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A rehabilitation programme for people with multimorbidity versus usual care: A pilot randomized controlled trial

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Abstract

Background: Multimorbidity, the coexistence of two or more chronic conditions, is common in clinical practice. Rehabilitation for people with multimorbidity may provide access to a rehabilitation programme that can address common symptoms and risk factors for multiple chronic diseases. **Objective:** The aims of this study were to (1) evaluate the feasibility of a rehabilitation programme compared to usual medical care (UMC) in people with multimorbidity and (2) gather preliminary data regarding clinical effects and impact on functional exercise capacity, activities of daily living, health-related quality of life and resource utilization. **Design:** A pilot feasibility parallel randomized controlled trial was undertaken. Adults with multimorbidity were randomized to the rehabilitation programme (intervention) or UMC (control). The duration of the rehabilitation programme was 8 weeks and comprised exercise (1 h, twice weekly) and education (1 h, once weekly). The UMC group did not participate in a structured exercise programme. **Results:** One hundred people were screened to recruit 16 participants, with a 71% completion rate for the intervention group. The rehabilitation group achieved a mean (standard deviation) improvement in 6-minute walk distance of 44 (41) m and the UMC group of 23 (29) m. **Conclusions:** This study suggests that it would be feasible to conduct a larger randomized control trial investigating a rehabilitation programme for people with multimorbidity. Low uptake of the study suggests that refinement of the inclusion criteria, recruitment sources and programme model will be needed to achieve the number of participants required.

Keywords

Multimorbidity, rehabilitation, randomized control trial, exercise, education

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Introduction

Multimorbidity, defined as the coexistence of two or more chronic conditions,[1] is an important problem in most healthcare systems and is common in clinical practice.[2] It is associated with increased mortality,[3,4] poorer functional status[5] and reduced health-related quality of life (HRQoL).[6] Multimorbidity is a rising healthcare burden internationally,[7–9] and as a result, policy and guideline makers need to ensure that this complex population have access to evidence-based and sustainable interventions.

A systematic review on interventions for improving outcomes in people with multimorbidity identified 18 randomized control trials (RCTs), testing heterogeneous interventions.[2] Findings suggested that interventions that focused on areas where people have difficulties, such as functional outcomes, led to modest improvements.[2] Even when clinical practice guidelines (such as pulmonary or cardiac rehabilitation) exist with recommendations based on high-level evidence and rehabilitation programmes focused on single diseases are well established, gaps remain in implementation.[10–12] Current chronic disease-specific clinical guidelines for rehabilitation do not meet the challenges of multimorbidity,[13] by overlooking the potential interaction of multiple diseases and their management, or fail to address or exclude people with multimorbidity.[13,14] It was shown that in a review of recent guidelines relevant to single-disease rehabilitation for people with chronic diseases, three of the seven do not mention coexisting conditions and an additional three only make passing mention of minor programme adaptations.[13] Within the research field on disease-specific rehabilitation programmes, there has been debate over the inclusion of people with complex conditions. This is highlighted in the analysis conducted on the studies on a Cochrane review of pulmonary rehabilitation in chronic obstructive pulmonary disease, which shows that 51% and 48% of the included studies excluded people with cardiac and musculoskeletal disease, respectively.[13] Due to the multitude of presentations within the multimorbidity population, many people do not fit the single-disease rehabilitation models. There are also several perceived barriers that prevent healthcare professionals from referring to rehabilitation programmes, which include awareness and familiarity, belief in health benefits, motivation and prioritization and the complexity of behavioural change required by the patient.[10,12]

Rather than using resources to increase the proportion of single-disease interventions, it has been suggested that multimorbidity interventions should be integrated into existing healthcare systems to support implementation and sustainability[15] and to apply and build on the evidence regarding effective interventions for single diseases to people with multimorbidity.[2] Many healthcare systems already include well-established disease-specific rehabilitation programmes and, therefore, are well placed to provide rehabilitation for people with multimorbidity, or to evolve the successful existing models, such as pulmonary rehabilitation, to more comprehensively address the needs of people with multimorbidity.[13] As evidence has shown that exercise and education can improve outcomes and mitigate the progression of many chronic diseases[16] and is recommended in guidelines for many single diseases, exercise-based rehabilitation for people with multimorbidity may have a role to play in addressing common symptoms and risk factors for multiple chronic diseases, rather than only focusing on management of one disease.

Objectives

The study aims were to (1) evaluate the feasibility of a rehabilitation programme for people with multimorbidity compared to usual medical care (UMC) in people with multimorbidity who are unable to access traditional disease-specific rehabilitation; (2) gather preliminary data regarding effects of these interventions on functional exercise capacity, activities of daily living (ADL), HRQoL and resource utilization; and (3) determine which multimorbidity measures would be most suitable for use in a larger scale trial.

Materials and methods

Study overview, design and setting

This trial was a pilot feasibility parallel RCT, conducted at Sunshine Hospital, Victoria, Australia. Participants were recruited from November 2014 to February 2015 and sourced from inpatient medical wards, outpatient clinics and the community-based rehabilitation service at Western Health. Informed consent was gained from all participants. Ethical approval was obtained from Melbourne Health Human Research Ethics Committee and La Trobe University. The trial was registered with Australian New Zealand Clinical Trials Registry (ACTRN 12614001187639) and reported according to Consolidated Standards of Reporting Trials (CONSORT) guidelines.[17]

Eligibility criteria

The inclusion criteria were adults (aged >18 years) with a physician diagnosis of two or more chronic conditions who met the defined list of multimorbidity by Barnett et al. (Online Supplementary Table 1).[1] This defined list of multimorbidity was used to ensure a consistent selection criterion for this trial, as there are no agreed clear and comprehensive criteria for the selection of chronic conditions which qualify for multimorbidity.[18] Participants were not eligible for traditional disease-specific rehabilitation programmes (cardiac, heart failure and pulmonary rehabilitation), because their primary diagnosis was another condition or their cardiorespiratory disease was deemed to be stable and not contributing to a decline in function. Exclusion criteria were an inability to walk 50 m, severe cognitive impairment, unstable cardiovascular

disease or diabetes and current participation in a structured exercise programme.

Randomization

Eligible participants were randomized in a 1:1 allocation. The allocation sequence was generated using computer-generated random numbers, and group allocation was placed into sealed opaque envelopes by an independent investigator not involved in recruitment or outcome measurement. Randomization occurred after the completion of the baseline data collection.

Interventions

Participants were randomized to either a rehabilitation programme (intervention) or UMC (control). The duration of the rehabilitation programme was 8 weeks and comprised exercise (1 h, twice weekly) and education (1 h, once weekly) in a group setting. The rehabilitation programme structure was developed according to current evidence-based cardiac, heart failure and pulmonary rehabilitation programmes. UMC included general inpatient or outpatient medical care, potentially including allied health; however, they did not participate in a structured exercise programme during the study period.

Exercise. The exercise programme consisted of aerobic and resistance exercises.

Aerobic component. Comprises walking (corridor or treadmill) and stationary cycling, for a total of 30 min, with 15 min for each activity. The initial walking prescription was calculated at 80% of peak walking speed or distance,[19,20] and stationary cycling intensity was calculated at 60–80% of the maximum work rate estimated from the 6-min walk test (6MWT).[21] Exercise prescription was progressed using a rating of perceived exertion (RPE) Borg scale (6–20) and dyspnoea modified Borg scale, aiming for an RPE score of 12–14 and a dyspnoea score of 3–4, correlating to moderate intensity exercise.[22]

Resistance component. Upper and lower limb exercises using free weights with four upper limb and three lower limb exercises. Components of the resistance exercise routine were based on functional exercises. The initial load corresponded to 10–12 repetition maximum (RM). A 10–12 RM is the weight that can be lifted correctly and comfortably at least 10 times but not more than 12.[23] Progression was undertaken using an RPE Borg scale (6–20), aiming for an RPE score of 12–14.

Cessation/withdrawal and safety criteria included a change in a participant's medical condition that deemed him/her unsuitable for exercise (for further detail, see Online Supplementary Material). The exercise prescription was modified for a participant's individual requirements, related to change in symptoms or limitations due to comorbidities. For example, a second walking session was included to replace cycling if the participant was unable to use a stationary bike due to back pain. A physiotherapist and a nurse were present during the exercise sessions.

Table 1. Education sessions.

1	Nursing
	What is multimorbidity?
	Managing multimorbidity – risk factors and setting goals.
	Finding useful resources.
2	Nursing
	Communication with healthcare professionals, family and friends.
	Smoking cessation.
	Blood pressure and cholesterol – how to manage.
3	Physiotherapy
	Why is exercise important?
	Types of exercise and how much to do.
	Precautions and warnings for exercise.
4	Dietetics
	Healthy eating.
	Weight management.
	Finding useful resources.
5	Diabetes educator
	What is diabetes?
	Managing blood sugar levels.
	Signs and symptoms of low/high blood sugar levels.
6	Pharmacy
	General medicine advice.
	Why am I taking so many medications?
	Home medicine review.
7	Occupational therapy
	Performing activities of daily living.
	Energy conservation.
	Relaxation and stress management.
8	Psychology
	Anger/shock/numbness/denial/disbelief.
	Acceptance and building problem-solving skills.
	Action towards achieving a modified healthy lifestyle.

Education. Education for the rehabilitation programme was delivered by multidisciplinary professionals using a didactic approach with handouts provided (Table 1). The rehabilitation programme education sessions aimed to enhance skills in general disease self-management and focused on common risk factor modification for chronic diseases.[24] Participants were directed towards finding relevant information and resources in disease management. The 'managing multimorbidity' session aimed to teach participants to recognize when their disease symptoms changed and consult their general practitioner (GP) for management. A diabetes education session was included due to the prevalence of diabetes in the study population. The pharmacy session focused on awareness of community services available through local pharmacies to assist people with managing polypharmacy, such as home medication review and medication distribution packs.

Pre- and post-assessments were conducted at baseline and following the intervention period, completed by blinded assessors.

Participant characteristics

Baseline demographics, medical history and multimorbidity measures[6] were collected. The use of multiple multimorbidity measures was to determine which would be most suitable for a larger scale trial for ease of use and information obtained. These included the Cumulative Illness Rating Scale for Geriatrics (CIRS(G)),[25] the Functional Comorbidity Index (FCI)[26] and the Duke Severity of Illness Checklist (DUSOI).[27] Illness perception was measured using the Multimorbidity Illness Perception Scale (MULTIPleS).[28] Detailed information regarding these measures is available in the Online Supplementary Document.

Feasibility measures

Feasibility of the trial was measured by numbers screened to achieve the target sample size, the number who agreed to participate and the number who completed the intervention. Programme completion was defined as attendance at 12 or more of the 16 sessions.[29]

Outcome measures

Primary outcome: Functional exercise capacity. The 6MWT was used to measure the primary outcome of change in functional exercise capacity. The 6MWT is a measure of functional exercise capacity in populations with multiple chronic diseases including cardiovascular disease, lung disease, arthritis, diabetes, and cognitive dysfunction and depression.[30] The 6MWT was administered according to standardized guidelines, with two tests conducted and the longest distance recorded.[31]

Secondary outcomes

Activities of daily living. The Katz Index of Independence in Activities of Daily Living (Katz ADL index) was used to measure functional ADL. It has been used in people with chronic disease[32] and in the older population[33] to measure function.

Health-related quality of life. Two generic instruments, the Assessment of Quality of Life (AQoL)[34,35] and EuroQol-5D-5L (EQ-5D-5L),[36,37] were used to measure HRQoL. The AQoL and EQ-5D-5L are valid and reliable instruments, with moderate levels of responsiveness and sensitivity in a wide range of health conditions.[34,37] The AQoL has Australian population norms, which was relevant to the participants in this trial.[38]

Resource utilization. Data on emergency department (ED) presentations, hospital admissions and GP presentations during the intervention period were collected to measure healthcare utilization. Consultant physician appointments, GP consultations and hospital admissions were also recorded by participants via a daily diary. Diary information was verified by participant interview at the post-intervention assessment. Hospital admissions and length of stay were verified from Western Health patient medical records.

Statistical methods

Sample size. Being a pilot trial, no sample size calculation was undertaken.[39] A sample of 16 participants was recruited due to the resources available and time frame to complete the intervention.

Statistical analysis. Feasibility was described in numbers and percentages. Continuous variables were reported as mean and standard deviation (SD) or median and interquartile range depending on data distribution. Continuous variables were analysed using paired or independent *t*-tests for normally distributed data and χ^2 or Mann–Whitney U test for non-normally distributed data. Data were analysed through Statistical Package for the Social Sciences Windows Version 23.0. Power calculations for a future, definitive randomized trial were conducted via online tools (www.sealedenvelope.com).[40]

Results

One hundred people were screened to recruit 16 participants (Figure 1). Of the 84 not included in the trial, 34 (40%) did not meet the inclusion criteria. The most common reasons were an inability to walk 50 m ($n = 6$) and neutropenia ($n = 6$). Fifty (60%) people met the inclusion criteria but did not participate in the trial, with 38 (45%) declining to participate and 12 (14%) identifying other reasons. Six people were not interested, and four stated it was too far to travel. Another common reason for not participating in the trial was work commitments ($n = 4$). Refer to Figure 1 for further details.

Randomization allocated eight participants each to the intervention and control groups. Seven of the eight participants in the rehabilitation programme group (RPG) received the intervention, with one participant withdrawing from the trial. One participant from each group was lost to follow-up. The primary outcome measure of 6MWT was analysed in six participants in the RPG and seven in the usual medical care group (UMCG).

Participant demographics are summarized in Table 2. The mean (SD) age was 65 (12) years, and body mass index (BMI) was 33 (8) kg/m^2. There was a total of five men (31%). The most common main diagnosis was cancer for both groups. The RPG's most common comorbidities were hypertension (88%), diabetes (63%) and cancer (38%). The UMCG's most common comorbidities were diabetes (50%), cancer (50%) and coronary heart disease (50%).

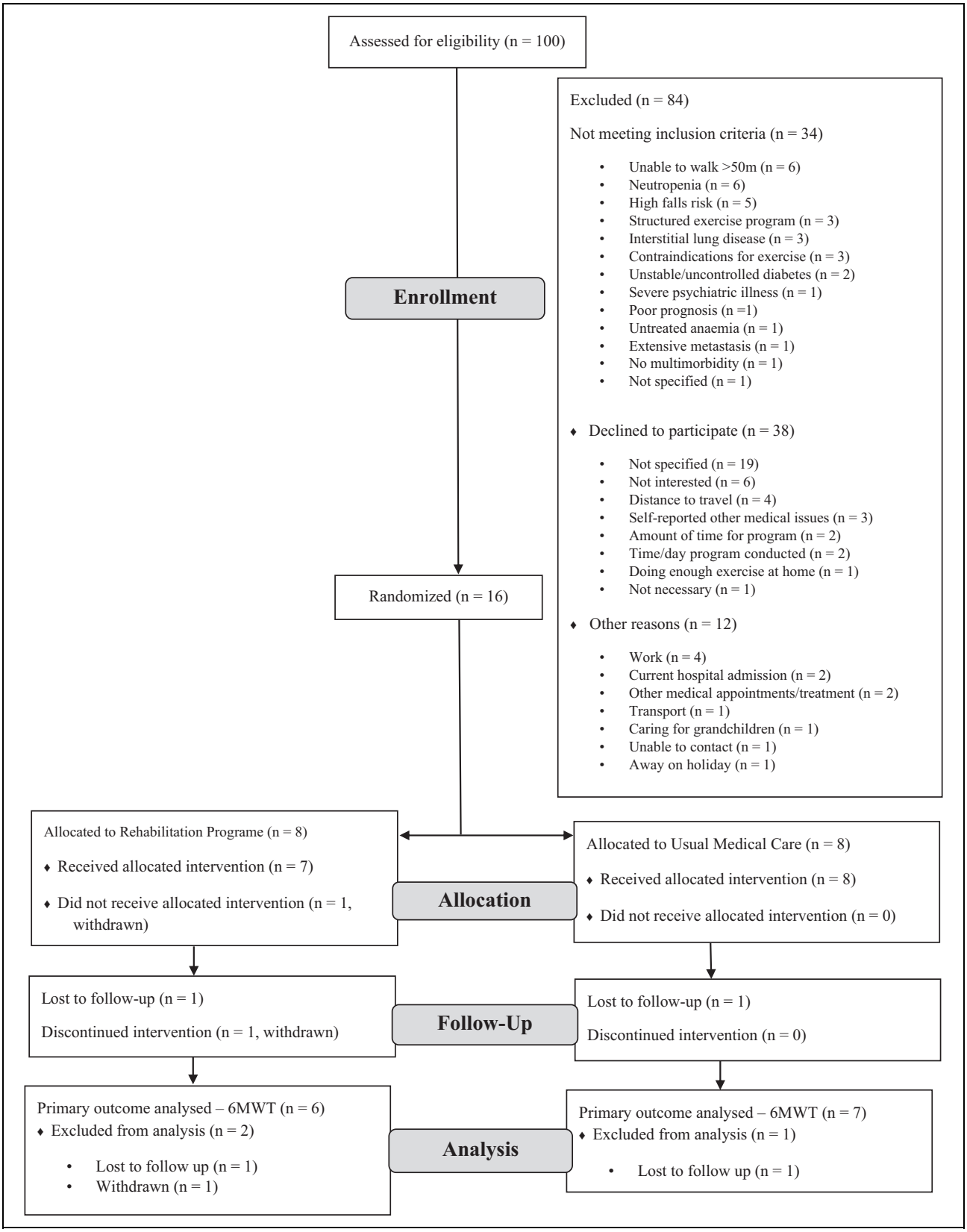

Figure 1. The CONSORT flow diagram of patient flow through the study.

Table 2. Participant characteristics.

	Rehabilitation programme ($n = 8$)	Usual care ($n = 8$)
Age (years), mean (SD)	67 (8)	63 (15)
Male, *n* (%)	1 (13)	4 (50)
BMI, mean (SD)	34 (10)	32 (5)
Main diagnosis, *n* (%)		
Cancer	2 (25)	2 (25)
Smoking status, *n* (%)		
Current	2 (25)	1 (13)
Ex-smoker	3 (38)	4 (50)
Never	3 (38)	3 (38)
Baseline 6MWD, mean (SD)	289 (135)	449 (88)
Other comorbidity, *n* (%)		
Hypertension	7 (88)	3 (38)
Diabetes	5 (63)	4 (50)
Cancer	3 (38)	4 (50)
Coronary heart disease	2 (25)	4 (50)
Number of comorbidities, mean (SD)	4 (2)	4 (1)
Functional Comorbidity Index, mean (SD)	6 (2)	6 (2)
Multimorbidity Illness Perception Scale, mean (SD)		
Treatment burden	3 (5)	6 (5)
Prioritization	7 (4)	7 (3)
Causal relationships	3 (3)	2 (2)
Activity restriction	5 (3)	3 (3)
Emotional representations	10 (11)	13 (11)
Summary scale	28 (22)	31 (21)
Cumulative Illness Rating Scale for Geriatrics, mean (SD)		
Total number of categories endorsed	6 (2)	6 (2)
Total score	10 (5)	11 (5)
Severity Index	2 (0)	2 (0)
Number of categories at level 3 severity	1 (1)	1 (1)
Number of categories at level 4 severity	0 (0)	0 (1)

SD: standard deviation; *n*: number; BMI: body mass index; 6MWD: 6-minute walk distance.

Each group had a similar number of comorbidities (mean (SD): RPG 4 (2) and UMCG 4 (1)). The UMCG had a higher baseline 6-min walk distance (6MWD) of 449 (88) m compared to the RPG with 289 (135) m.

Both groups had a similar FCI with a mean (SD) of 6 (2), indicating similar physical function.[26] The higher MULTIPleS summary scale in the UMCG indicated worse perception of their multiple diseases.[28] The total score, indicating medical burden,[25] in the CIRS(G) was slightly higher for the UMCG mean 11 (5) compared to the RPG with 10 (5). The severity index was the same, with similar numbers of categories at level three and four severity in both groups (Table 2), indicating little difference in disease severity or number of chronic problems between groups. The DUSOI data were not reported due to issues encountered in tool use. All assessors found the tool difficult to use, and several assessors administered the tool incorrectly, by asking participants rather than clinicians to select categories.

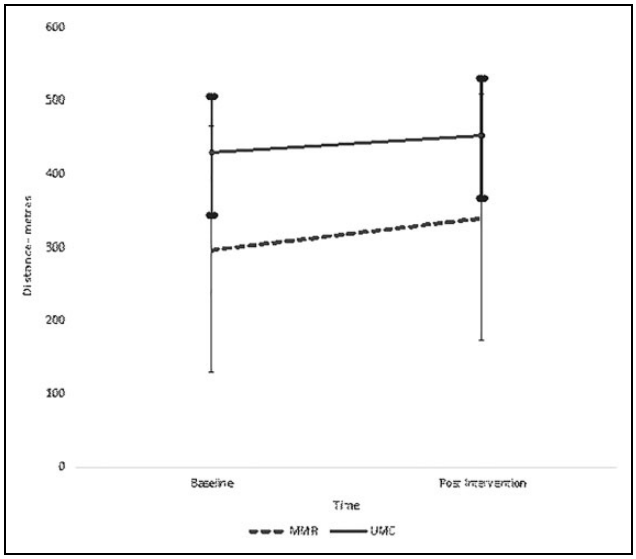

Figure 2. Six-minute walk distance.
MMR: multimorbidity rehabilitation programme; UMC: usual medical care. Data are presented as mean and standard deviation.

In the RPG, 71% of participants completed the rehabilitation programme, with a mean of 11 (6) sessions (of the 16 possible sessions) attended. One adverse event occurred during the intervention. A participant fell while performing the walking component of the rehabilitation programme. The participant tripped while walking, and this occurred as they were no longer wearing an ankle–foot orthosis (AFO) previously prescribed (due to poor fit). No injuries were sustained, and the participant resumed the programme at the following session, with follow-up organized to have the AFO refitted.

The RPG achieved a mean improvement in 6MWD of 44 (41) m and the UMCG of 23 (29) m, $p = 0.13$ (Figure 2 and Table 3). Only the RPG achieved the minimal important difference (MID) of least 30 m[31] for the mean change in 6MWD. However, in both groups, 25% of participants individually achieved the MID. One participant in the RPG became very unwell for reasons unrelated to the intervention and had a lengthy hospital admission (16 days). They were unable to complete the intervention and as a result, their change in 6MWD (−127 m) did not reflect the intervention. Data for this participant were removed as an extreme outlier.

No significant differences were observed between groups for improvement in the AQoL, Katz ADL index and EQ-5D-5L (Table 3). There was a mean increase in the AQoL utility score for both groups, with a greater increase in the UMCG; however, it was not significantly different ($p = 0.81$). Four participants from each group achieved the MID of 0.06 in the AQoL.[41]

Seven participants returned their daily diaries (RPG 2 and UMCG 5) with resource utilization recorded. Four participants in the UMCG reported GP visits, with a mean

Table 3. Primary and secondary outcome measures.

	Rehabilitation programme ($n = 6$)			Usual medical care ($n = 7$)			
	Baseline	Post	Change	Baseline	Post	Change	p Value[a]
Primary							
6MWD (m), mean (SD)	296 (170)	340 (167)	44 (41)	430 (77)	453 (86)	23 (29)	0.13
Secondary							
AQoL utility, mean (SD)	0.513 (0.278)	0.560 (0.361)	0.047 (0.271)	0.482 (0.275)	0.675 (0.272)	0.193 (0.203)	0.81
Usual care ($n = 6$)							
Katz ADL index, mean (SD)	5.33 (0.52)	5.67 (0.52)	0.33 (0.52)	4.86 (1.68)	5.14 (1.22)	0.29 (0.95)	0.84
EQ-5D-5L visual analogue scale, mean (SD)	70 (18)	77 (16)	7 (17)	69 (21)	76 (16)	8 (15)	0.88

n: number; 6MWD: six-minute walk distance; SD: standard deviation; AQoL: assessment of quality of life; ADL: activities of daily living; EQ-5D-5L: EuroQol-5D-5L.
[a]*p* Value represents comparison between groups for change over the course of the programme.

(SD) of 3 (3) visits and no visits for the RPG. Two participants, one from each group, presented to ED, and three participants (RPG 2 and UMCG 1) were admitted to hospital during the intervention period.

Due to error during the trial period, an outcome measure reported in the trial registry (Short Form 36 (SF-36)) was not collected, with the SF-36 form not included in the outcome measure packs during data collection.

Discussion

Summary

This study suggests that it would be feasible to conduct an RCT of a rehabilitation programme for people with multimorbidity compared to UMC. Outcomes relevant to a larger trial, including exercise capacity and HRQoL, could be collected consistently, and there was preliminary evidence of benefit for functional capacity. The study has provided direction on outcome measures, education and models of care which will inform the design of a suitably powered study.

Comparison with existing literature

This study is focused on interventions that are organizationally based and professionally led, which are targeting functional limitations. This is similar to the design of the OPTIMAL trial, an occupational therapy-led self-management support programme for people with multimorbidity.[42] The OPTIMAL trial showed significantly improved frequency of participation, self-efficacy and quality of life.[42] The intervention for the OPTIMAL trial was completed using some of the same health professionals as this study, including physiotherapy, occupational therapy and pharmacy. A study that used a home-based occupational and physical therapy intervention to address functional limitations showed improvements in survival; the home-based model used may have contributed to the excellent retention seen in this study.[43] The difference in location of therapy compared to this study should also be considered for the model of a future RCT as this may have contributed to a greater recruitment rate.

Strengths and limitations

Our study required screening six times the number of participants needed to achieve full recruitment. Most people who did not participate in the trial met the criteria, but frequently declined. Lack of willingness to attend/participate or travel to attend was frequently cited as a reason for refusal. The low recruitment rate of this trial may have impacted on the representation of the multimorbidity population studied and potentially accounting for the disparity in baseline measures between groups of the primary outcome measure (6MWT); this may also limit the applicability of the findings in a larger RCT. A potential solution is the recruitment process. Increasing the recruitment areas, such as including endocrinology outpatient clinics and GP practices, may increase the rate of recruitment and allow for a more comprehensive representation of the multimorbidity population. Other factors that could be refined in the design of a larger RCT are inclusion criteria and model of rehabilitation. To ensure consistency in the selection criteria, a defined list of diseases was used. However, as shown in a systematic review on multimorbidity indices, there is a lack of clear and comprehensive criteria for the chronic conditions which qualify for multimorbidity.[18] The use of wider criteria of chronic diseases may allow for recruitment of participants who were not considered for this trial.

Once recruited, people were willing to attend the rehabilitation programme, with a programme completion rate of 71%. The rehabilitation classes were successfully conducted with a physiotherapist and a nurse present. Informal feedback from the blinded assessors and participants indicated that the assessment process was lengthy and some outcome measures were difficult to administer and complete, particularly the CIRS(G) and DUSOI. There was also a poor return rate of the daily diaries. To improve the

processes in a larger RCT, a more efficient approach of reducing the number of measures and including the simplest to complete is required.

The small number of participants in this feasibility trial limits the conclusions that can be drawn from the primary and secondary outcome measures. A larger RCT will be required to determine the effect of rehabilitation for people with multimorbidity on function, HRQoL and resource utilization. This trial did not address whether the method of delivery of rehabilitation, twice weekly exercise and weekly education group sessions in a hospital outpatient setting, is the most suitable from the participant's perspective. This model of rehabilitation and the setting and access may have impacted on the uptake of participation in the trial. Further qualitative data collection using consumer focus groups or individual participant interviews may allow for constructive information on the model of rehabilitation provided and the most suitable service delivery model.

Multimorbidity measures were used in this trial to describe a complex population. Interventions could have varied the effects depending on the degree of multimorbidity.[2] A systematic review has highlighted the variation in definitions of multimorbidity and a need for clear reporting of participant characteristics.[2] The FCI appeared to be the most suitable for a larger scale RCT in terms of population suitability, ease of use, information obtained and relevance to intervention. The FCI is simple to administer and score and was designed to focus on physical function.[33] Physical function is an important aspect of exercise rehabilitation, and therefore, the FCI is a valuable measure. The DUSOI was a difficult measure to use with several issues encountered. The CIRS(G) was a time-consuming measure to administer. It was also difficult to obtain all required information to accurately score each category, with participants not undergoing investigations or results not available. The clinical expertise of blinded assessors can affect accurate scoring of the CIRS(G) due to the decision process required to clarify complex medical problems or their severity.[25]

Future research implications

Healthcare resources are limited, and in most high-income countries, health policy focuses on the reduction of spending growth and strategies to increase efficiency.[44] Addressing multimorbidity in a single rehabilitation programme is potentially a more cost-effective and sustainable model of delivering rehabilitation compared to single-disease models. Currently, there is limited clinical guidance on the optimal modality of exercise and rehabilitation programmes for people with several chronic diseases, such as diabetes and cancer.[45,46] Many people with chronic diseases do not have access to any rehabilitation programme, despite significant limitations in physical function. This is particularly true for the people living with cancer, the largest group in our trial, in whom there is emerging evidence for exercise-based rehabilitation programmes[47–49] but access is extremely poor.[50] The rehabilitation programme model for people with multimorbidity, including exercise and education, offers a potential solution for improved healthcare access and addressing the needs of the multimorbidity population. Addressing and evaluating some of the components of access being approachability, acceptability, availability and accommodation, affordability and appropriateness[51] in a larger RCT could be of value to shape the implementation of this new model of care. Previous research suggests that interventions that are more likely to be effective for multimorbidity are those that are targeted at areas where people have difficulties, such as functional ability.[2] Further development of this model should ensure that it addresses these features and is inclusive of the range of people with multimorbidity, including those with low physical capacity.

Developing a novel model of rehabilitation for people with multimorbidity allows for a renewed approach to content and delivery of education, compared to disease-specific focus approaches. In this trial, the education sessions were presented with a focus on self-management and resource awareness, delivered in a didactic method, which was anecdotally well received by participants. In a larger RCT, formal evaluation of the education topics and content could inform the development of an education programme that best addresses the needs of the multimorbidity population. How to most effectively deliver education in rehabilitation programmes is another question that is currently under consideration. In disease-specific rehabilitation, alternative delivery models are being investigated, such as DVD,[52] manuals[53] and digital technology.[54] Development of flexible programmes may best accommodate different people's needs and choices.[55]

Both groups had a mean BMI that would be classified as obese. Obesity is a known risk factor for a number of chronic diseases, including diabetes, cardiovascular disease and cancer,[56] and therefore, it is likely that the multimorbidity population will have a higher prevalence of obesity. This may have an impact on programme development, design and implementation, as exercise prescription and equipment might need modifying to accommodate this and potentially highlighting a need for nutritional management and counselling as a core component of the programme. This was evident in this trial with factors such as ensuring equipment, for example, exercise bikes, had suitable load capacities and appropriate seating was available.

The results of this study allow estimation of sample sizes for a future RCT comparing a rehabilitation programme for people with multimorbidity to UMC. We calculate that 92 participants would be required to have an 80% chance of detecting, as significant at the 5% level, an increase in the primary outcome measure 6MWD of 30 m.[40] This is based on the MID for the 6MWD in patients with chronic respiratory disease[31] and assumes an SD of change in 6MWD of 51 m, based on data collected in this trial. Given the large confidence intervals, this estimation

for adequate power should be interpreted with caution. Given this number of participants and the screening required for this study, it is likely a multicentre trial would be needed to achieve recruitment.

Conclusion

This study suggests that it would be feasible to conduct an RCT of a rehabilitation programme for people with multimorbidity compared to UMC. Our data suggest that a future large RCT is feasible, with adequate power to reach conclusions about the primary and secondary outcomes of exercise capacity, HRQoL and resource utilization. It is likely that a multicentre trial would be required. Further refinement of the study design, including inclusion criteria, recruitment sources and programme model, is needed to improve recruitment rates to achieve the number of participants required.

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Supplemental material

Supplementary material for this article is available online.

References

1. Barnett K, Mercer SW, Norbury M, et al. Epidemiology of multimorbidity and implications for health care, research, and medical education: a cross-sectional study. *Lancet* 2012; 380(9836): 37–43. DOI: 10.1016/S0140-6736(12)60240-2.
2. Smith SM, Wallace E, O'Dowd T, et al. Interventions for improving outcomes in patients with multimorbidity in primary care and community settings. *Cochrane Database Syst Rev* 2016; 3: CD006560. DOI: 10.1002/14651858.CD006560.pub3.
3. Gijsen R, Hoeymans N, Schellevis FG, et al. Causes and consequences of comorbidity: a review. *J Clin Epidemiol* 2001; 54(7): 661–674. DOI: 10.1016/S0895-4356(00)00363-2.
4. Caughey GE, Ramsay EN, Vitry AI, et al. Comorbid chronic diseases, discordant impact on mortality in older people: a 14-year longitudinal population study. *J Epidemiol Community Health* 2010; 64(12): 1036–1042. DOI: 10.1136/jech.2009.088260.
5. Bayliss EA, Steiner JF, Fernald DH, et al. Descriptions of barriers to self-care by persons with comorbid chronic diseases. *Ann Fam Med* 2003; 1(1): 15–21. DOI: 10.1370/afm.4.
6. Fortin M, Hudon C, Dubois MF, et al. Comparative assessment of three different indices of multimorbidity for studies on health-related quality of life. *Health Qual Life Outcomes* 2005; 3: 1–7. DOI: 10.1186/1477-7525-3-74.
7. van den Akker M, Buntinx F, Roos S, et al. Problems in determining occurrence rates of multimorbidity. *J Clin Epidemiol* 2001; 54(7): 675–679. DOI: 10.1016/S0895-4356(00)00359-9.
8. Uijen AA and van de Lisdonk EH. Multimorbidity in primary care: prevalence and trend over the last 20 years. *Eur J General Pract* 2008; 14(Suppl 1): 28–32. DOI: 10.1080/13814780802436093.
9. Fortin M, Soubhi H, Hudon C, et al. Multimorbidity's many challenges – time to focus on the needs of this vulnerable and growing population. *BMJ* 2007; 334(7602): 1016–1017. DOI: 10.1136/bmj.39212.467037.BE.
10. Johnston KN, Young M, Grimmer-Somers KA, et al. Why are some evidence-based care recommendations in chronic obstructive pulmonary disease better implemented than others? Perspectives of medical practitioners. *Int J Chron Obstruct Pulmon Dis* 2011; 6: 659–667. DOI: 10.2147/COPD.S26581.
11. Duncan A, Natarajan M and Schwalm J. Assessing physician barriers to cardiac rehabilitation referral rates in a tertiary teaching centre. *Canad J Gen Int Med* 2016; 11(1): 14–18.
12. Ghisi GL, Polyzotis P, Oh P, et al. Physician factors affecting cardiac rehabilitation referral and patient enrollment: a systematic review. *Clin Cardiol* 2013; 36(6): 323–335. DOI: 10.1002/clc.22126.
13. Holland AE, Harrison SL and Brooks D. Multimorbidity, frailty and chronic obstructive pulmonary disease: are the challenges for pulmonary rehabilitation in the name? *Chronic Resp Dis* 2016; 13(4): 372–382.
14. McCarthy B, Casey D, Devane D, et al. Pulmonary rehabilitation for chronic obstructive pulmonary disease. *Cochrane Database Syst Rev* 2015; 2: CD003793. DOI: 10.1002/14651858.CD003793.pub3.
15. Boult C, Reider L, Frey K, et al. Early effects of 'guided care' on the quality of health care for multimorbid older persons: a cluster-randomized controlled trial. *J Gerontol* 2008; 63A(3): 321–327.

16. Roberts CK and Barnard RJ. Effects of exercise and diet on chronic disease. *Appl Physiol* 2005; 98(1): 3–30. DOI: 10.1152/japplphysiol.00852.2004.
17. Schulz KF, Altman DG, Moher D, et al. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMJ* 2010; 340: c332. DOI: 10.1136/bmj.c332.
18. Diederichs C, Berger K and Bartels DB. The measurement of multiple chronic diseases – a systematic review on existing multimorbidity indices. *J Gerontol A Biol Sci Med Sci* 2011; 66(3): 301–311. Epub ahead of print 26 November 2010. DOI: 10.1093/gerona/glq208.
19. Pulmonary Rehabilitation Toolkit. http://www.pulmonaryrehab.com.au/welcome.asp (accessed 30 April 2016).
20. Heart Online. http://www.heartonline.org.au (accessed 30 April 2016).
21. Hill K, Jenkins SC, Cecins N, et al. Estimating maximum work rate during incremental cycle ergometry testing from six-minute walk distance in patients with chronic obstructive pulmonary disease. *Arch Phys Med Rehabil* 2008; 89(9): 1782–1787. DOI: 10.1016/j.apmr.2008.01.020.
22. Garber CE, Blissmer B, Deschenes MR, et al. Quantity and quality of exercise for developing and maintaining cardiorespiratory, musculoskeletal, and neuromotor fitness in apparently healthy adults: guidance for prescribing exercise. *Med Sci Sport Exercise* 2011; 43(7): 1334–1359. DOI: 10.1249/mss.06013e318213fefb.
23. Kraemer WJ and Ratamess NA. Fundamentals of resistance training: progression and exercise prescription. *Med Sci Sport Exercise* 2004; 36(4): 674–688. DOI: 10.1249/01.mss.0000121945.36635.61.
24. Australian Institute of Health and Welfare 2014. *Australia's Health 2014. Autralia's health series no. 14. Cat. no. AUS 178*. Canberra: AIHW.
25. Miller MD, Paradis CF, Houck PR, et al. Rating chronic medical illness burden in geropsychiatric practice and research: application of the cumulative illness rating scale. *Psychiatr Res* 1992; 41(3): 237–248. DOI: 10.1016/0165-1781(92)90005-N.
26. Groll DL, To T, Bombardier C, et al. The development of a comorbidity index with physical function as the outcome. *J Clin Epidemiol* 2005; 58(6): 595–602. DOI: 10.1016/j/jclinepi.2004.10.018.
27. Parkerson GR, Eugene Broadhead W, Chiu-Kit J, et al. The Duke severity of illness checklist (DUSOI) for measurement of severity and comorbidity. *J Clin Epidemiol* 1993; 46(4): 379–393. DOI: 10.1016/0895-4356(93)90153-R.
28. Gibbons CJ, Kenning C, Coventry PA, et al. Development of a Multimorbidity Illness Perceptions Scale (MULTIPleS). *PLoS ONE* 2013; 8(12): e81852. DOI: 10.1371/journal.pone.008.1852.
29. Holland AE, Hill CJ, Conron M, et al. Short term improvement in exercise capacity and symptoms following exercise training in interstitial lung disease. *Thorax* 2008; 63(6): 549–554. DOI: 10.1136/thx.2007.088070.
30. Enright P, McBurnie M, Bittner V, et al. The 6-min Walk Test: a quick measure of functional status in elderly adults. *Chest* 2003; 123(2): 387–398. DOI: 10.1378/chest.123.2.387.
31. Holland AE, Spruit MA, Troosters T, et al. An official European Respiratory Society/American Thoracic Society technical standard: field walking tests in chronic respiratory disease. *Eur Respir J* 2014; 44(6):1428–1446. DOI: 10.1183/09031936.00150314.
32. Wallace M and Shelkey M. Katz index of independence in activities of daily living (ADL). *Annal Long Term Care* 2006; 14(11).
33. Katz S, Downs TD, Cash HR, et al. Progress in development of the index of ADL. *Gerontologist* 1970; 10: 20–30.
34. Hawthorne G, Richardson J, Day NA, et al. Construction and utility scaling of the Assessment of Quality of Life (AQoL) Instrument. Centre for Health Program Evaluation, Working Paper 101, March 2000.
35. Hawthorne G, Richardson J and Osborne RH. The assessment of quality of life instrument: a psychometric measure of health-related quality of life. *Qual Life Res* 1999; 8: 209–224.
36. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011; 20(10): 1727–1736. DOI: 10.1007/s11136-01109903-x.
37. EQ-5D. http://www.euroqol.org (accessed 18 April 2016).
38. Hawthorne G, Korn S and Richardson J. Population norms for the AQoL derived from the 2007 Australian National Survey of Mental Health and Wellbeing. *Aust N Z J Public Health* 2013; 37(1): 7–16. DOI: 10.1111/1753-6405.12004.
39. Thabane L, Ma J, Chu R, et al. A tutorial on pilot studies: the what, why and how. *BMC Med Res Methodol* 2010; 10(1): 1–10. DOI: 10.1186/1471-2288-10 -1.
40. Power calculator for continuous outcome superiority trial. https://www.sealedenvelope.com/power/continuous-superiority (accessed 10 October 2017).
41. Hawthorne G and Osborne R. Population norms and meaningful differences for the Assessment of Quality of Life (AQoL) measure. *Aust NZ J Pub Health* 2005; 29(2): 136–142. DOI: 10.1111/j.1567-842X.2005.tb00063.x.
42. Garvey J, Connolly D, Boland F, et al. OPTIMAL, an occupational therapy led self-management support programme for people with multimorbidity in primary care: a randomized control trial. *BMC Family Pract* 2015; 16: 59. DOI: 10.1186/s12875-015-0267-0.
43. Gitlin LN, Hauk WW, Dennis MP, et al. Long-term effect on mortality of a home intervention that reduces functional difficulties in older adults: results from a randomized trial. *J Am Geriat Soc* 2009; 57(3): 476–481. DOI: 10.1111/j.1532-5415.2008.02147.x.
44. Dieleman JL, Campbell M, Chapin A, et al. Future and potential spending on health 2015–40: development assistance for health, and government, prepaid private, and out-of-pocket health spending in 184 countries. *Lancet* 2017; 389(10083): 2005–2030. DOI: 10.1016/s0140-6736(17)30873-5.

45. Lakoski SG, Eves ND, Douglas PS, et al. Exercise rehabilitation in patients with cancer. *Nat Rev Clin Oncol* 2012; 9(5): 288–296. DOI: 10.1038/nrclinonc.2012.27.
46. Mourot L, Boussuges A, Maunier S, et al. Cardiovascular rehabilitation in patients with diabetes. *J Cardiopulm Rehab Prevent* 2010; 30: 157–164.
47. Spence RR, Heesch KC and Brown WJ. Exercise and cancer rehabilitation: a systematic review. *Cancer Treat Rev* 2010; 36(2): 185–196. DOI: 10.1016/j.ctrv.2009.11.003. Epub ahead of print 4 December 2009.
48. Scott DA, Mills M, Black A, et al. Multidimensional rehabilitation programmes for adult cancer survivors. *Coch Database Syst Rev* 2013; (3): CD007730. DOI: 10.1002/14651858.CD007730.pub2.
49. Mishra SI, Scherer RW, Snyder C, et al. Exercise interventions on health-related quality of life for people with cancer during active treatment. *Coch Database Syst Rev* 2012; (8): CD008465. DOI: 10.1002/14651858.CD008465.pub2.
50. Dennett AM, Peiris CL, Shields N, et al. Exercise therapy in oncology rehabilitation in Australia: a mixed-methods study. *Asia Pac J Clin Oncol* 2007; 13(5): e515–e527. DOI: 10.1111/ajco.12642. Epub ahead of print 22 December 2016.
51. Levesque J, Harris M and Grant R. Patient-centred access to health care: conceptualising access at the interface of health systems and populations. *Int J Equity Health* 2013; 12(18).
52. Ward S, Sewell L, Singh S, et al. P144 evaluation of multidisciplinary pulmonary rehabilitation education delivered by either DVD or spoken talk. *Thorax* 2011; 66(Suppl 4): A125–A126. DOI: 10.1136/thoraxjnl-2011-20154c.144.
53. Mitchell KE, Johnson-Warrington V, Apps LD, et al. A self-management programme for COPD: a randomised controlled trial. *Eur Resp J* 2014; 44(6): 1538–1547. DOI: 10.1183/09031936.00047814.
54. Barberan-Garcia A, Vogiatzis I, Solberg HS, et al. Effects and barriers to deployment of telehealth wellness programs for chronic patients across 3 European countries. *Respir Med* 2014; 108(4): 628–637. DOI: 10.1016/j.rmed.2013.12.006.
55. Man WD, Chowdhury F, Taylor RS, et al. Building consensus for provision of breathlessness rehabilitation for patients with chronic obstructive pulmonary disease and chronic heart failure. *Chron Respir Dis* 2016; 13(3): 229–239. DOI: 10.1177/1479972316642363.
56. World Health Organisation. http://www.who.int/features/factfiles/obesity/facts/en/ (accessed 5 September 2017).