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Enhancing self-management of multimorbidity in primary care

Submission date
13/08/2013

Recruitment status
No longer recruiting

Registration date
30/08/2013

Overall study status
Completed

Last Edited
10/02/2022

Condition category
Other

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

Plain English summary of protocol

Background and study aims
There is a high prevalence of multiple chronic conditions (also referred to as multimorbidity) in Irish general practices, which is associated with increased healthcare use and prescriptions. Issues that interfere with everyday activities and functioning for people with multimorbidity, include: (i) physical symptoms and their impact on function; (ii) psychological issues and (iii) impact on work and leisure activities. The physical symptoms include reduced mobility, physical limitations, pain and fatigue. Psychological issues include anxiety and feelings of inadequacy. With respect to work and leisure activities, multimorbidity interferes with social and leisure activities and job performance. This study investigates the effectiveness of OPTIMAL, an occupational therapy (OT) group-based intervention for individuals with multimorbidity.

Who can participate?
To take part in the study, participants must be over 40 years of age, have two or more chronic conditions and be on four or more repeat medications.

What does the study involve?
Participants are randomly allocated to a treatment group or to a waiting-list control group. The treatment group will receive the 6-week occupational therapy led self-management programme (OPTIMAL) and the control group will continue to receive care as usual and will be placed on a waiting list to receive the programme when the trial is complete. Topics covered in the self-management groups will include: activity and health, fatigue and energy management, managing stress and anxiety and maintaining mental health and well-being, keeping physically active, healthy eating, managing medications, communication skills and goal setting. All participants in the treatment group will receive the same programme.

What are the possible benefits and risks of participating?
Possible benefits of the 6-week programme include increased awareness of strategies for chronic disease management and increased ability to manage disease symptoms, and the groups will provide an opportunity to meet other individuals experiencing similar difficulties to gain insight into their self-management techniques. There are no risks of participating in the study.

Where is the study run from?
The study will be run across a number of local health or primary care centres in Dublin, Kildare and Wicklow. Participants will attend their local health centre for assessment and intervention.

When is the study starting and how long is it expected to run for?
Recruitment for the study will begin in February 2015 and the study will be completed in September 2018.

Who is funding the study?
This study is being funded by the Health Research Board (HRB) Research Training Fellowship for Healthcare Professionals and The Health Research Board Centre for Primary Care Research. The Health Research Board is the lead agency in Ireland supporting and funding health research.

Who is the main contact?
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Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
The OPTIMAL study: A randomized controlled trial and process evaluation of an OccuPaTIonal therapy led self MAnagement support programme designed to improve occupational performance and outcomes for patients with muLtimorbidity in primary care

Acronym
OPTIMAL

Study objectives
An occupational therapy group-based chronic disease self-management intervention may improve outcomes for individuals with multimorbidity living in the community.

Pilot study registered under ISRCTN70201320: http://www.isrctn.com/ISRCTN70201320

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Exploratory study: Trinity College Dublin, Research Ethics Committee, 21/11/2012, ref: 21 November, 2012
2. Follow-up study: Trinity College Dublin, Faculty of Health Sciences Research Ethics Committee, 24/11/2015, ref: 150900

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Multimorbidity

Interventions
Participants in the intervention group will attend the OPTIMAL programme, a weekly chronic disease self management group facilitated by two primary care occupational therapists. Each session will last two and a half hours with a tea and coffee break in the middle. In total, three

programmes will be run for the exploratory study (in three different primary care centres in Dublin - Ballyfermot, Rathmines and Thomas Street) and nine programmes will be run in different primary care centres in the follow-up study (in Dublin, Kildare and Wicklow). Participants will attend the group in their local primary care centre to allow for ease of access.

The content of the intervention is based on interventions delivered in the pilot study. The program content is based on chronic disease self management groups, and the priorities and difficulties experienced by people with multimorbidity as documented in literature.

Each weekly session is divided into two halves, one which addresses an educational topic and the second half to address participants' individual goals. This group structure was chosen as self management programmes with the greatest impact are those which adopt a flexible approach to both delivery and content.

The educational topics for the group sessions include: activity and health; fatigue management; healthy eating; maintaining physical activity (delivered by a community physiotherapist); maintaining mental health; managing medications (delivered by a pharmacist) and communicating effectively with health professionals. The format of this half of the session will include both group discussion and group activities.

The second half of the session, individual goal setting, will involve the OTs and participants reviewing and setting identified goals, progress and addressing any barriers to goal achievement. All participants will complete a Canadian Occupational Performance Measure (COPM) as part of baseline assessment with intervention participants completing Goal Attainment Scaling. These are then used as the basis for the weekly goal setting in which individuals address personal goals in occupational performance and strategies to manage their conditions.

The control group will continue to receive care as usual, and will act as a waiting-list control group. They will be offered the group sessions when the trial is complete if the programme is found to be effective.

The intervention is of a 6-week duration. Primary outcome measures will be taken immediately post-intervention for both the intervention and the control group. Primary and secondary outcome measures will be taken 6- months post intervention for both the intervention and the control group. The control group will not receive the intervention but will complete follow-up at the same time as the control group.

Intervention Type
Behavioural

Primary outcome(s)
Exploratory study:
The Frenchay Activities Index (FAI) is a self-report questionnaire designed to measure participation in social and instrumental activities of daily living. It measures how often the person has engaged in these activities (in the past 3 or 6 months depending on the nature of the activity). The measure contains 15 items divided into three sub scales (domestic chores, leisure work and outdoor activities) with five items in each. Measured at baseline (before programme commenced) and and two weeks post intervention at follow-up.

Follow-up study:
1. The EQ-5D (quality of life measure) is a valid and reliable self report questionnaire which

measures current health related quality of life (Aggarwal, 2009). It is a two-part measure consisting of a self-reported description (EQ-5D) and self-rated valuation (EQ-VAS).
2. The Frenchay Activities Index (activity participation) is a self report questionnaire designed to measure frequency of participation in social and instrumental activities of daily living and contains 15 items divided into 3 sub scales (domestic chores, leisure work and outdoor activities) with 5 items in each (Miller, Deathe & Harris, 2004).

To be measured at baseline (before the programme commences), immediately post-intervention and 6 months post intervention.

Key secondary outcome(s))

Exploratory study:
1. The Canadian Occupational Performance Measure (COPM) is a client-centered outcome measure designed for use by occupational therapists to detect change in a client's self-perception of occupational performance over time. The COPM is a standardsed instrument administered in a semi-structured interview format at the beginning and end of OT intervention. Areas assessed using the COPM include the client's most important problems in occupational performance, perceptions of their performance in these activities and their level of satisfaction with their performance.
2. The Nottingham Extended Activity of Daily Living Scale (NEADL) is a self-report scale measuring performance of activities of daily living, comprised of 22 items divided into four sections mobility, kitchen, domestic and leisure. Each item is given one of four responses (able, able with difficulty, able with help, unable)
3. Hospital Anxiety and Depression Scale is a reliable and valid self-assessment scale used to detect and indicate the severity of anxiety and depression in a hospital medical outpatient setting and was utilised in the previous research study. It consists of two subscales, anxiety (HADS-A) and depression (HADS-D) with seven items in each.
4. Stanford Chronic Disease Self-Efficacy Scale (6-item) measures study participants' confidence levels in managing various elements of their chronic diseases such as exercise, social activities, household tasks, medication management and symptom management.
5. EQ-5D (Euroqol) is a valid and reliable self report questionnaire which measures current health related quality of life. The EQ-5D is a self report questionnaire for describing and valuing health-related quality of life (Aggarwal, 2009). It is a two-part measure consisting of a self-reported description (EQ-5D) and a self-rated valuation (EQ-VAS). The self reported description (EQ-5D) comprises five questions on mobility, self care, pain, usual activities, and anxiety/depression. The self rated valuation uses a vertical visual analogue scale (EQ-VAS) in which respondents rate their health today
6. The Health Education Impact Questionnaire (HeiQ) is an outcomes and evaluation measure for patient education and self-management interventions for people with chronic conditions. The HEIQ contains 40 items on a 4-point Likert scale, measuring eight independent constructs. The areas covered by this assessment include positive and active engagement in life, health-directed activities, skill and technique acquisition, constructive attitudes and approaches, self-monitoring and insight, health service navigation, social integration and support and emotional distress.
7. Goal Attainment Scale (GAS) is a standardised method of scoring the extent to which patient's individual goals are achieved in the course of intervention. The goals, which reflect what the patient wishes to achieve, are defined and quantified by five indicators of potential outcome, ranging from -2 to 2.
8. Health care utilization (based on patient self-report):
8.1. GP visits in previous 6 months
8.2. PN visits in previous 6 months
8.3. Hospital admissions in previous 6 months

All above outcomes measured at baseline (before programme commenced) and and two weeks post intervention at follow-up.

