Coaching Older Adults and Carers to have their preferences Heard (COACH): A randomised controlled trial in an intermediate care setting (study protocol)

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Abstract

Background
Frail older people who are considering movement into residential aged care or returning home following a hospital admission often face complex and difficult decisions. Despite research interest in this area, a recent Cochrane review was unable to identify any studies of interventions to support decision-making in this group that met the experimental or quasi-experimental study design criteria.

Aims
This study tests the impact of a multi-component coaching intervention on the quality of preparation for care transitions, targeted to older adults and informal carers. In addition, the study assesses the impact of investing specialist geriatric resources into consultations with families in an intermediate care setting where decisions about future care needs are being made.

Method
This study was a randomised controlled trial of 230 older adults admitted to intermediate care in Australia. Masked assessment at 3 and 12 months examined physical functioning, health-related quality of life and utilisation of health and aged care resources. A geriatrician and specialist nurse delivered a coaching intervention to both the older person and their carer/family. Components of the intervention included provision of a Question Prompt List prior to meeting with a geriatrician (to clarify medical conditions and treatments, medications, 'red flags', end of life decisions and options for future health care) and a follow-up meeting with a nurse who remained in telephone contact. Participants received a printed summary and an audio recording of the meeting with the geriatrician.

Conclusion
The costs and outcomes of the intervention are compared with usual care. Trial registration: Australian New Zealand Clinical Trials Registry (ACTRN12607000638437).

Key Words
Caregivers; continuity of patient care; cost-benefit analysis; health care costs; intermediate care facilities; patient-centred care; quality of life; randomised controlled trial

Background

Many older people face difficult choices during or following an acute hospital episode; a period when they are particularly vulnerable. Cognitive impairments or physical disabilities may interfere with the ability to advocate for themselves and navigate within and between health and aged care systems.[1] Older people and their families are often unprepared for what will happen following discharge from hospital and their respective roles and responsibilities in this process.[2, 3] A sense of abandonment, disregard for individual preferences and lack of input to care plans have been reported. [4, 5]

A Cochrane review indicated that interventions to support decision-making processes for older adults facing the possibility of long-term residential care lack a rigorous evidence base. The review was unable to find any studies that compared the effects of a decision-support intervention with the routine process of entry to long-term residential care.[6]

To participate in their own health care, consumers must understand and act on information given to them by health providers, a concept referred to as health literacy.[7] Health information is complex and often poorly understood,[8-10] and information processing can be impaired in illness.[11] Specifically, many older people and their carers do not understand discharge medications, diagnoses or treatment plans,[12] and those with limited health literacy are less likely to ask questions of clinicians.[13] Limited health literacy disproportionately affects older adults and people with chronic disease[14] and is associated with increased risk of hospital readmission,[15] other health care utilisation[8] and even death.[16,17]

In the USA a coaching program to prepare older adults for post hospital transfers reported reductions in readmission rates. The program focused on medication self-management, use of a patient-centred record, preparation for medical visits, understanding 'red flags' (i.e. signs of deterioration) and when to seek help.[18]

Information strategies used with older people commonly focus on the informal carer. However, this approach may contribute to the disempowerment experienced by older persons in health care settings.[19] Information improves knowledge, satisfaction and mood and the benefits are greatest when patients are active participants.[20] A Cochrane review of interventions directed at patients to help them gather information in their health care consultations indicated that patient coaching and written materials prior to consultations lead to more involvement through question initiation, increased levels of satisfaction and reductions in anxiety.[21] Audio recordings and written summaries of consultations improve recall and are used to share information with family members and general practitioners.[22] Patients with advanced cancer also have complex information needs[23,24] and work exploring ways to improve their level of participation in treatment decisions has suggested that Question Prompt Lists promote discussion about prognosis and end of life issues.[25,26]

The current study aimed to determine whether a coaching intervention delivered by a geriatrician and specialist nurse in a post hospital (intermediate) care setting improved older adults' and carers' assessment of the quality of preparation for transfers. A secondary question was whether this approach improved quality of life and reduced health care resource utilisation compared with usual care.

Method
Design
A single blind randomised controlled trial with masked outcome assessments at 3 and 12 months was conducted with 230 older persons (>65 years) who entered Transition Care (TC) following an acute hospital admission. An informal carer for each participant also took part in the trial (see Figure 1).

TC was established in Australia in 2005-06 to provide time-limited (up to 12 weeks) care for older people who have completed their hospital episode and who needed more time and support to make a decision on their long-term aged care options. Entry was via a formal assessment conducted by an Aged Care Assessment Team (ACAT) and referrals were accepted from both public and private hospitals. TC aimed to facilitate improved capacity in activities of daily living and provides low intensity therapy, medical, nursing and social work support, personal care and case management, as required to meet the assessed needs of the individual.[27] TC can be provided in the community or in a residential setting (most often aged care), or as a combination of both.

A medical and nursing intervention that provided individual coaching to older adults and families on their medical conditions, medications, and future planning was compared with 'usual care' to see if the approach improved older adults' and families' assessment of the quality of preparation for discharge from TC. Recruitment closed when the target of 230 older adult and carer dyads was achieved.

Study participants
Eligible study participants were identified from consecutive admissions to a single residential TC facility in Adelaide, South Australia. Eligible participants were able to communicate in English and to nominate an informal carer who agreed to participate in the study (defined as a relative or friend with whom the participant felt comfortable discussing their medical conditions and future care needs). People who did not have an informal carer or did not wish their carer to be approached about the study were not eligible.

Sample size and statistical power
To assess the effects of the intervention, the mean scores on the Care Transition Measure (CTM-15)[28] — the primary outcome measure — were compared for the intervention and usual care groups. Data from participants and informal carers was analysed separately. To demonstrate a 10% improvement in the CTM-15 on an expected mean of 67.34 (SD 13.67), based on Coleman et al. 2005[29] as statistically significant (assuming alpha $\alpha=0.05$ and power=0.80), 132 participants (66 in each arm of the study) were required. To

allow for 40% attrition, a total of 230 patient/carer dyads were recruited. The high attrition rate was based on 27% attrition in four months in a previous RCT in a similar population and setting. [30] While the study was not powered a priori to assess differences in quality of life, function and use of health and aged care resources, these measures were considered in the economic analyses.

Procedures

Ethics and privacy considerations

The study was reviewed and approved by the Repatriation General Hospital Research and Ethics Committee (90/07). Approval to access participant data relating to utilisation of pharmaceutical and medical benefits was provided by Medicare Australia, subject to provision of individually signed consent forms.

Recruitment and screening

Once an older adult and their informal carer agreed to participate in the study, written informed consent was sought from both parties. A modified Zelen randomised consent design[31] was used. The study team have used this design in a previous study in the same setting. [30] The modified Zelen design is employed when standard consent procedures may lead to unnecessary confusion or distress. [32] The initial consent provided a full description of baseline and outcome measures and included a simple description of the intervention. Following allocation, participants assigned to the intervention group were given detailed information about each of the components of the intervention and informed consent to participate was sought. Those assigned to usual care were not re-approached. Proxy consent was sought for those with an appointed guardian or impaired cognition.

Randomisation

Permuted block randomisation was used to achieve balanced treatment allocation.[33] A random number sequence was generated for the order of treatment allocation within the blocks using the SPSS v15 RV.UNIFORM function by a statistician external to the trial. Varying block sizes were used. The blocks were randomly arranged within larger sized blocks. Random group allocation was managed by a clinical trials pharmacist at the Repatriation General Hospital. Sequentially numbered, opaque sealed envelopes were used to conceal treatment allocation.

Allocation concealment

Research staff screened for inclusion criteria, sought informed consent and conducted the baseline assessment. Following completion of the baseline assessment, a research staff member telephoned the clinical trials pharmacist at the hospital; the participant was assigned a unique participant number and allocated to the intervention or control group. While staff performing the outcome assessments were blinded to group allocation, it was not possible to blind participants and staff administering interventions to group allocation.

Usual care

All participants received usual care at the TC facility. A multidisciplinary team was responsible for comprehensive geriatric assessment, goal setting, care plans and periodic review at regular case conference meetings.

Physiotherapy, occupational therapy and speech therapy were provided in individual and/or group sessions. A pharmacist reviewed patient medications, documented changes during hospital admission and the period of TC and provided education for older adults who were discharged to home. Social workers assisted older adults and their families to make decisions about living arrangements and aged care services and to access legal and social security services if required. An initial medical consultation was provided by a geriatrician but most medical care was provided by a general practitioner and a geriatric medicine advanced trainee who visited the TC facility twice weekly, with telephone support available 24 hours a day via an on-call roster. The geriatricians only met with the patient or carer if clinically indicated after the initial review. Each patient was discussed at a multi-disciplinary case conference in the week after their admission and then was discussed again at four and eight weeks if still in the program. There was a separate weekly discharge planning meeting involving allied health and nursing staff.

Intervention

The intervention was delivered in addition to usual care and addressed health literacy in relation to participant and carer understanding of the participant's medical conditions and medications, and encouraged participation in decisions about future health care needs. Issues relating to the participant's wishes about end of life care were also canvassed. The intervention comprised four components: a Question Prompt List (QPL); medical and nursing meetings; written summary; and telephone call post discharge.

Question Prompt List

Participants and carers received a Question Prompt List (QPL) a week prior to meeting with a geriatrician (see Table 1). A structured list of questions has been shown to enhance patient participation in oncology settings[25] and their use aims to improve patient and carer involvement in care planning and encourage discussion about sensitive

issues such as diminished capacity, long-term care options and end of life care.

Table 1: Question prompts

I'm not sure what the best decision is for the future, in terms of living arrangements?
Some days I'm okay, other times I'm unsteady on my feet. What can I do to help this problem?
I'm worried about Dad's memory and if it's safe for him to continue living alone?
I don't know if this is normal after a stroke, but I'm concerned that Mum seems to have given up on life?
Where do I go for advice about Power of Attorney and Guardianship?

Geriatrician and nurse meetings

A checklist was used to guide the consultation with a geriatrician and nurse and as a record of the meeting (see Table 2). The checklist was developed by consultant geriatricians and included the core information components of the Care Transition Intervention, specifically: the reason for hospital admission and comorbid diagnoses, current medications and 'red flags' indicative of a worsening condition.[18] Additional topics were those generally covered as part of a comprehensive geriatric assessment (CGA) and included: depression, falls, continence, cognition, behaviour, nutrition, decision-making capacity, advanced care planning and end of life care. The participants' and family members' preferences for discharge destination were elicited and, where appropriate, discussion included information about the risks associated with each of the options and strategies to mitigate those risks. Geriatricians had access to hospital and TC facility records and current medication charts immediately prior to the family meetings and brief nursing notations on the checklist were used to highlight key dates (e.g. orthopaedic review), results of cognitive testing, and clinical observations.

Table 2: Checklist for geriatrician meeting

Medical conditions
Medications – purpose, precautions
Red flags
Depression
Falls
Continence
Dementia
Behaviour
Nutrition
Discharge destination (risk)
Decision-making capacity
Good Palliative Care Plan

Participants received an audio recording of the consultation.[34, 35] The nurse met with the participant and carer two weeks after the initial consultation to consolidate key educational messages concerning medications and red flags. Falls prevention, self-care, continence and behaviours associated with dementia were discussed as appropriate. Permission was sought to conduct meetings in aged care facilities for those participants who entered permanent care prior to the scheduled meetings.

Written summary

Participants and carers received a written summary of the study meetings with the geriatrician and nurse. The personal summary adopted a conversational tone and utilised images and colour to improve readability. It described the medical condition that resulted in hospital admission and other medical diagnoses. The summary also included a reconciled list of medications and a description of the medications' purposes and possible side effects. Extracts from a de-identified summary are provided as a supplementary file. Participants were encouraged to share their summary with their doctor, formal carers, and family members as appropriate.

Telephone call post discharge

The study nurse telephoned the participant or carer two to three weeks after discharge from the TC facility to enquire about medical follow-up, medication supply and community and aged care services. Participants were asked to rate the usefulness of the QPL (see Table 3), meetings with the geriatrician and nurse, audio-recording and written summary of health conditions and medications.

Data collection, measures and outcomes

Baseline measures

Baseline measures were recorded prior to randomisation. In addition to demographic details and descriptions of health conditions, the following measures were collected:

interRAI Post-Acute Care (interRAI-PAC)[36] is one of a suite of standardised instruments developed by an international research consortium known as interRAI (RAI = Resident Assessment Instrument). Development and validation of the RAI for nursing homes was funded by the USA government in 1987 to enable comparison of resident needs across institutions, inform resource allocation, and as a foundation for care improvement.[37] An assessment of patient performance and clinical characteristics were conducted across a three-day period (and within seven days of admission) by a health professional with interRAI certification. The interRAI-PAC provides summary scores on eight scales: (i) cognitive performance; (ii) communication;

(iii) Changes in Health, End-stage disease and Signs and Symptoms scale (CHESS); (iv) depression; (v) Activities of Daily Living (ADL) – short form; (vi) ADL – long form; (vii) pain; (viii) Instrumental Activities of Daily Living (IADL); and Body Mass Index (BMI).[38]

Table 3: Components of the coaching intervention

Component	Procedure
QPL	Handed to patient and carer one week prior to meeting with geriatrician and nurse
Meetings	Week 4 and Week 6 or as negotiated Information component Review of reason for hospital admission Medical conditions Medications and side effects 'Red Flags' for review Information on health care choices End of life planning Doctor facilitation of patient participation Checks patient understanding Elicits participant and carer questions and values Offers choices, acknowledges trade offs
Summary	Checked by geriatrician and delivered to patient and carer
Telephone	2-3 weeks post discharge

Standardised Mini Mental State Examination (SMMSE)[39] Assesses verbal memory and attention and is a widely used measure in screening for dementia and delirium. Total scores range from 0-30 with lower scores indicating greater cognitive impairment. Values of 23 or less generally indicate significant impairment. [40]

Charlson Comorbidity Index (CCI) [41] This is a widely used index of comorbidity and a strong indicator of mortality at one-year follow-up. The index encompasses 19 medical conditions weighted 1–6 with total scores ranging from 0-37.[42] Higher scores indicate greater disease burden. The CCI has been adapted and validated for use with the International Classification of Disease 9th Revision (ICD-9) and 10th Revisions (ICD-10) and the Australian modification (AM) of the ICD-10. For the current study, the CCI was calculated based on the ICD-10-AM codes at hospital discharge.[43]

Health care utilisation Hospital admissions and Medicare Australia information relating to pharmaceutical and medical benefits was collected for the 12 month period prior to study entry, as a baseline measure of health care utilisation.

Primary outcome
The primary outcome for the study is the 15 item Care Transition Measure (CTM-15)[28] which was completed by participants and carers at the three-month outcome assessment. The CTM-15 assesses the quality of preparation for care transfers. The measure includes four major domains identified through qualitative research to be important to an individual's experience of a change in care setting, namely: (i) critical understanding; (ii) respect for individual preferences; (iii) preparation for self-management; and (iv) a written care plan.[44] The CTM-15 is scored between 0 and 100, with higher scores indicating a better transition. The tool has been found to discriminate between patients who do, and do not, re-present to hospital for their original condition.[4, 45]

Secondary outcomes
Secondary outcomes were assessed at 3 and 12 months by a research assistant who was blind to group allocation. A summary of primary and secondary outcomes is provided in Table 2. Measures include:

Health and aged care service utilisation Hospitalisations and admissions to aged care facilities in the preceding period were recorded at 3 and 12-month assessments and confirmed from hospital records and/or the appropriate facility. Community service use was also recorded at each assessment, based on self or proxy reports and will be used in the economic analyses.

Deaths were recorded and verified with reference to hospital, general practitioner or residential aged care records.

EQ-5D[46] is a well validated and widely used generic preference based measure of health-related quality of life for application in economic evaluation. The instrument comprises two main components: a visual analogue scale (VAS) (0-100, representing worst imaginable to best imaginable health state) and five dimensions with three levels (of increasing severity) attached to each dimension: mobility; self-care; usual activities; pain/discomfort; and anxiety/depression. Respondents were asked to rate their own health on the VAS and indicate which of the three levels for each dimension best corresponded to their health on the day of assessment. Individual responses to the five dimension questions are converted to utilities through application of a scoring algorithm based upon general population values for all possible health states defined by the instrument.[47, 48]

Modified Barthel Index (MBI)[49] is a simple and rapid measure of functional independence with high reliability (0.9). The MBI has 10 items, each scored from unable to perform task to fully independent with a total score of 100 indicating complete independence. The MBI is a mandatory assessment tool for TC in Australia.[27]

Short Physical Performance Battery (SPPB) [50] assesses gait, balance and lower extremity strength and endurance. The SPPB incorporates tests of standing balance (tandem, semi-tandem and side--by--side), a timed 2.4m walk at a normal pace and a timed test of five repetitions of rising from a chair and sitting down and is highly predictive of subsequent disability.[51]

Geriatric Depression Scale (GDS--15)[52] is a 15--item short-form self--report assessment designed specifically to identify depression in the elderly. Each item requires a yes/no response and total scores range from 0--15, with higher scores indicating greater illness severity. The GDS--15 can reliably detect the presence of a major depressive episode among older adults as defined by current diagnostic criteria --- the International Classification of Diseases, 10th revision (ICD--10) and Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM--IV).[53]

Multidimensional Health Locus of Control Scale (MHLC) – Form A[54] is a widely used scale to characterise a person's beliefs about control over health status. The instrument consists of three six--item scales: Internality (IHLC); Powerful Others externality (PHLC); and Chance externality (CHLC). The score on each subscale is the sum of the values circled for each item on the subscale where 1 = strongly disagree and 6 = strongly agree. Evidence for the validity of the MHLC is described as modest.[55, 56]

Client Satisfaction Questionnaire[57], 8--item version (CSQ--8) [58] is a self--report measure of satisfaction with treatment, originally developed to evaluate mental health services. Each item is scored from 1--4 with higher scores indicating higher satisfaction with the treatment received. The CSQ--8 assesses global patient satisfaction and also provides a general score ranging from 8 to 32.[59] The CSQ--8 is a widely used instrument with published data on reliability and validity[60] and is available in several languages.

Patient experience was assessed against the key requirements of the Transition Care Program (TCP) in Australia,[61] using an instrument that was developed as part of the National Evaluation of the TCP.[62] TC recipients (or their proxies) were asked to rate the extent to which their experience matched TCP requirements for care to be goal oriented, patient--centred, seamless and to optimise independence. Initial testing of the 9--item instrument demonstrated test--retest reliability and construct validity.[63]

Secondary outcomes for carers included carer burden and self--efficacy. In addition to the CTM--15, carers completed:

Bakas Caregiving Outcomes Scale (BCOS)[64]. This scale is a 10--item uni--dimensional scale of carer burden with good psychometric properties.[65] The BCOS provides an overall score of how the carer's life has changed while providing care to the participant. The BCOS uses a 7--point Likert scale that ranges in response from 'changed for the worst' to 'changed for the best' to measure change in relationships, physical health, and subjective wellbeing.

New General Self--Efficacy Scale (NGSE)[66]. This 8--item scale assesses perceived self--efficacy regarding coping and adaptation abilities in both daily activities and isolated stressful events. Tests using item response theory (IRT) confirm that the NGSE has acceptable psychometric properties.[67]

Table 4: Baseline and outcome measures

Measure	pre	0 mo	3 mo	12 mo
CTM--15			✓	
interRAI-PAC		✓		
MMSE		✓		
Charlson comorbidity		✓		
Hospitalisations	✓	✓	✓	✓
MBS/PBS	✓	✓	✓	✓
Aged care admissions		✓	✓	✓
Community services		✓	✓	✓
Death			✓	✓
EQ-5D		✓	✓	✓
MBI		✓	✓	✓
SPPB		✓		✓
GDS--15		✓		✓
MHLC		✓		✓
CSQ-8			✓	
Patient experience			✓	
BCOS		✓		✓
NGSE		✓		✓

pre= premorbid, mo=months

Data analyses

Statistical analyses

The primary analysis was by intention to treat based on group allocation.[68] For continuous measures, the difference in means and 95% confidence intervals were calculated. The

difference between intervention and control for discrete variables were summarised using appropriate risk ratios and 95% confidence intervals. The time to first rehospitalisation (excluding elective admissions) for each participant was analysed using a Cox proportional hazards model, with a censoring date set at 3 or 12 months follow-up for participants who were not re-admitted. A per protocol analysis of those who received the whole intervention were also performed as a secondary analysis.

Economic analysis

An assessment of the incremental costs and effects of a coaching intervention relative to usual care was undertaken. The economic analysis was conducted alongside the randomised controlled trial and comprised a cost effectiveness study of the intervention versus usual care. The primary measure of outcome for the economic analysis was the incremental cost per quality adjusted life year (QALY) as measured by the EQ-5D. Resource use collected within the evaluation included that associated with the provision of the intervention plus the frequency and duration of in-patient admissions, Pharmaceutical Benefits Scheme (PBS) and Medicare Benefits Schedule (MBS) utilisation for all trial participants. Resource use associated with the intervention included staff time spent preparing and administering the intervention according to the frequency, type and level of health care professional. Data on the frequency and duration of hospital in-patient admissions was obtained from medical records, and PBS and MBS utilisation data from Medicare. Unit costs were derived from published data sets including PBS, MBS and Australian Refined Diagnosis Related Groups (AR-DRG) cost weights.[69]

Confidence intervals are presented around the incremental cost effectiveness ratios and cost effectiveness acceptability curves for varying threshold values of cost effectiveness will also be presented.[70] An assessment of the sensitivity of the results obtained to variation in measured resource use, effectiveness and/or unit costs was undertaken using appropriate one-way and multi-way sensitivity analysis.[71]

Discussion

This study tested the impact of a multi-component coaching intervention on older adults' and carers' assessments of the quality of preparation for discharge from TC. The impact of the intervention on carer burden and self-efficacy was assessed, as was the risk of subsequent hospital admissions and adverse drug events (ADE) that frequently accompany transfers between different care settings. In addition, the current study assesses the impact of investing specialist geriatric resources into consultations with families in an intermediate care setting where decisions about returning to community living or moving into long-term care are being made.

Reducing the risks associated with transfers for older people is increasingly a key aim for many health systems around the world. Up to one in five people aged 65 years or older discharged from hospital to home health services have been reported to experience an ADE in the first month following discharge.[72] Prospective review of medical records and patient interviews suggest that 53% of ADE related admissions are preventable.[73] Deficits in self-care knowledge[74] and absence of timely medical review following hospital discharge increase the risk of re-hospitalisation related to the original admission and costs of care. Medicare claims data in the USA has revealed that half of all patients readmitted to hospital within 30 days have not been billed for a doctor's visit between the date of discharge and readmission.[75] The intervention described in this manuscript addressed both medications and signals for medical review, with a focus on empowering older people and preparing families for their role as health advocates. Appointment of a health advocate is recommended as an effective 'work around' strategy to address the impact of health literacy limitations that disproportionately affect older adults on health outcomes and health care utilisation.[76]

An important aspect of this study is the setting selected to deliver the intervention in – a residential TC (or intermediate care) facility. For older people approaching the end of life an episode of acute hospitalisation is associated with a high risk of institutionalisation and several countries have introduced intermediate care units where older people can transfer for several weeks to recover function and confidence. Staff in this setting often focus on improving function but the time spent in these units also provides an opportunity to deliver interventions, which empower families and older people[77] and prepare them for future care transitions. One of the core underpinnings of the TC program in Australia is that frail older adults and their families need time to decide on the most appropriate future care options and that this decision should be made once the older person's independence has been optimised. This principle recognises that, for older adults and their families, decision-making is a process rather than a discrete action.[78] Health literacy is a key component of consumer centred care in the Australian Safety and Quality Framework for Health Care and a critical requirement for effective participation of patients and carers in health decisions.[79] Having specialist medical and nursing professionals deliver the intervention provides scope and flexibility in responding

to the complex and diverse medical, legal and psychosocial needs of older adults in an intermediate care setting.

Conclusion

Making a decision about whether to move into residential care or to stay at home is a complex decision for both older people and their carers. Older adults with delirium or cognitive impairment are frequently excluded from research projects yet this is the group most likely to be confronted with this dilemma. Little is known about the best ways to provide older people and their families in this situation with support. [80] We have removed cognitive impairment and end stage disease as exclusion criteria, meaning that our study results will be generalisable to the population of older adults who have experienced an acute hospital admission and have not fully recovered, and are at risk of movement into residential care.

Informal carers often have limited experience of aged care; are unprepared for their role as health care advocates and guardians; and face a myriad of demands within the context of a limited choice of aged care places and pressure to make rapid decisions. The current study recognises the crucial role of the informal carer and purposively recruits the carer as a research participant in his or her own right.

As the intervention involves specialist medical and nursing staff it is expensive. A careful assessment of the costs and benefits of the intervention is required in this group who are known to have high mortality and readmission rates. [62] A pragmatic clinical trial design, policy relevant endpoints and economic evaluation will optimise our understanding of the usefulness of the approach with vulnerable older adults in a residential TC setting. If the study findings are positive and indicate favourable cost effectiveness, the multi-component coaching intervention approach to supporting health literacy, participation and decision-making in those on the brink of entering the residential care system could be more widely adopted by other post-acute services.

References

1. Coleman EA. Falling through the cracks: challenges and opportunities for improving transitional care for persons with continuous complex care needs. J Am Geriatr Soc. 2003 Apr; 51(4): 549-55.
2. Grimmer KA, Moss JR, Gill TK. Discharge planning quality from the carer perspective. Qual Life Res. 2000; 9(9): 1005-13.
3. Grimmer K, Moss J, Falco J. Experiences of elderly patients regarding independent community living after discharge from hospital: a longitudinal study. Int J Qual Health Care. 2004 Dec; 16(6): 465-72.
4. Coleman EA, Smith JD, Frank JC, Eilertsen TB, Thiare JN, Kramer AM. Development and testing of a measure designed to assess the quality of care transitions. Int J Integr Care. 2002 Apr-Jun; 2:e02.
5. vom Eigen KA, Walker JD, Edgman-Levitan S, Cleary PD, Delbanco TL. Carepartner Experiences With Hospital Care. Med Care. 1999 Jan; 37(1): 33-8.
6. Gravolin M, Rowell K, de Groot J. Interventions to support the decision-making process for older people facing the possibility of long-term residential care. Cochrane Database Syst Rev. 2007(3):CD005213.
7. Institute of Medicine. Health Literacy: A Prescription to End Confusion. Washington, DC: National Academies Press; 2004.
8. Adams RJ, Appleton SL, Hill CL, Dodd M, Findlay C, Wilson DH. Risks associated with low functional health literacy in an Australian population. Med J Aust. 2009 Nov 16; 191(10): 530-4.
9. Australian Bureau of Statistics. Adult literacy and life skills survey, summary results, Australia, 2006 (ABS Cat. No. 4228.0) Canberra: ABS; 2007.
10. Oates DJ, Paasche-Orlow MK. Health literacy: communication strategies to improve patient comprehension of cardiovascular health. Circulation. 2009 Feb 24; 119(7): 1049-51.
11. Brown SC, Park DC. Theoretical models of cognitive aging and implications for translational research in medicine. Gerontologist. 2003 Mar; 43 Spec No 1:57-67.
12. Makaryus AN, Friedman EA. Patients' understanding of their treatment plans and diagnosis at discharge. Mayo Clin Proc. 2005 Aug; 80(8): 991-4.
13. Katz MG, Jacobson TA, Veledar E, Kripalani S. Patient literacy and question-asking behavior during the medical encounter: a mixed-methods analysis. J Gen Intern Med. 2007 Jun; 22(6): 782-6.
14. Oates DJ, Silliman RA. Health literacy: improving patient understanding. Oncology (Williston Park). 2009 Apr 15; 23(4): 376, 9.
15. Baker DW, Parker RM, Williams MV, Clark WS. Health literacy and the risk of hospital admission. J Gen Intern Med. 1998 Dec; 13(12): 791-8.
16. Adams RJ, Appleton SL, Hill CL, Ruffin RE, Wilson DH. Inadequate health literacy is associated with increased asthma morbidity in a population sample. J Allergy Clin Immunol. 2009 Sep; 124(3): 601-3.
17. Baker DW, Wolf MS, Feinglass J, Thompson JA, Gazmararian JA, Huang J. Health literacy and mortality among elderly persons. Arch Intern Med. 2007 Jul 23; 167(14): 1503-9.
18. Coleman EA, Smith JD, Frank JC, Min SJ, Parry C, Kramer AM. Preparing patients and caregivers to participate in care delivered across settings: the Care Transitions Intervention. J Am Geriatr Soc. 2004 Nov; 52(11): 1817-25.
19. Edvardsson D, Nordvall K. Lost in the present but confident of the past: experiences of being in a psychogeriatric unit as narrated by persons with dementia. J Clin Nurs. 2008 Feb; 17(4): 491-8.
20. Smith J, Forster A, House A, Knapp P, Wright J, Young J. Information provision for stroke patients and their caregivers. Cochrane Database Syst Rev. 2008(2):CD001919.
21. Kinnersley P, Edwards A, Hood K, Cadbury N, Ryan R, Prout H, et al. Interventions before consultations for helping

patients address their information needs. Cochrane Database Syst Rev. 2007(3):CD004565.

22. Pitkethly M, Macgillivray S, Ryan R. Recordings or summaries of consultations for people with cancer. Cochrane Database Syst Rev. 2008(3):CD001539.

23. Leydon GM, Boulton M, Moynihan C, Jones A, Mossman J, Boudioni M, et al. Cancer patients' information needs and information seeking behaviour: in depth interview study. BMJ. 2000 Apr 1; 320(7239): 909–13.

24. Fleissig A. Information needs of patients with cancer. Patients are frightened and their information needs fluctuate. BMJ. 2000 Sep 9; 321(7261): 632; author reply 3.

25. Clayton JM, Butow PN, Tattersall MH, Devine RJ, Simpson JM, Aggarwal G, et al. Randomized controlled trial of a prompt list to help advanced cancer patients and their caregivers to ask questions about prognosis and end–of–life care. J Clin Oncol. 2007 Feb 20; 25(6): 715–23.

26. Gaston CM, Mitchell G. Information giving and decision–making in patients with advanced cancer: a systematic review. Soc Sci Med. 2005 Nov; 61(10): 2252–64.

27. Department of Health and Ageing. Transition Care Program Guidelines 2011 Publications Approval Number–D0459. Canberra: DOHA 2011.

28. Coleman EA, Smith JD, Frank JC, Eilertsen TB, Thiare JN, Kramer AM. Development and testing of a measure designed to assess the quality of care transitions. Int J Integr Care. 2002; 2:e02.

29. Coleman EA, Mahoney E, Parry C. Assessing the quality of preparation for posthospital care from the patient's perspective --- The care transitions measure. Med Care. 2005 Mar; 43(3): 246–55.

30. Crotty M, Whitehead CH, Wundke R, Giles LC, Ben–Tovim D, Phillips PA. Transitional care facility for elderly people in hospital awaiting a long term care bed: Randomized controlled trail. BMJ. 2005; 331(7525): 1110(4).

31. Zelen M. A new design for randomized clinical trials. N Engl J Med. 1979 May 31; 300(22): 1242–5.

32. Steiner A, Walsh B, Pickering RM, Wiles R, Ward J, Brooking JI. Therapeutic nursing or unblocking beds? A randomised controlled trial of a post–acute intermediate care unit. BMJ. 2001 Feb 24; 322(7284): 453–60.

33. Beller EM, Gebski V, Keech AC. Randomisation in clinical trials. Med J Aust. 2002 Nov 18; 177(10): 565–7.

34. Koh TH, Budge D, Butow P, Renison B, Woodgate P. Audio recordings of consultations with doctors for parents of critically sick babies. Cochrane Database Syst Rev. 2005(1):CD004502.

35. Koh TH, Butow PN, Coory M, Budge D, Collie LA, Whitehall J, et al. Provision of taped conversations with neonatologists to mothers of babies in intensive care: randomised controlled trial. BMJ. 2007 Jan 6; 334(7583): 28.

36. Landi F, Bernabei R, Russo A, Zuccala G, Onder G, Carosella L, et al. Predictors of rehabilitation outcomes in frail patients treated in a geriatric hospital. J Am Geriatr Soc. 2002 Apr; 50(4): 679–84.

37. Milbank Memorial Fund. Implementing the Resident Assessment Instrument: case studies of policymaking for long–term care in eight countries. New York: Milbank Memorial Fund; 2003. Available from: http://www.milbank.org/reports/interRAI/030222interRAI.h tml#foreword.

38. Hirdes JP, Ljunggren G, Morris JN, Frijters DH, Finne Soveri H, Gray L, et al. Reliability of the interRAI suite of assessment instruments: a 12–country study of an integrated health information system. BMC Health Serv Res. 2008; 8:277.

39. Molloy DW, Alemayehu E, Roberts R. Reliability of a Standardized Mini–Mental State Examination Compared with the Traditional Mini–Mental State Examination. The Am J Psychiatry. 1991 Jan; 148(1): 102–5.

40. Woodford HJ, George J. Cognitive assessment in the elderly: a review of clinical methods. QJM. 2007; 100(8): 469–84.

41. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. J Chronic Dis. 1987; 40(5): 373–83.

42. Hall WH, Ramachandran R, Narayan S, Jani AB, Vijayakumar S. An electronic application for rapidly calculating Charlson comorbidity score. BMC Cancer. 2004 Dec 20; 4:94.

43. Sundararajan V, Henderson T, Perry C, Muggivan A, Quan H, Ghali WA. New ICD–10 version of the Charlson comorbidity index predicted in–hospital mortality. J Clin Epidemiol. 2004 Dec; 57(12): 1288–94.

44. Coleman EA, Mahoney E, Parry C. Assessing the quality of preparation for posthospital care from the patient's perspective: the care transitions measure. Med Care. 2005 Mar; 43(3): 246–55.

45. Coleman EA, Parry C, Chalmers S, Min SJ. The care transitions intervention: results of a randomized controlled trial. Arch Intern Med. 2006 Sep 25; 166(17): 1822–8.

46. Rabin R, de Charro F. EQ–5D: a measure of health status from the EuroQol Group. Ann Med. 2001 Jul; 33(5): 337–43.

47. Brazier J, Ratcliffe J, Salomon J, Tsuchiya A. Measuring and valuing health benefits for economic evaluation. Oxford: Oxford University Press; 2007.

48. Viney R, Norman R, King MT, Cronin P, Street DJ, Knox S, et al. Time trade–off derived EQ–5D weights for Australia. Value Health. 2011 Sep–Oct; 14(6): 928–36.

49. Shah S, Vanclay F, Cooper B. Improving the sensitivity of the Barthel Index for stroke rehabilitation J Clin Epidemiol. 1989; 42(8): 703–9.

50. Guralnik JM, Simonsick EM, Ferrucci L, Glynn RJ, Berkman LF, Blazer DG, et al. A short physical performance battery assessing lower extremity function: association with self–reported disability and prediction of mortality and nursing home admission. J Gerontol. 1994 Mar; 49(2): M85–94.

51. Guralnik JM, Ferrucci L, Simonsick EM, Salive ME, Wallace RB. Lower–extremity function in persons over the age of 70 years as a predictor of subsequent disability. N Engl J Med. 1995 Mar 2; 332(9): 556–61.

52. Yesavage JA, Brink TL, Rose TL, Lum O, Huang V, Adey M, et al. Development and validation of a geriatric depression screening scale: A preliminary report. J Psychiatr Res. 1982; 17(1): 37–49.

53. Almeida OP, Almeida SA. Short versions of the geriatric depression scale: a study of their validity for the diagnosis of a major depressive episode according to ICD–10 and DSM–

IV. Int J Geriatr Psychiatry. 1999 Oct; 14(10): 858–65.

54. Wallston KA, Wallston BS, DeVellis R. Development of the Multidimensional Health Locus of Control (MHLC) Scales. Health Educ Monogr. 1978 Spring; 6(2): 160–70.

55. Wallston KA. The validity of the multidimensional health locus of control scales. J Health Psychol. 2005 Sep; 10(5): 623–31.

56. Wallston KA, Wallston BS, Smith S, Dobbins CJ. Perceived Control and Health. Curr Psychol Res Rev. 1987 Spr; 6(1): 5–25.

57. Larsen DL, Attkisson CC, Hargreaves WA, Nguyen TD. Assessment of client/patient satisfaction: development of a general scale. Eval Program Plan. 1979; 2(3): 197–207.

58. Nguyen TD, Attkisson CC, Stegner BL. Assessment of patient satisfaction: development and refinement of a service evaluation questionnaire. Eval Program Plan. 1983; 6(3–4): 299–313.

59. Marchand KI, Oviedo–Joekes E, Guh D, Brissette S, Marsh DC, Schechter MT. Client satisfaction among participants in a randomized trial comparing oral methadone and injectable diacetylmorphine for long–term opioid–dependency. BMC Health Serv Res. 2011; 11:174.

60. Greenfield TK, Attkisson CC. Steps toward a Multifactorial Satisfaction Scale for Primary Care and Mental–Health Services. Eval Program Plan. 1989; 12(3): 271–8.

61. Department of Health and Ageing. Transition Care Program Guidelines 2005. Canberra: DOHA 2005.

62. Giles L, Halbert J, Stepien–Hulleman J, Eckermann S, Masters S, Prendergast J, et al. National Evaluation of the Transition Care Program: final evaluation report Canberra: Department of Health and Ageing; 2008. Available from: http://www.health.gov.au/internet/main/publishing.nsf/Content/13539979243E2556CA2574BB00152A2E/$File/TCPEvaluReport.pdf.

63. Masters S, Giles L, Halbert J, Crotty M. Development and testing of a questionnaire to measure older people's experience of the Transition Care Program in Australia. Australas J Ageing. 2010 Dec; 29(4): 172–8.

64. Bakas T, Champion V. Development and Psychometric Testing of the Bakas Caregiving Outcomes Scale. Nurs Res. 1999; 48(5): 250–9.

65. Deeken JF, Taylor KL, Mangan P, Yabroff KR, Ingham JM. Care for the caregivers: a review of self–report instruments developed to measure the burden, needs, and quality of life of informal caregivers. Journal of Pain and Symptom Management. 2003; 26(4): 922–53.

66. Chen G, Gully SM, Eden D. Validation of a New General Self–Efficacy Scale. Organizational Research Methods. 2001 Jan 1; 4(1): 62–83.

67. Scherbaum CA, Cohen–Charash Y, Kern MJ. Measuring general self–efficacy – A comparison of three measures using item response theory. Educ Psychol Meas. 2006 Dec; 66(6): 1047–63.

68. Lachin JL. Statistical considerations in the intent–to–treat principle. Control Clin Trials. 2000 Oct; 21(5): 526.

69. Australian Institute of Health and Welfare. Australian hospital statistics 2010–11. Health services series no. 43. Cat. no. HSE 117. Canberra: AIHW 2012.

70. Glick HA, Briggs AH, Polsky D. Quantifying stochastic uncertainty and presenting results of cost–effectiveness analyses. Expert Rev Pharmacoecon Outcomes Res. 2001 Oct; 1(1): 25–36.

71. Briggs AH, O'Brien BJ, Blackhouse G. Thinking outside the box: recent advances in the analysis and presentation of uncertainty in cost–effectiveness studies. Annu Rev Public Health. 2002; 23:377–401.

72. Gray SL, Mahoney JE, Blough DK. Adverse drug events in elderly patients receiving home health services following hospital discharge. Ann Pharmacother. 1999 Nov; 33(11): 1147–53.

73. Chan M, Nicklason F, Vial JH. Adverse drug events as a cause of hospital admission in the elderly. Intern Med J. 2001 May–Jun; 31(4): 199–205.

74. Dedhia P, Kravet S, Bulger J, Hinson T, Sridharan A, Kolodner K, et al. A quality improvement intervention to facilitate the transition of older adults from three hospitals back to their homes. J Am Geriatr Soc. 2009 Sep; 57(9): 1540–6.

75. Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee–for–service program. N Engl J Med. 2009 Apr 2; 360(14): 1418–28.

76. Berkman ND, Sheridan SL, Donahue KE, Halpern DJ, Viera A, Crotty K, et al. Health Literacy Interventions and Outcomes: An Updated Systematic Review. Evidence Report/Technology Assessment No. 199. AHRQ Publication No. 11–E006. Rockville, MD: Agency for Healthcare Research and Quality 2011.

77. Andrews J, Manthorpe J, Watson R. Involving older people in intermediate care. J Adv Nurs. 2004 May; 46(3): 303–10.

78. Popejoy L. Health–related decision–making by older adults and their families: how clinicians can help. J Gerontol Nurs. 2005 Sep; 31(9): 12–8.

79. Australian Commission on Safety and Quality in Health Care (ACSQHC). Australian Safety and Quality Framework for Health Care. Canberra: ACSQHC 2010.

80. Van Spall HG, Toren A, Kiss A, Fowler RA. Eligibility criteria of randomized controlled trials published in high–impact general medical journals: a systematic sampling review. JAMA. 2007 Mar 21; 297(11): 1233–40.

ACKNOWLEDGEMENTS

PEER REVIEW

Not commissioned. Externally peer reviewed.

CONFLICTS OF INTEREST

The authors declare that they have no competing interests.

FUNDING

ETHICS COMMITTEE APPROVAL

Repatriation General Hospital Research and Ethics Committee, approval reference number 90/07.

Figure 1: Participant flow