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A randomised trial of the Flinders Program to improve patient self-management competencies in a range of chronic conditions: study rationale and protocol

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PROTOCOL

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Abstract

Background
Supporting self management is seen as an important health service strategy in dealing with the large and increasing health burden of chronic conditions. Several types of self-management programs are available. Evidence to date suggests that disease-specific and lay-led self management programs provide only part of the support needed for improved outcomes. The Flinders Program is promising as a generic self management intervention, which can be combined with targeted disease-specific and lay-led interventions, but it has yet to be evaluated for a range of chronic conditions using a rigorous controlled trial design. This paper gives the rationale for a randomised controlled trial and process evaluation of the Flinders Program of chronic condition self-management in community practice, and details and justifies the design of such a study.

Method
The design for a randomised trial and associated process evaluation, suited to evaluation of a complex and behavioural intervention as it is applied in actual practice, is presented and justified.

Conclusion
A randomised trial of the Flinders Program is required and a functional design is presented. Results from this trial, currently underway, will test the effectiveness of the Flinders Program in improving patient competencies in self-management of chronic conditions in practice conditions. A process evaluation alongside the trial will explore system, provider and patient factors associated with greater and lesser Program effectiveness.

Key Words
Chronic illness; self-management; randomised controlled trial; protocol; mixed methods

Background

Supporting self management by people who have chronic conditions is seen as an important element of health service strategies to reduce the huge and increasing disease burden and cost of caring for people with chronic conditions.[1 2] While different types of self-management programs have been used, they generally aim to increase active participation of the person with the condition in monitoring their health, making decisions about care, or both.[3]

Research to date on self-management support interventions has mostly focussed on two types of intervention; disease-specific patient education programs and lay-led programs. Disease-specific programs provide organised learning experiences designed to facilitate the adoption of health-promoting behaviours for one particular condition, and are usually delivered by health professionals. Meta-analyses of controlled trials of disease-specific programs[3 4] have shown these programs to be effective in improving some clinical outcomes in diabetes, asthma and hypertension but not in arthritis, with a publication bias towards positive studies noted. Disease-specific programs have also been criticised as potentially confusing for the many people dealing with multiple morbidities.[5] Lay-led group programs aim to improve participants' confidence in managing both their chronic conditions, in partnership with health professionals, and their lives. They are applicable for all chronic conditions and delivered by peers trained in the program. A Cochrane meta-analysis of controlled trials of lay-led programs concluded that while they may lead to small short term improvements in outcomes such as self-efficacy, there was no evidence of effect on symptoms, quality of life or health care use from these programs.[6] Low recruitment has also been noted especially among men, minority groups and people with least formal

education.[7] Clearly, current disease-specific and lay-led programs provide, at best, only part of the support needed for large-scale improvement in self management, and research is still required before an optimum program or range of programs can be specified.

The Flinders Program is a further, overarching, approach applicable to any medical or psychiatric condition and to co-morbidities. It was developed from the SA HealthPlus coordinated care trial[8] where it was observed that patients required co-ordinated care only where there were gaps in their ability to self-manage.[9] A major feature of the Flinders Program is that it addresses both patient behaviours and clinician behaviours that are necessary for sustained gain in health outcomes. The Program provides a generic set of tools and a structured process that enables health workers and patients to collaboratively assess self-management behaviours, identify problems, set goals, and develop individual care plans covering key self-care, medical, psycho-social and carer issues. Based on cognitive behaviour therapy and motivational interviewing, the tools include the Partners in Health Scale (PIH), Cue and Response Interview (C&R), Problem and Goals assessment (P&G) and an integrated self-management and evidence-based medical care plan. The PIH is a self-rated questionnaire for the patient to assess their self-management knowledge, attitudes, behaviours and impacts of their chronic condition. The health worker administered C&R explores the same questions as the PIH via open-ended questions with responses, rated from the health provider's perspective, shared with the patient. The P&G is a health worker administered tool based on behavioural psychotherapy and uses open-ended questions to determine patient-identified problems and formulate goals to address those problems. These behavioural changes are written down, scored, monitored and progressively implemented at the pace of the patient. Strengths, barriers and priorities identified through collaborative discussion of PIH, C&R and P&G are incorporated into a fully negotiated care plan. The care plan includes health worker and patient identified issues, management aims, agreed interventions, responsibilities and review dates. All tools use Likert-type scales which allow change and progress to be measured and recorded during reviews. As the Flinders Program care plan tailors a range of possible self-management interventions (such as disease-specific patient education programs or lay-led programs) to the individual, it is compatible with both disease-specific and lay-led programs rather than an alternative stand-alone approach. The Flinders care plan is provided to the patient and all health professionals involved in the patient's care and can be incorporated into the patient's overall medical care plan.

Pre-post studies have shown improvements associated with use of the Flinders Program. In the Whyalla Sharing Health Care self-management project 176 patients with a variety of chronic conditions received the Flinders Program. There were significant improvements in self-management and measures of pain, fatigue and service usage which were maintained at 18 months follow-up.[10] Improvements in patient-reported and clinical outcomes were also seen in two pilot studies of the Flinders Program, one in aboriginal community members with diabetes[11] and the other in patients with chronic severe mental health disorders.[12] However, the effectiveness of the Flinders Program over a range of chronic conditions has yet to be evaluated using a rigorous controlled trial design. This paper gives the protocol for such a trial to test the effectiveness of the Flinders Program in improving patient competencies in self-management of chronic conditions.

The primary objective of this study is therefore to evaluate the effectiveness of the Flinders self-management care planning approach in improving patient competencies in the management of their chronic conditions. The primary study hypothesis is that use of the Flinders care planning approach will result in improved patient self-management competencies over a 6-12 month period compared to a usual care control group. As improved competencies are expected to translate to clinical benefits and reduced burden, secondary objectives are to evaluate the effectiveness of the Flinders self-management care planning approach in increasing quality of life, increasing energy and reducing fatigue, and reducing health distress. Self efficacy is proposed as a requirement for success in self-management therefore a self efficacy measure is included as an intermediate outcome.[13]

The aim for this study is to evaluate an intervention as it is applied in actual health care service settings rather than in ideal conditions, therefore a practice-based trial design is applicable. Such trial designs have the advantage of direct applicability to usual practice. They are characterised by wide participant inclusion criteria, some clinician flexibility in applying the intervention, some possible contamination of the control group by similar interventions available in usual practice, and the variability in patient adherence which is seen in usual practice.[14-16]

Process evaluations are increasingly recommended as integral methodological components in clinical trials of complex interventions such as educational, behavioural and service delivery interventions.[17-19] The process evaluation for the trial of the Flinders Program will explore system, provider and patient factors associated with greater and lesser Program effectiveness.

Method

This study received approval from the Flinders Clinical Research Ethics Committee (FCREC), and was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12609000631202).

Choice of measures for primary and secondary outcomes

Primary outcome measure

The primary outcome, patient self-management competencies, will be measured using the PIH. There are two available scales which are applicable across a range of chronic conditions: the PIH [20] which assesses self-management and the Health Education Impact questionnaire [21] which evaluates the success of patient education programs. The PIH was selected for this trial as a low-burden scale specifically designed to measure patient abilities to self-manage. Preliminary psychometric analysis indicated satisfactory validity and good internal consistency reliability with Chronbach's alpha 0.88.[20] Subsequent statistical analysis of the 12 item version has also shown good internal consistency, with Chronbach's alpha 0.82, and good construct validity with principal components extraction finding 4 factors; knowledge, symptom management, adherence and coping which together accounted for 80% of the variance (Petkov, Harvey, & Battersby in submission). This trial will use the expanded 14-item version of the PIH.

Secondary outcome measures

Quality of life will be measured using the SF12v2. This instrument is derived from the internationally validated and widely used SF-36 quality of life questionnaire and retains good precision while reducing respondent burden.[22] Measures of self management self-efficacy, energy/fatigue and health distress will be those used in other trials of self-management interventions by Stanford University School of Medicine researchers [23-26] and others.[13 27] These are the 6-Item Chronic Disease Self-Efficacy, the Energy/Fatigue scale and the Health Distress scale.[28]

Process evaluation measures and data

The C&R interview score[20] and the P&G assessment score[29] are generated as part of the Flinders Program and will be collected as intervention process measures. The C&R serves as a health professional rated measure of patient self management competencies. The P&G records progress in achieving the patient's self-identified main goal and reflects an outcome of patient competencies. The Assessment of Chronic Illness Care (ACIC) scoring tool[30] measures elements of the chronic care model[31] and will be used to assess organisational capacity for chronic condition management. A further component of the process evaluation, to be reported separately, will use qualitative methods to explore barriers and facilitating factors from the perspectives of health professionals, managers and patients.

Setting

The trial will be conducted in the region served by Southern Adelaide Health Service, Health Department of South Australia. Southern Adelaide Health Service provides public hospital and community care to a population of 325,000 people with a diverse community including areas of socio economic disadvantage and higher than national average aged populations. Health services for people living in the community with chronic conditions are provided by local general practitioners, hospital outpatient clinics, Southern Adelaide Health Service's community clinics and non-government community and residential care service providers. The Flinders Program and lay-led courses are among the services offered by Southern Adelaide Health Service and non-government providers. As part of standard care, Southern Adelaide Health Service's Chronic Disease Community Program (CDCP) actively identifies community-dwelling and hospitalised patients with chronic disease to discuss and make referrals to community-based services including self-management programs.
Trial participants will be recruited through current patient identification and care routes i.e. CDCP and two non-government providers, ACH Group and Resthaven Incorporated. In this practice-based trial, participants will be able to access all components of standard care except for the Flinders Program, which will be delivered through usual community services but only to those randomised to intervention. People with chronic obstructive pulmonary disease (COPD), cardiovascular disease, diabetes type I or II, or musculoskeletal conditions, priority chronic conditions associated with high rates of hospital admission in South Australia[32] will be included.

Inclusion criteria and recruitment procedures

Inclusion criteria

Patients will be invited if they meet the following criteria:

- aged over 45
- primary or secondary diagnosis of chronic obstructive pulmonary disease (COPD), coronary artery disease, cerebrovascular disease, chronic heart failure, diabetes type I or II, or musculoskeletal disorders
- able to understand the (English language) information sheet and consent form
- not physically or mentally distressed so that the trial would be burdensome
- not diagnosed with dementia
- not taken part in Flinders or lay-led self-management programs in past 3 years.

Patients with more than one chronic condition including mental health co-morbidities will be included.

Participant Selection

Patients with appointments at CDCP and the two non-government providers and who meet study criteria will be invited to participate. Recruitment will be conducted over an 11 month period, from September 2009 to July 2010, with follow up to February 2011. Outcome measures will be obtained at baseline, 6, 12 and 18 months or end of time in trial, depending on time of recruitment.

Randomisation and allocation concealment

Randomisation will be blocked to ensure nearly equal group sizes, using varying block sizes to protect concealment. Randomisation will be stratified to ensure that each arm contains a similar ratio of hospital discharge patients to community patients. A statistician will independently generate random sequences for each stratum using Stata (StataCorp, Texas USA) software and deliver to the clinical trials call centre of the Flinders Medical Centre Pharmacy. When baseline data is completed for each participant, trial enrolment staff will phone the call centre to assign the next random allocation. Intervention participants will receive usual care plus the Flinders Program, and control participants usual care only.

Interventions

In line with current care, intervention participants will be referred to a convenient participating site for delivery of the Flinders Program. The Program will comprise an initial assessment session using the PIH, C&R and P&G and producing a care plan, with follow ups 2-4 weekly for up to 6 months to complete the Program and to monitor progress. The Program will be delivered by Program-accredited clinicians assessed against 2009 standards.
Usual care for both groups may include general practice and outpatient clinic services and a range of nursing and allied health services, e.g., diabetes education, respiratory education, podiatry, nutrition advice, physiotherapy, and occupational therapy.
Usual care will be delivered by different staff to those administering the Flinders Program.

Blinding

Baseline outcomes will be obtained before randomisation and are therefore free of any assignment-related bias. Following this stage, blinding will differ for participants, clinicians, data collection/data entry staff, and those performing statistical analysis as is usual for trials of behavioural interventions.[33]
Participants: Informed consent procedures inform participants that the trial is testing a self-management program and participants will become aware of whether or not they receive such a program. However, informed consent information conveys equipoise by presenting proposed benefits of both intervention and control conditions and does not therefore imply that a particular group will experience most benefit. Participants will be asked not to discuss their allocation with trial staff.
Clinicians administering interventions: Clinicians delivering the Flinders Program will also be necessarily unblinded therefore equipoise is also emphasised in training for trial clinicians. To reduce any influence of the clinician on outcome measurements, outcome data will be collected by trial research staff and at a different place and time from delivery of the intervention.
Staff collecting and entering outcome measures: Random assignments will be concealed from staff entering trial data and will be recorded in a separate password-protected database accessed from a separate computer.
Statisticians analysing data: Data sets for outcome analysis will not show which set is control and which intervention.

Data collection

Data collection is summarised in Table 1.

In addition to demographic and risk-factor data, the following measures will be recorded:

Outcome measures

PIH, SF12v2, 6-Item Chronic Disease Self-Efficacy, Energy/Fatigue scale and Health Distress scale will be collected at baseline, 6 months, 12 months and 18 months (or end of trial if sooner) by participant questionnaire. Repeat mail outs followed by phone calls will be used to ensure maximum return rate before ceasing data collection attempts.[34 35]

Process measures

Quantitative data will include C&R and P&G for intervention participants at baseline, 6 and 12 months. The ACIC will be scored for each of the three trial recruitment and intervention-delivery organisations, by facilitated discussion and consensus among a team from each organisation, near the start of the trial and at 12-18 months. Data relating to clinician demographics and professional background and experience will be collected and de-identified.

Study management

Study investigators include senior academics from disciplines of psychiatry, general practice, respiratory medicine, biostatistics, population health, and managers from health care delivery organisations. The investigator group is led by principal investigator, Professor Malcolm Battersby, Director of the Flinders Human Behaviour and Health Research Unit, Flinders University, South Australia.

Monitoring and recording adverse events

Adverse events from this educational/counselling intervention are unlikely. However, clinicians and participants will be asked to report any adverse events which could be attributable to the intervention and these will be assessed by the Chief Investigator and research staff. If any are reported resulting in death, serious injury or hospitalisation they will be reported in writing to the Flinders Clinical Ethics Review Committee.

Data management

Data will be entered by a trained staff member. Random checks will be conducted by a separate staff member and if errors are found, double-entering will be instituted. Data files will be secure and backed up daily.

Staff training

Staff conducting recruitment will receive training, relevant study documents and updates from the Flinders Human Behaviour & Health Research Unit. Clinicians delivering the Flinders Program will be trained and accredited and assessed as competent against current standards.

Delivery of intervention

Records will be kept of places times and staffing for delivery of the intervention.

Statistical aspects and data analysis

Sample size

A sample size calculation based on detecting the expected[10] clinically significant difference (10%) between baseline and follow up for the 14 item PIH with 90% power provided an estimated 83 subjects for each of the intervention and control and groups. Sample size requirements for the SF-12v2 to detect a between-group change of 10% with 90% power, type 1 error rate α=0.05 are 97 for each of the intervention and control groups. Allowing for about 15% drop out, a total of 230 subjects (115 in each group) will be recruited.

Statistical analyses

All statistical analyses will be conducted using Stata (StataCorp, Texas USA) software. An initial data analysis will be carried out to check for data quality including allowable ranges, missing data, data structure and errors. Univariate between groups analyses will be performed on baseline demographic measures of age, gender, education level, occupation and primary diagnoses, numbers of co-morbidities, and questionnaire scores using t tests for continuous variables, and $\chi 2$ tests of association for categorical variables.
For the study outcome measures, a Type 1 error rate of alpha=0.05 will be used in all analyses to test for statistical significance. To check for potential bias of available data, missing values will be imputed using best-subset regression. Mixed-effects linear regression models will be used to assess change over time and differences between groups from baseline to follow up at 6, 12 and 18 months.
The PIH will be analysed for total score and for each individual questions. The SF12v2 will be analysed for total score and for the first, general health, question.
The research outcomes will be analysed and reported in two levels of analysis: “intention to treat” and “on program’ analysis or ‘as treated’. Statistical analyses will include response-shift-adjusted change.
Quantitative analysis of the ACIC defined domains of organisational capacity to support chronic care will be assessed using a multilevel regression approach. Agency scores at baseline for each of the 6 ACIC domains, and patient and health professional demographic data will be assessed as independent predictors of each patient competency score at the end of follow up.

Conclusion

A randomised trial of the Flinders Program is required and a functional design has been presented. Results from this trial, currently underway, will provide high quality evidence of the effectiveness of the Flinders Program, as implemented in standard care in South Australia, in improving self management abilities in patients with a range of chronic conditions and comorbidities. A process evaluation alongside the trial will explore system, provider and patient factors associated with greater and lesser Program effectiveness and will inform future targeting and modifications in service delivery.

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PEER REVIEW

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CONFLICTS OF INTEREST

The authors declare that they have no competing interests.

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Figures and Tables

Table 1
Measures and data collection intervals for each study aim

Study Aim	Measure/ Data	Base-line	6 months	12 months or trial end	18 months or trial end
All participants:					
1	Partners In Health scale	√	√	√	√
2	SF12v2	√	√	√	√
	Self-Efficacy for Managing Chronic Disease 6-Item Scale	√	√	√	√
	Energy/Fatigue scale	√	√	√	√
	Health Distress scale	√	√	√	√
3	Demographics	√			
Intervention participants only:					
3	Cue & Response score	√	√	√	√
	Problems & Goals score	√	√	√	√
Recruitment/intervention-delivery organisations:					
3	Assessment of Chronic Illness Care tool score	√			√