Follow-up study:
1. The Stanford Chronic Disease Self-Efficacy Scale (self-efficacy) measures confidence levels in managing various elements of chronic diseases such as exercise, social activities, household tasks, medication management and symptom management.
2. Canadian Occupational Performance Measure (occupational performance/satisfaction) is a client-centred outcome measure designed for use by occupational therapists to detect change in a client's self-perception of occupational performance over time.The COPM is a standardized instrument administered in a semi-structured interview format at the beginning and end of OT intervention.
3. The Nottingham Extended Activities of Daily Living (activity independence) is a self-report scale measuring performance of activities of daily living, comprised of 22 items divided into four sections mobility, kitchen, domestic and leisure.
4. The Hospital Anxiety and Depression Scale (anxiety and depression) is a reliable and valid self-assessment scale used to detect and indicate the severity of anxiety and depression in a hospital medical outpatient setting.
5. The Goal Attainment Scale is a standardised method of scoring the extent to which patient's individual goals are achieved in the course of intervention.
6. Health Care Utilisation (based on patient self-report)
6.1. GP visits in previous 6 months
6.2. Number of visits to PCT professionals in previous 6 months
6.3. Number of OPD speciality visits in previous 6 months
6.4. Hospital admissions in previous 6 months (number of admissions and number of days spent in hospital)

Measured at baseline (before the programme commences) and 6 months post intervention

Completion date
07/09/2018

Eligibility

Key inclusion criteria
Exploratory study:
1. Over 18 years of age, both male and female
2. Has a minimum of two chronic conditions
3. Has a minimum of four repeat medication
4. If a primary care clinician identifies they might benefit from the study

Follow-up study:
1. Multimorbidity, defined as two or more discrete conditions. This is the internationally accepted definition and encompasses a broad range of patients
2. Age > 40 years. This limit was chosen as multimorbidity is relatively uncommon in patients younger than this and it facilitates targeted recruitment. There is no upper age limit
3. Polypharmacy, defined as four or more repeat medications. This criterion was added in order to identify a group within the broader multimorbidity population that is at increased risk of poor health outcomes and therefore more likely to benefit from an intervention
4. Ability to attend a local community healthcare centre to participate in data collection and the intervention groups

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
149

Key exclusion criteria
Exploratory study:
1. If unable to travel to centre in which groups were held
2. If person had participated in the feasibility study (O'Toole, Connolly & Smith, 2013)

Follow-up study:
1. Psychiatric/psychological morbidity (such as psychosis) or cognitive impairment sufficient to impair participation in the intervention as confirmed by the individual's GP and/ or practice nurse.
2. Terminal illness likely to lead to death or major disability during the study follow-up period.
3. Inability to attend intervention sessions held outside the home.
4. Participated in the previous pilot studies or exploratory trial.

Date of first enrolment
29/11/2012

Date of final enrolment
17/04/2017

Locations

Countries of recruitment
Ireland

Study participating centre
Royal College of Surgeons
Dublin
Ireland
2

Study participating centre
Trinity Centre for Health Sciences
Discipline of Occupational Therapy
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Study participating centre
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Sponsor information

Organisation
HRB Centre for Primary Care Research

ROR
https://ror.org/003hb2249

Funder(s)

Funder type
Government

Funder Name
The Health Research Board Centre for Primary Care Research (Ireland), ref: HRC-1-2014

Funder Name
HRB Research Training Fellowship for Healthcare Professionals ref: HPF-2015-972

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/05/2015		Yes	No
Results article	Cost-effectiveness results	05/02/2022	10/02/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes