants with their pseudonymised data will be stored on an encrypted drive accessed only by the principal investigator, and kept separately from the hard copy data at all times. It will be destroyed as soon as data analysis is complete.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/02/2021	28/09/2021	Yes	No
Results article		21/04/2022	11/08/2022	Yes	No
Basic results		09/09/2019	09/09/2019	No	No
Participant information sheet		30/11/2016	30/11/2016	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes