Effect of the OPTIMAL programme on self-management of multimorbidity in primary care: a randomised controlled trial

Lynn O’Toole, Deidre Connolly, Fiona Boland and Susan M Smith

Abstract

Background
Effective primary care interventions for multimorbidity are needed.

Aim
To evaluate the effectiveness of a group-based, 6-week, occupational therapy-led self-management support programme (OPTIMAL) for patients with multimorbidity.

Design and setting
A pragmatic parallel randomised controlled trial across eight primary care teams in Eastern Ireland with 147 patients with multimorbidity, from November 2010 to December 2018. Intervention was OPTIMAL with a usual care comparison.

Method
Primary outcomes were health-related quality of life (EQ-5D-3L) and frequency of activity participation (Frenchay Activities Index [FAI]). Secondary outcomes included independence in activities of daily living, occupational performance and satisfaction, anxiety and depression, self-efficacy, and healthcare utilisation. Complete case linear regression analyses were conducted. Age (<65/≥65 years) and the number of chronic conditions (<4/≥4) were explored further.

Results
A total of 124 (83.2%) and 121 (81.2%) participants had complete data at immediate and 6-month follow-up, respectively. Intervention participants had significant improvement in EQ-VAS (visual analogue scale) at immediate follow-up (adjusted mean difference [aMD] = 7.86; 95% confidence interval [CI] = 4.04 to 11.68) and greater improvement in FAI (aMD = 7.86; 95% CI = 1.92 to 14.80) but no difference in index time point. The 3D study,4 examined the effect of general practice-based 6-monthly patient multidisciplinary reviews of the dimensions of drugs, depression, and health, based on multimorbidity guidelines. It found no effect on health-related quality of life (HRQoL) but did report significant improvements in patients’ experience of care.

Conclusions
Self-management interventions aim to maximise physical and psychosocial functioning by providing individuals with skills to manage symptoms, treatments, and the psychosocial consequences of living with a chronic condition.5,6 The clinical and cost-effectiveness of such interventions for multimorbidity remain unclear.7 Studies of the popular peer-led Stanford chronic illness self-management programme have produced modest effects when delivered in settings outside of the US.8 The Medical Research Council framework for complex interventions9 was used to develop and pilot OPTIMAL, a professionally-led 6-week group self-management support programme for multimorbidity.10,11 The OPTIMAL programme is underpinned by self-efficacy theory, focusing on topics of concern to those with multimorbidity, and is professionally led by primary care occupational therapists, because of the profession’s focus on function, with input from a physiotherapist and pharmacist. Further details of the OPTIMAL programme content and delivery are outlined in Boxes 1 and 2. A pilot RCT of the OPTIMAL programme provided preliminary evidence that the programme significantly improved frequency of activity participation in instrumental activities of daily living, self-efficacy, and HRQoL immediately post-intervention.11

The aim of the present study was to conduct a definitive RCT to evaluate the effectiveness of the OPTIMAL programme in improving HRQoL and frequency of activity participation, and to test its sustainability after programme completion, as per Stage III of the Medical Research Council framework.9

INTRODUCTION

Individuals with multimorbidity, the presence of ≥2 chronic conditions, have poorer health outcomes, higher health service utilisation, and higher healthcare costs.1,2 The 2016 updated Cochrane review of interventions for multimorbidity in primary care found limited evidence on effectiveness. Included interventions predominately centred on care organisation such as case management or patient-oriented interventions, for example, patient education interventions. The review concluded that previous interventions focused predominantly on people with defined comorbid conditions or on multimorbidity in patients aged ≥65 years, and recommended a focus on risk factors common across comorbid conditions or generic outcomes such as daily functioning.3 In 2018, the largest randomised controlled trial (RCT) of a multimorbidity intervention, the 3D study,4 examined the effect of general practice-based 6-monthly patient multidisciplinary reviews of the dimensions of drugs, depression, and health, based on multimorbidity guidelines. It found no effect on health-related quality of life (HRQoL) but did report significant improvements in patients’ experience of care.

Self-management interventions aim to maximise physical and psychosocial functioning by providing individuals with skills to manage symptoms, treatments, and the psychosocial consequences of living with a chronic condition.5,6 The clinical and cost-effectiveness of such interventions for multimorbidity remain unclear.7 Studies of the popular peer-led Stanford chronic illness self-management programme have produced modest effects when delivered in settings outside of the US.8 The Medical Research Council framework for complex interventions9 was used to develop and pilot OPTIMAL, a professionally-led 6-week group self-management support programme for multimorbidity.10,11 The OPTIMAL programme is underpinned by self-efficacy theory, focusing on topics of concern to those with multimorbidity, and is professionally led by primary care occupational therapists, because of the profession’s focus on function, with input from a physiotherapist and pharmacist. Further details of the OPTIMAL programme content and delivery are outlined in Boxes 1 and 2. A pilot RCT of the OPTIMAL programme provided preliminary evidence that the programme significantly improved frequency of activity participation in instrumental activities of daily living, self-efficacy, and HRQoL immediately post-intervention.11

The aim of the present study was to conduct a definitive RCT to evaluate the effectiveness of the OPTIMAL programme in improving HRQoL and frequency of activity participation, and to test its sustainability after programme completion, as per Stage III of the Medical Research Council framework.9

Keywords
multimorbidity; occupational therapy; randomised controlled trial; self-management.

L O’Toole, BSc (Cur Occ), MSc, PhD, health research board fellow; D Connolly, MSc, PhD, associate professor, Discipline of Occupational Therapy, School of Medicine, Trinity College Dublin, St James’s Hospital, Dublin; F Boland, BSc, MSc, PhD, lecturer in biostatistics and research methods, Data Science Centre, Royal College of Surgeons in Ireland, Dublin.

Address for correspondence
Lynn O’Toole, Discipline of Occupational Therapy, School of Medicine, Trinity College Dublin, Trinity Centre for Health Sciences, St James’s Hospital, James’s Street, Dublin 8, Ireland.

Email: otoolel@tcd.ie

Submitted: 17 May 2020; Editor’s response: 23 June 2020; final acceptance: 2 October 2020.

©The Authors

This is the full-length article (published online 9 Mar 2021) of an abridged version published in print. Cite this version as: Br J Gen Pract 2021; DOI: https://doi.org/10.3399/bjgp20X714185
How this fits in

Existing interventions for multimorbidity are associated with little benefit to quality of life. The 2016 updated Cochrane review of interventions for multimorbidity concluded that interventions may be more effective if they focus on risk factors common across comorbid conditions or generic outcomes, such as daily functioning. The OPTIMAL programme, a 6-week, professionally-led, self-management support group intervention, aimed to have a specific focus on function and issues relevant to multimorbidity. The present study showed that, overall, there was no evidence the intervention had an effect on quality of life or functioning at 6-month follow-up. There remains a need to develop effective interventions to improve outcomes for patients with multimorbidity in primary care.

METHOD

Design

A pragmatic parallel two-arm RCT was reported following CONSORT guidelines for the design, conduct, and analysis of RCTs.\(^1\)

Setting

The study was carried out in the Irish primary care health system in the greater Dublin region. Ireland has a mixed public and private primary healthcare system, with one-third of the population entitled to free primary care based on low income through the General Medical Services Scheme. Primary care teams typically include GPs and practice nurses who are independent contractors, and allied health practitioners including community nurses, occupational therapists, physiotherapists, dietitians, and social workers, all of whom are employees of the public health system, that is, the Health Service Executive. Primary care in Ireland remains underdeveloped and fragmented;\(^13\) a process evaluation was also conducted alongside the OPTIMAL trial to evaluate its implementation within existing primary care services in Ireland and will be reported separately.

Participants and recruitment

Participants with multimorbidity were recruited through primary care team members and self-referral across eight Health Service Executive primary care areas in which participating occupational therapists were based. Recruitment and intervention delivery was conducted over four sequential time blocks, with two primary care team areas in each time block. Referring clinicians were informed about the study via post, email, and presentations at primary care team meetings. Referrals were forwarded to a gatekeeper in each area’s occupational therapy department who contacted referred patients 7–10 days after referral to confirm their participation.

The following participant inclusion criteria were applied: age ≥40 years; ≥2 chronic conditions; ≥4 repeat medications; and an ability to travel to the centre where the intervention would be delivered. These criteria were the same as those used in the exploratory RCT, which proved to be effective, with the exception of age.\(^1\) The age limit of ≥40 years was chosen because multimorbidity is relatively uncommon in patients younger than this and to facilitate targeted recruitment.\(^6\)\(^7\)

A broad, inclusive, and commonly used definition of ≥2 chronic conditions was used. The World Health Organization’s definition of chronic diseases as health problems that require ongoing management over a period of years or decades was used.\(^18\) The inclusion criteria of ≥4 repeat medications was included to identify a group in the broader multimorbidity population that is at increased risk of poor health outcomes and more likely to benefit from an intervention.\(^3\) Written informed consent was obtained from all trial participants. The trial ran from November 2015 to December 2018.

Intervention and control groups

Following baseline data collection for each site (area), participants were individually

| Box 1. OPTIMAL programme elements |
|-----------------------------------|
| **Theory:** Self-efficacy theory incorporating influencers including performance accomplishments, vicarious learning, social/verbal persuasion, reinterpretation of physiological and emotional states |
| **Format:** Group-based programme delivered over 6 consecutive weeks; 2.5 hour session with tea/coffee break |
| **Location:** Primary care centres or community resource centres |
| **Mode of delivery:** Educational (includes participant interaction and discussion) and goal-setting components |
| **Facilitators:** Health Service Executive (HSE) primary care occupational therapists with input from physiotherapist and pharmacist |
| **Educational component:** Week 1: Introduction to self-management, activity and health, and goal-setting; Week 2: Fatigue management and healthy eating; Week 3: Maintaining physical activity; Week 4: Maintaining mental wellbeing; Week 5: Managing medications; Week 6: Communication and programme review |
| **Goal-setting component:** Overall programme goals set in Week 1. Weekly goal-setting and review |
| **Resources:** Participant booklet, relaxation CD, information on local resources, HSE health promotional resources, such as exercise booklets, get active your way, healthy eating, and information on generic medicines and mental health |
randomised into intervention (OPTIMAL programme) or control (waiting list continuing to receive care as usual) groups. Randomisation and allocation was carried out remotely by an independent statistician. Randomisation was performed using Stata (version 14.1), was stratified by sex, and random permuted blocks of size 2 and 4 were used. Couples who were recruited were randomised as a unit to avoid contamination. The independent statistician informed therapists at each site of participant allocation and therapists in turn informed participants of their allocation by telephone 1–2 weeks before the intervention began.

**Intervention**

Full details of the OPTIMAL programme have been published previously and the programme content is summarised in Boxes 1 and 2.10,11 Before programme delivery, occupational therapists received a half-day of training and a facilitator manual to standardise programme delivery and maintain intervention fidelity.

**Outcomes**

Outcomes were chosen to reflect the intervention’s theoretical underpinnings and based on the previous OPTIMAL pilot studies.10,11 Outcomes were collected immediately post-intervention (primary outcome measures only) and 6 months post-intervention.

Baseline assessments were conducted via interview with occupational therapists in each site. Immediately post-intervention, intervention and control participants self-completed primary outcomes by postal survey (in a 3-week period of intervention completion). All 6-month follow-up (post-intervention completion) assessments were collected via interviews, with a researcher blinded to participant allocation and a record of broken blinding was maintained. Because of the nature of the intervention, it was not possible to blind participants to their group allocation. Data collection for control participants was matched to intervention participants in the same time block to ensure an equal length of follow-up.

Two primary outcome measures were used: HRQoL (measured using the EQ-5D-3L) and frequency of activity participation (measured using the Frenchay Activities Index [FAI]).19,20 The EQ-5D-3L comprises two parts, the descriptive system and a visual analogue scale (EQ-VAS). The descriptive system consists of five dimensions including mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, each of which is rated on three severity levels. The EQ-VAS is a vertical visual analogue scale whereby participants rate their perceived health status from 0 (worst imaginable health) to 100 (best imaginable health). The EQ-5D-3L descriptive system can be converted to an index score based on societal preferences for health states.21 Secondary outcome measures included the Nottingham Extended Activities of Daily Living scale,22 the Stanford Chronic Disease Self-Efficacy 6-item Scale (SEMCD),23 the Hospital Anxiety and Depression Scale (HADS),24 and the Canadian Occupational Performance Measure (COPM).25 Self-reported healthcare utilisation, including GP visits, emergency department visits, outpatient appointments, hospital admissions, and nights spent in hospital was collected for 6 months before baseline data collection and 6 months post-intervention (see Supplementary Table S1 for additional details of the outcomes and scoring interpretation).

**Sample size calculation**

A sample size of 200 participants was calculated, using pilot trial data, based on 90% power to detect a clinically relevant change in both primary outcome measures at a 0.05 significance level and to allow for 30% loss to follow-up (see Supplementary Box S1 for details). However, difficulties with recruitment resulted in revision of the sample size using interim trial baseline data (n = 108) and 80% power. Furthermore, retention was 10% higher at follow-up than originally anticipated. In the EQ-VAS, improvements of 14 points have been reported as representing a large effect size.26 Interim mean EQ-VAS baseline scores were 59.1 (standard deviation [SD] 20.3). To improve a baseline EQ-VAS score of 59.1 by 14 points, with 80% power, required a total sample size of 68 (n = 34 per group). Improvements of 4 points in FAI total scores have been reported as clinically significant.17 Interim mean FAI baseline scores were 25.3 (SD 7.5). To improve a baseline FAI score by 4 points, with 80% power, a sample size of 114 in total (n = 57 per group) was required. The revised sample size calculation indicated that the study required 144 participants, which incorporated a 20% loss to follow-up.

**Data analysis**

All results were analysed using Stata (version 14). For primary and secondary outcomes, the primary analysis was intention to treat, including all randomised participants, all retained in the group to which they were allocated, and using complete case analyses. All analyses used multiple linear regression models.
Participants were recruited between February 2016 and February 2018. In total, 149 participants consented and completed baseline data collection (Figure 1). A total of 124 (83.2%) and 121 (81.2%) participants had complete data at immediate and 6-month follow-up, respectively. Most of the intervention group attended ≥3 sessions (n = 59; 75.6%). Table 1 summarises participants’ baseline characteristics. Table 2 presents adjusted intention-to-treat analyses for primary and secondary outcomes. Unadjusted intention-to-treat analyses (see Supplementary Table S4 for details) and per protocol analyses (see Supplementary Tables S5 and S6 for details) of outcomes were conducted.

**Primary outcomes**

For HRQoL (EQ-VAS), significant differences were seen in favour of the intervention group at 6-month follow-up (adjusted MD = 7.86; 95% CI = 0.92 to 14.80; P = 0.027). However, there were no differences between intervention and control groups in the EQ-5D-3L index (adjusted MD = 0.04; 95% CI = –0.06 to 0.13; P = 0.992) and frequency of activity participation (adjusted MD = 1.22; 95% CI = –0.84 to 3.29; P = 0.243) at immediate follow-up. There were no differences in primary outcomes at 6-month follow-up (Table 2). There were no differences between intervention and control groups in the EQ-5D-3L index and frequency of activity participation at immediate and 6-month follow-up.

**Subgroup analyses of primary outcomes**

Pre-planned subgroup analyses examined the effect of age (<65 and ≥65 years) and number of conditions (<4 and ≥4) on primary outcomes (Table 3). Immediately post-intervention, for those

![Figure 1. CONSORT flow diagram. EQ-VAS = EQ visual analogue scale. FAI = Frenchay Activities Index. RCT = randomised controlled trial.](image_url)
aged <65 years, compared with those aged ≥65 years, no evidence of a difference was found in HRQoL (EQ-VAS), however, there was a significant effect in favour of the intervention for frequency of activity participation (adjusted MD = 6.13; 95% CI = 1.93 to 10.34; P = 0.005).

At 6-month follow-up, in those aged <65 years, compared with those aged ≥65 years, the effect of the intervention compared with usual care was significant for HRQoL (EQ-VAS) only (adjusted MD = 25.39; 95% CI = 6.81 to 43.98; P = 0.008).

Secondary outcomes
Secondary outcomes were examined at 6 months and no evidence of significant differences were seen in activities of daily living (Nottingham Extended Activities of Daily Living scale), self-efficacy (SEMCD), or anxiety and depression (HADS-A and HADS-D) (Table 2). While there was no difference in perceptions of occupational satisfaction (COPM-S) in the intervention compared with the control group (adjusted MD = 1.24; 95% CI = 0.43 to 2.06; P = 0.003). While no differences were found in other elements of self-reported healthcare utilisation, a significant difference was seen in favour of the intervention group in hospital outpatient appointments (adjusted MD = –1.69; 95% CI = –2.66 to –0.72; P = 0.001).

Adjusted per protocol analyses found significant differences in favour of the intervention in self-efficacy (SEMCD), satisfaction with and ability to perform activities (COPM-S and COPM-P), and self-reported outpatient appointments, and nights spent in hospital (see Supplementary Table S4 for details).

DISCUSSION
Summary
This study is the first definitive RCT of OPTIMAL, an occupational therapy self-management support programme for individuals with multimorbidity in primary care.3 The programme was effective in improving HRQoL, as measured by the EQ-VAS, at immediate follow-up, although this effect was not maintained at 6-month follow-up, and there was no effect on the EQ-5D index at either time point. The EQ-VAS provides data presenting participant’s self-assessment of their health, while the index score is based on societal preferences for health states.19 There was evidence, based on pre-planned subgroup analyses, that the programme was effective for younger participants, aged <65 years, in improving HRQoL. Regarding secondary outcomes, OPTIMAL showed an effect on occupational satisfaction and self-reported hospital outpatient appointments at 6-month follow-up, but had no effect on all other outcomes.

Strengths and limitations
This RCT, which investigated OPTIMAL, was based on previous feasibility and pilot studies, as per the Medical Research Council framework for complex interventions, which was a strength, and it was reported following CONSORT guidelines for parallel trials.10,11 The pragmatic nature of the RCT,
conducted in Irish primary care settings and using referral processes similar to those used in practice, was designed to include participants representative of those with multimorbidity in primary care. Study retention was high.

Data regarding the number of patients approached by GPs and primary care team clinicians were not collected given the pragmatic nature of the study, reflecting routine service referral pathways. It is therefore not possible to determine an overall response rate or draw definitive conclusions about the programme’s generalisability to individuals with multimorbidity in primary care. However, the participants were a fairly representative group of individuals with complex multimorbidity having an average of four conditions, eight to nine regular medications, and a mean age of 65 years, which is younger than previous multimorbidity trials.3,4

A further limitation is that multiple assessors conducted baseline assessments, however, training was provided in outcome measure administration to minimise the risk of rater bias.31 One researcher conducted all 6-month follow-up assessments via interview, blinded to allocation. The original power calculation was revised downwards from 90% to 80% because of recruitment

Table 2. Adjusted multiple linear regression intention-to-treat analyses for primary and secondary outcomes using complete case analyses

| Outcome                  | Immediate follow-up | 6-month follow-up |
|--------------------------|---------------------|-------------------|
|                          | Mean difference     | P-value            | Mean difference | P-value  |
| Primary outcomes         |                     |                   |                 |          |
| EQ-VAS                   | 7.86 (0.92 to 14.80) | 0.027             | 6.07 (1.77 to 13.91) | 0.127 |
| EQ-5D-3L index score     | 0.04 (–0.06 to 0.13) | 0.992             | 0.10 (–0.01 to 0.22) | 0.077 |
| FAI                      | 1.22 (–0.84 to 3.29) | 0.243             | 1.20 (–0.89 to 3.29) | 0.257 |
| Secondary outcomes      |                     |                   |                 |          |
| NEADL scale              | 1.84 (–0.89 to 4.58) | 0.184             |                   |          |
| SEMCD                    | 0.52 (0.00 to 1.05)  | 0.052             |                   |          |
| HADS-A                   | –0.45 (–1.59 to 0.69) | 0.436             |                   |          |
| HADS-D                   | –0.89 (–1.61 to 0.03) | 0.387             |                   |          |
| COPM-PA                  | 0.75 (–0.07 to 1.57) | 0.073             |                   |          |
| COPM-S                   | 1.24 (0.63 to 2.06)  | 0.003             |                   |          |
| GP visits                | –0.24 (–1.40 to 0.91) | 0.676             |                   |          |
| Emergency visits         | –0.05 (–0.43 to 0.34) | 0.807             |                   |          |
| Hospital outpatients     | –1.64 (–2.66 to –0.72) | 0.001           |                   |          |
| Hospital visits          | –0.20 (–0.45 to 0.04) | 0.131             |                   |          |
| Hospital nights          | –2.87 (–5.92 to 0.19) | 0.066             |                   |          |

P-values ≤ 0.05 are shown in bold. Adjusted for sex, baseline score, area, number of conditions at baseline, and age. Seven participants did not identify goals in the COPM at baseline, that is, 142 provided COPM baseline data, 114 provided COPM data at 6-month follow-up. COPM-P = Canadian Occupational Performance Measure: Performance subscale. COPM-S = Canadian Occupational Satisfaction Measure: Satisfaction subscale. EQ-VAS = EQ visual analogue scale. FAI = Frenchay Activities Index. HADS-A = Hospital Anxiety and Depression Scale: Anxiety subscale. HADS-D = Hospital Anxiety and Depression: Depression subscale. NEADL = Nottingham Extended Activities of Daily Living. SEMCD = Stanford Chronic Disease Self-Efficacy 6-item Scale.

Table 3. Adjusted multiple linear regression intention to treat and per protocol of primary outcomes using complete case analyses exploring the interaction with age (<65 versus ≥65) and number of conditions (<4 versus ≥4)

| Outcome                  | Intention to treat | Per protocol |
|--------------------------|--------------------|--------------|
|                          | Immediate follow-up| 6-month follow-up | Immediate follow-up | 6-month follow-up |
|                          | Mean difference    | Mean difference | P-value | Mean difference | Mean difference | P-value |
| Age, years               |                     |                 |         |                 |                 |         |
| EQ-VAS                   |                     |                 |         |                 |                 |         |
| Age (<65 versus ≥65)     | 11.47               | 25.39           | 0.008   | 8.49            | 23.13           | 0.024   |
|                          | [–3.23 to 26.18]    | [6.81 to 43.98] |         | [–6.72 to 23.70] | [3.19 to 43.06] |         |
| FAI                      |                     |                 |         |                 |                 |         |
| Age (<65 versus ≥65)     | 6.13                | 4.74            | 0.077   | 4.90            | 4.98            | 0.066   |
|                          | [1.93 to 10.34]     | [–0.53 to 10.01] |         | [1.49 to 8.30]  | [–0.34 to 10.30] |         |
| Number of conditions     |                     |                 |         |                 |                 |         |
| EQ-VAS                   |                     |                 |         |                 |                 |         |
| Conditions (<4 versus ≥4) | –2.68              | –5.57           | 0.570   | –3.10           | –3.01           | 0.775   |
|                          | [–17.25 to 11.88]   | [–25.01 to 13.88] |         | [–18.04 to 11.82] | [–23.94 to 17.93] |         |
| FAI                      |                     |                 |         |                 |                 |         |
| Conditions (<4 versus ≥4) | –3.45              | –0.74           | 0.785   | –3.48           | 0.55            | 0.839   |
|                          | [–7.84 to 0.95]     | [–6.07 to 4.60]  |         | [–8.15 to 1.18]  | [–5.91 to 4.81]  |         |

P-values ≤ 0.05 are shown in bold. Adjusted for sex, baseline EQ-VAS, area, and number of conditions at baseline. Adjusted for sex, baseline FAI total, area, and number of conditions at baseline. Adjusted for sex, baseline EQ-VAS, area, and age. Adjusted for sex, baseline FAI total, area, and age. EQ-VAS = EQ visual analogue scale. FAI = Frenchay Activities Index.
difficulties. This limitation increases the possibility of making a type II error due to an inadequate sample size, that is, a ‘false negative’ finding. Bias as a result of selective outcome reporting is a concern in trial reporting. The Goal Attainment Scale was included as a secondary outcome measure in the trial registry. However, in both the pilot trial and the present study, the Goal Attainment Scale was used with the intervention group participants only during intervention to assist in goal setting. There was no comparison with control group participants.

In the present study there were some inconsistencies in use of the Goal Attainment Scale to guide programme goal setting across sites. As the measure was a secondary outcome measure with no comparison, these results are not reported.

The subgroup analyses were pre-planned based on the literature, which recommends targeting of multimorbidity interventions across the age range and evidence suggesting that those with higher levels of morbidity are at risk of poorer outcomes. While such analyses can be useful in individualising patient care and provide evidence that can guide targeting of interventions, these should be interpreted with caution given the study was not powered to detect these subgroup differences.

Comparison with existing literature

The updated 2018 meta-analysis of HRQoL from the Cochrane review conducted by the 3D team included 14 studies with a range of interventions, but found little or no benefit. A 2019 study of a clinical medication review for patients with multimorbidity found no improvements in the EQ-5D index score but, like OPTIMAL, the present study did find improvements in the EQ-VAS. It is not clear why these interventions have shown significant improvements in the EQ-VAS but not in the index, and there is a need for further consideration of measures used to detect changes in HRQoL (see Supplementary Table S7 for a comparison of OPTIMAL EQ-5D index scores with the 3D trial).

Core OPTIMAL programme components including information provision, problem solving, and goal setting, targeted risk factors and health behaviours. Those with multimorbidity may require more intensive or ongoing interventions to improve outcomes such as HRQoL. While there was an improvement in HRQoL at immediate follow-up, as measured by the EQ-VAS, this was not sustained at 6-month follow-up. The immediate effect on HRQoL may reflect the short-term benefit gained from the programme’s social interaction. Subgroup analyses for patients aged <65 years suggested HRQoL improvements at 6-month follow-up and improved frequency of activity participation immediately post-intervention. Older individuals with multimorbidity may have developed coping strategies over the years, or may have less capacity to adopt new behaviours. Approaches such as OPTIMAL may be more effective for adults aged 40–65 years with multimorbidity to develop self-management strategies, thus enhancing elements of HRQoL.

The OPTIMAL programme did not have an effect on frequency of activity participation. Previous studies have suggested that interventions may be effective if they target functioning. While the OPTIMAL programme focuses on improving activity participation and is led by occupational therapists, it covers a wide range of topics, and may not have sufficiently targeted participants’ functional concerns. While subgroup analyses results should be interpreted with caution, it is possible that younger participants with multimorbidity were initially less active in social and community activities, and had more scope for improvement. However, it does not appear that this effect was sustained after programme completion.

There were mixed effects on secondary outcomes relating to function. The significant difference in satisfaction with occupational (activity) performance (COPM-S) is consistent with previous research, suggesting that satisfaction with participation for those with multimorbidity had a greater effect on wellbeing than performance or activity accomplishment.

The OPTIMAL programme was guided by self-efficacy, a concept developed from social cognitive theory by Bandura. While intention-to-treat analysis found no significant differences in self-efficacy, as measured by the SEMCD, the per protocol analysis found a statistically significant difference for intervention participants at 6-month follow-up. The original RCT of the Stanford chronic disease self-management programme also reported improved self-efficacy that was associated with improved health status and reduced healthcare utilisation. However, these findings have not been replicated in settings outside the US, and the present study does not provide clear evidence of an impact on self-efficacy.

Patients with multimorbidity have higher levels of mental health problems, which are associated with increased healthcare utilisation, cost, and activity limitations.
No differences were found in anxiety and depression at 6-month follow-up. Only one of the OPTIMAL programme sessions specifically addressed mental wellbeing, which may not sufficiently address anxiety and depression.

Previous studies of chronic disease self-management programmes have found minimal improvements in depression, despite emotional management being a core aspect of effective self-management. A significant difference was found in self-reported hospital outpatient appointments but not in other elements of healthcare utilisation. Previous studies of self-management programmes produced inconsistent results regarding healthcare utilisation. OPTIMAL includes strategies for improving communication with healthcare providers and managing multiple medications, and it is possible that the programme resulted in more effective use of healthcare providers. OPTIMAL may have improved the patient’s experience of care like the 3D study, but this was not measured. However, self-management programmes alone may be insufficient to reduce healthcare utilisation in multimorbidity. Self-reported healthcare utilisation was used because of logistical difficulties in accessing clinical records across multiple sites, and under-reporting can be a limitation.

The authors of the present study plan to publish articles on the process evaluation and economic evaluation, which will add further to interpretation of trial results.

**Implications for research**
While this trial of an occupational therapy-led self-management support programme found no effect at 6-month follow-up, subgroup analyses suggested a benefit for younger participants with multimorbidity. There remains a need to develop effective interventions targeting both HRQoL and function for patients with multimorbidity in primary care.

Future research should evaluate in more detail the effectiveness of the OPTIMAL programme in younger individuals with multimorbidity, given that patients in this subgroup appear to be at risk of poorer outcomes and existing multimorbidity interventions tend to focus on older adults.

**Funding**
This study was funded by the Health Research Board (HRB) Research Training Fellowship for Healthcare Professionals (reference number: HPF 2015-972). The HRB is the lead agency in Ireland supporting and funding health research. Additional support was received from the HRB Trials Network and HRB Centre for Primary Care Research. Susan M Smith and Fiona Boland are supported by the HRB funded Primary Care Research Centre.

**Ethical approval**
Ethical approval was granted by Trinity College Dublin Faculty of Health Sciences Ethics Committee (reference number: 150900) and registered as ISRCTN67235963. Approval from the Health Service Executive (HSE) Primary Care Research Committee was given for HSE primary care professionals to be involved in the study.

**Provenance**
Freely submitted; externally peer reviewed.

**Competing interests**
The authors have declared no competing interests.

**Acknowledgements**
The authors wish to thank the participating primary care clinicians for their help with trial recruitment and intervention delivery, as well as the participants who took part in the study.

**Open access**
This article is Open Access: CC BY 4.0 licence (http://creativecommons.org/licenses/by/4.0/).

**Discuss this article**
Contribute and read comments about this article: bjgp.org/letters
REFERENCES

1. Xu X, Mishra GD, Jones M. Evidence on multimorbidity from definition to intervention: an overview of systematic reviews. Ageing Res Rev 2017; 37: 53–68.

2. Marengoni A, Angleman S, Melis R, et al. Aging with multimorbidity: a systematic review of the literature. Ageing Res Rev 2011; 10(4): 430–439.

3. Smith SM, Wallace E, O’Dowd T, Fortin M. Interventions for improving outcomes in patients with multimorbidity in primary care and community settings. Cochrane Database Syst Rev 2016; 3(3): CD008566.

4. Salisbury C, Man M-S, Bower P, et al. Management of multimorbidity using a patient-centred care model: a pragmatic cluster-randomised trial of the 3D approach. Lancet 2018; 392(10141): 41–50.

5. Schulman-Green D, Jaser S, Martin F, et al. Processes of self-management in chronic illness. J Nurs Scholarsh 2012; 44(12): 136–144.

6. Lorig KR, Holman H. Self-management education: history, definition, outcomes, and mechanisms. Ann Behav Med 2003; 24(1): 1–7.

7. Health Information and Quality Authority. Health technology assessment of chronic disease self-management support interventions. 2015. https://www.hiqa.ie/sites/default/files/2017-01/HTA-chronic-disease-support-interventions. pdf (accessed 1 Mar 2021).

8. Franek J. Self-management support interventions for persons with chronic disease: an evidence-based analysis. Oit Health Technol Assess Ser 2013; 13(9): 1–60.

9. Craig P, Dieppe P, MacIntyre S, et al. Developing and evaluating complex interventions: new guidance. London: Medical Research Council, 2008.

10. O’Toole L, Connolly D, Smith S. Impact of an occupation-based self-management programme on chronic disease management. Aust Occup Ther J 2013; 60(1): 30–38.

11. Garvey J, Connolly D, Boland F, Smith SM. OPTIMAL, an occupational therapy led self-management support programme for people with multimorbidity in primary care: a randomized controlled trial. BMC Fam Pract 2015; 16: 59.

12. Schulz KF, Altman DG, Moher D, CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. pdf (accessed 1 Mar 2021).

13. Ritter PL, Lorig K. The English and Spanish Self-Efficacy to Manage Chronic Disease Scale measures were validated using multiple studies. J Clin Epidemiol 2014; 67(11): 1265–1273.

14. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatr Scand 1983; 67(6): 361–370.

15. Law M, Baptiste S, Carwell A, et al. COPM: Canadian Occupational Performance Measure. 5th edition. Ottawa: Canadian Association of Occupational Therapists, 2014.

16. Roset M, Badia X, Mayo NE. Sample size calculations in studies using the EuroQol SD. Qual Life Res 1999; 8(6): 539–549.

17. Forster A, Young J, Green J, et al. Structured re-assessment system at 6 months after a disabling stroke: a randomised controlled trial with resource use and cost study. Age Ageing 2009; 38(5): 576–583.

18. European Medicines Agency (EMA). Guideline on adjustment for baseline covariates in clinical trials. London: EMA, 2015.

19. Griffiths C, Motlib J, Azad A, et al. Randomised controlled trial of a lay-led self-management programme for Bangladeshi patients with chronic disease. Br J Gen Pract 2005; 55(520): 831–837.

20. Sun X, Ioannidis JPA, Agoritsas T, et al. How to use a subgroup analysis: users’ guide to the medical literature. JAMA 2014; 311(4): 405–411.

21. Hoyt WT. Rater bias in psychological research: when is it a problem and what can we do about it? Psychol Methods 2000; 5(1): 64–86.

22. Turner-Stokes L. Goal attainment scaling (GAS) in rehabilitation: a practical guide. Clin Rehabil 2009; 23(4): 362–370.

23. Verdoorn S, Kwint H-F, Blom JW, et al. Effects of a clinical medication review focused on personal goals, quality of life, and health problems in older persons with polypharmacy: a randomised controlled trial (DREAMER-study). PLoS Med 2019; 16(5): e0100729.

24. N’Goran AA, Dérueux-Luyet A, Haller DM, et al. Comparing the self-perceived quality of life of multimorbid patients and the general population using the EQ-5D-3L. J Clin Epidemiol 2016; 71(5): e100729.

25. Noel PH, Fruh BC, Lampe AC, Pugh JA. Collaborative care needs and preferences of primary care patients with multimorbidity. Health E spotlight 2005; 8(1): 54–63.

26. Cheraghi-Sohi S, Morden A, Bower P, et al. Exploring patient priorities among long-term conditions in multimorbidity: a qualitative secondary analysis. SAGE Open Med 2013; DOI: 10.1177/2050312113503955.

27. Abay D, Milner WC, Jarus T, et al. Participation and well-being among older adults living with chronic conditions. Soc Indic Res 2011; 100(1): 171–183.

28. Bandura A. The explanatory and predictive scope of self-efficacy theory. J Soc Clin Psychol 1986; 4(3): 359–373.

29. Lorig KR, Sobel DS, Stewart AL, et al. Evidence suggesting that a chronic disease self-management program can improve health status while reducing hospitalization: a randomized trial. Med Care 1999; 37(1): 5–14.

30. Griffiths C, Foster G, Ramsay J, et al. How effective are expert patient (lay led) education programmes for chronic disease? BMJ 2007; 334(7604): 1254–1256.

31. Rogers A, Kennedy A, Bower P, et al. The United Kingdom Expert Patients Programme: results and implications from a national evaluation. Med J Aust 2006; 185(10): 521–524.

32. Gunn JM, Atyon DR, Densley K, et al. The association between chronic illness, multimorbidity and depressive symptoms in an Australian primary care cohort. Soc Psychiatry Psychiatr Epidemiol 2012; 47(2): 175–184.

33. Vancampfort D, Koyanagi A, Hallgren M, et al. The relationship between chronic physical conditions, multimorbidity and anxiety in the general population: a global perspective across 42 countries. Gen Hosp Psychiatry 2017; 45: 1–6.

34. Fortin M, Bravo G, Hudon C, et al. Psychological distress and multimorbidity in primary care. Ann Fam Med 2006; 4(5): 417–422.

35. Fortin M, Hudon C, Bayliss EA, et al. Caring for body and soul: the importance of recognizing and managing psychological distress in persons with multimorbidity. Int J Psychiatry Med 2007; 37(1): 1–9.

36. Nolle S, Osborne RH. A systematic review of outcomes of chronic disease self-management interventions. Qual Life Res 2013; 22(7): 1805–1816.

37. Brady TJ, Murphy L, O’Colmain BJ, et al. A meta-analysis of health status, health behaviors, and health care utilization outcomes of the Chronic Disease Self-Management Program. Prev Chron Dis 2013; 10: E120112.

38. Bhandari A, Wagner T. Self-reported utilization of health care services: improving measurement and accuracy. Med Care Res Rev 2006; 63(2): 217–235.

39. Ritter PL, Stewart AL, Raymaz H, et al. Self-reports of health care utilization compared to provider records. J Clin Epidemiol 2001; 54(2): 136–141.