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Developing a new quality of life instrument with older people for economic evaluation in aged care: study protocol

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Manuscripts

1 Developing a new quality of life instrument with older people for economic evaluation in aged care:
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3 study protocol
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Abstract

Introduction

The ageing of the population represents a significant challenge for aged care in Australia and in many other countries internationally. In an environment of increasing resource constraints, new methods, techniques and evaluative frameworks are needed to support resource allocation decisions that maximise the quality of life and wellbeing of older people. Economic evaluation offers a rigorous, systematic and transparent framework for measuring quality and efficiency, but there is currently no composite mechanism for incorporating older people's values into the measurement and valuation of quality of life for quality assessment and economic evaluation. In addition, to date relatively few economic evaluations have been conducted in aged care despite the large potential benefits associated with their application in this sector. This study will generate a new preference based older person specific quality of life instrument designed for application in economic evaluation and co-created from its inception with older people.

Methods and analysis

A candidate descriptive system for the new instrument will be developed by synthesizing the findings from a series of in-depth qualitative interviews with 40 older people currently in receipt of aged care services about the salient factors which make up their quality of life. The candidate descriptive system will be tested for construct validity, practicality and reliability with a new independent sample of older people (n=100). Quality of life state valuation tasks using best worst scaling (a form of discrete choice experiment) will then be undertaken with a representative sample of older people currently receiving aged care services across five Australian states (n=500). A multinomial (conditional) logistic framework will be used to analyse responses and generate a scoring algorithm for the new preference-based instrument.

Ethics and dissemination

The new quality of life instrument will have wide potential applicability in assessing the cost effectiveness of new service innovations and for quality assessment across the spectrum of aging and aged care. Results will be disseminated in ageing, quality of life research and health economics journals and through professional conferences and policy forums. This study has been reviewed by the Human Research Ethics Committee of the University of South Australia and has ethics approval (Application ID: 201644).

Strengths and limitations of this study

- The new quality of life instrument developed will be co-created with older people and will provide a composite mechanism or incorporating older people's values into the measurement and valuation of quality of life for quality assessment and economic evaluation.
- Inclusivity will be enhanced by incorporating the preferences of older people from a variety of care settings (including those with mild cognitive impairment and mild dementia, previously excluded from research of this nature) in the development, validation and valuation of the new instrument.
- The study has a broad range of investigators with input into the study protocol from consumers, aged care practitioners and providers.
- The best worst scaling approach utilised for the valuation may not be easily understood by older people receiving aged care services and therefore this may limit their ability to value quality of life from their own perspective.
- The ability of the study to generate a new quality of life instrument which is co-developed with and representative of older people receiving aged care services may be compromised if older people from a variety of care settings do not elect to participate.

INTRODUCTION

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3 People, aged 65 years and over, represent a rapidly growing age group and are major users of health and aged
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5 care services. In 2013–14, recurrent Australian Government expenditure on aged care programs and services
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7 was \$14.8 billion and this is forecast to increase to \$80 billion by 2054–55.¹ Annual health system
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9 expenditures for older people are four to five times higher than those in their early teens and increase
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11 exponentially beyond 65 years of age.¹ Recently, a number of policy initiatives have been introduced to break
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13 down boundaries in care settings and build partnerships between aged care organizations and the health care
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15 sector.^{2,3} Examples include the use of multi-disciplinary aged care teams and mechanisms to allow services
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17 traditionally provided in a hospital setting to be provided in the community, in an older person's home or
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19 within aged care facilities. These reforms have been designed to reduce fragmentation and to improve quality
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21 and efficiency in the care provided to older people.^{2,3} Economic evaluation is a powerful tool that can help
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23 decision makers across health and aged care sectors to drive quality and efficiency improvements and
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25 thereby make the most of limited resources. Economic evaluation offers a systematic and robust
26
27 methodological framework for comparing the costs and outcomes of new and existing services and
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29 programs.^{4,5}

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37 The measurement and valuation of quality of life represents the cornerstone of cost utility analysis, the most
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39 prevalent form of economic evaluation. Within cost utility analysis, outcomes are typically captured and
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41 reported in terms of quality adjusted life years (QALYs). The QALY combines quality of life and length of life
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43 into a single index on a "0" to "1" (dead - full health) scale. As a generic measure, the QALY facilitates
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45 comparisons of the benefits generated from disparate interventions.⁵ Despite the label 'quality of life', to date
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47 QALY's have narrowly focused upon health status. This priority may be viewed as appropriate for curative
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49 interventions in the health care sector where the main objective is to improve health.⁵ However, the aged care
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51 sector has broader and more inclusive goals, especially those that emphasize improvements to the quality of
52
53 life and wellbeing of older people.^{5,6} Prior research conducted by our team strongly indicates that quality of
54
55 life attributes that transcend health e.g. independence and control, social participation, safety and dignity are
56
57 highly valued by older people.^{7,8} Many innovations in aged care seek to improve the quality of life of older
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59 people by promoting these quality of life attributes. For example, consumer directed care (CDC) empowers
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1 older people to live independently through the ability to exercise autonomy and choice.⁹ Similarly emerging
2 models of reablement seek to maintain an older person's capacity to live as independently as possible and
3 actively participate in home-life, community and society.¹⁰ Whilst such models of care may not impact directly
4 upon the health status of an older person, they may result in cost savings to government and society whilst
5 delivering overall improvements in quality of life.
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14 Our team has successfully conducted two pilot studies highlighting the central importance of quality of life
15 attributes to older people. Our first pilot study employed a mixed methods (quantitative and qualitative)
16 design with two separately convened focus groups of older people (N=21) recovering from illness.⁷ Whilst
17 health status was valued as an important contributor to overall quality of life, other broader aspects of quality
18 of life including independence, control and social relationships were also consistently highly valued.⁷ Our
19 large-scale pilot study, recently published in the international journal *Quality of Life Research* compared the
20 preferences of younger adults aged 18 to 64 years (n=500) with those of older adults aged 65 years and
21 above (n=500) as to the relative importance of key quality of life attributes utilizing ranking and best worst
22 scaling (BWS-a form of discrete choice experiment or DCE).⁸ The findings from this study indicated that the
23 preferences of younger and older people in relation to the relative importance of the attributes of quality of
24 life embedded in health status and broader attributes of quality of life were not the same. The ability to be
25 independent, physically mobile and have control over their daily lives was found to be the most important
26 determinant of older people's quality of life. No currently existing instrument incorporates these quality of
27 life attributes for the calculation of QALYs. Many recent innovations in service delivery targeted for older
28 people including consumer directed care, reablement and frailty interventions are designed to improve older
29 peoples' ability to be independent, physically mobile and have control over their daily lives. The new
30 instrument will provide a robust mechanism for capturing these attributes within quality adjusted life years
31 for economic evaluation. New methods, techniques and evaluative frameworks are needed to overcome
32 resource constraints while maximising the quality of life and wellbeing of older people.
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1 This project will fill this gap through the development of a new preference based older person specific quality
2 of life instrument designed for application in economic evaluation and co-created from its inception with older
3 people.
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9 AIMS

10 This study has three main objectives:

- 11 • Identify the quality of life attributes relevant to older people in receipt of aged care, going beyond
12 those captured by existing instruments.
- 13 • Develop and validate the descriptive system for the new quality of life instrument to appropriately
14 capture those attributes.
- 15 • Engage older people with discrete choice experiments to produce a scoring system for the new
16 instrument that is compatible with the QALY scale and has wide applicability for economic
17 evaluation.
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32 METHODS AND ANALYSIS

33 This three-phase multimethod project will be conducted over a three year time frame (January 2019-
34 December 2021) and will utilise a qualitative and quantitative design including semi-structured interviews
35 and DCE's. We will build upon the methodological and project management approaches successfully
36 employed by our team in our previous ARC linkage project to develop a health economics model for the
37 development and evaluation of Consumer Directed Care in community aged care services.⁹ A particular
38 strength of our proposed project is its inclusivity. We will build on our collective research and practical
39 stakeholder experience to incorporate the preferences of older people from a variety of care settings
40 (including those with mild cognitive impairment and mild dementia, previously excluded from research of
41 this nature) in the development, validation and valuation of the new quality of life instrument. The research
42 team has extensive experience in recruitment and the conduct of research studies with older people
43 including those with cognitive impairment, the development of aged care services for older people and the
44 translation of research into practice.
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Participants

Older people (aged 65 years and above) will be recruited for each phase of the project via the client base of our partner organizations aged care services in South Australia (ECH and Helping Hand), Victoria (Uniting Age Well), Australian Capital Territory and New South Wales (Uniting ACT NSW and Presbyterian Aged Care). We will recruit participants with a range of cognitive abilities including older people living with mild cognitive impairment and mild dementia, (defined according to a mini-mental state examination (MMSE) score of 19-23) according to their prevalence amongst older people in receipt of aged care services.

Individuals who are unable to communicate in English, with moderate or severe dementia and/or delirium will be excluded. Older people will be optimally supported to participate in all phases of the project by enabling participation from a variety of care settings including the older person's home, community centre, retirement village or aged care facility and at a time to suit their (and, if necessary, their family carers) needs.

Phase 1: Development of the Descriptive System

The first phase of the project will address Aim 1. A descriptive system for the new instrument will be developed which encapsulates the key attributes of quality of life from the perspective of older people. Traditionally, descriptive systems for existing preference-based measures of quality of life have been developed using top down methods whereby the content of descriptive systems has been derived from existing measures and/or the literature. A contrasting approach is to employ a bottom up approach using qualitative research methods which encompasses the views of older people themselves about the factors which make up their quality of life. This approach will ensure the descriptive system has appropriate language, facilitate content validity and responsiveness to change. Qualitative research methods have been used successfully recently in the development of descriptive systems for several preference based instruments and are recommended as best practice methods for guiding attribute selection.^{11,12}

Qualitative Interviews

A series of qualitative semi-structured interviews will be conducted initially with older people who consent to be interviewed. Participants will be purposively chosen to reflect a range of socio-demographic

1 characteristics including: age, gender, living situation (living alone or with family/carer or in the role of an
2 older family carer), location (urban vs country areas), physical functioning (absence or presence of
3 physical impairment), cognitive functioning (absence or presence of mild cognitive impairment and mild
4 dementia) the level of aged care services being received (home care package level). Our previous experience and
5 recommendations from the literature indicate that a maximum sample size of N=40 will be sufficient to
6 reach 'data saturation' (i.e. where no new views or themes are expressed).¹³ The qualitative interviews will
7 be semi-structured and designed to build upon our previous pilot studies to confirm the content and
8 interpretation of the key quality of life attributes for older people. The interviews will probe factors and
9 issues relating to quality of life including: What does the term 'quality of life' mean to an older person?
10 How does quality of life relate to health status? What are the defining characteristics or attributes that
11 determine the quality of life of older people? The interviews will also investigate the relationship between
12 quality of life and the characteristics of the older person and/or their environment (e.g. older people living
13 with mild cognitive impairment and mild dementia, older people living in country vs urban areas).

14 All interviews will be recorded and transcribed verbatim and data entered into the qualitative data analysis
15 software package NVIVO to assist in the analysis. Thematic content analysis will be conducted involving
16 three stages, according to established methods to provide a descriptive, or thematic, account.¹⁴ The first
17 stage will involve detailed listening, reading and re-reading of each interview transcript, to allow for
18 continual data immersion. The second stage will involve the process of coding parts of the interview
19 transcripts, sorting and tagging data to develop a coding framework and the final stage will involve
20 identifying links between codes and the creation of broader categories or over-riding themes in the data.

21 The inductive analysis will be utilized together with the findings from our previous pilot studies and best
22 practice guidance from the methodological literature to inform the development of the draft descriptive
23 system.^{11,15} The qualitative interviews will be used to guide the wording of the attributes and the
24 categorization and wording of the levels attached to each attribute to ensure that all language is clear,
25 relevant and understandable to the intended population. Negatively worded questions will be avoided and
26 the levels assigned to each attribute will be ordinal, with discrete responses for the instrument
27 attributes.^{11,15,16}

Phase 2: Development and validation of the new descriptive system

The second phase of the project will address **Aim 2**. Psychometric testing will be employed to assess the construct validity, practicality and reliability of the newly developed descriptive system with a new independent sample of older people recruited via our partner organizations care networks previously specified. Our previous experience indicates that a sample size of N=100 will be sufficient to adequately represent and evaluate the psychometric properties.^{5,16,17} Construct validity is defined as the extent to which the description comprehensively covers the different attributes of quality of life, is sufficiently sensitive to change and the quality of life state descriptions appears to be realistic. Participants will be asked to rank the levels of each attribute in order of their severity, to complete the instrument and provide feedback on the descriptions of the attributes and levels to test content validity. The level rankings will also be analyzed empirically using mean rankings and variation and by using Kendall's coefficient of concordance test statistic.

Factor analysis will be undertaken to ensure the instrument uses the minimum number of items to represent the attributes of quality of life included.¹¹ The practicality of administering the new instrument depends upon its acceptability to older people and the cost of administration (in terms of time).¹⁵⁻¹⁷ This will be investigated by assessing how long the instrument takes to administer in different populations (e.g. differentiated according to the presence or absence of mild cognitive impairment), different modes of administration (e.g. electronic or hard copy version), and settings and the proportion of completed responses. Reliability is the ability of a descriptive system to produce the same responses on two separate occasions when there has been no change in quality of life.^{15,16} This will be assessed by a sub sample of participants (N=40) who will complete the instrument on two separate occasions separated by an interval of one week. The results from each stage of the psychometric testing will be used to inform any refinement of the descriptive system prior to valuation.

Phase 3: Determining weights for the descriptive system using DCE methodology

The third phase of the project will address **Aim 3**, determining the relative value or weight assigned to each attribute defined by the descriptive system and to produce a preference based scoring algorithm for the calculation of QALYs for economic evaluation.^{5,18,19} Our previous DCE studies with older people have

1 indicated that an interview mode of administration is preferable to self-completion postal or on-line surveys
2 as this helps to aid participant understanding and promotes completion rates.²⁰⁻²² The BWS task will be
3 developed for administration via a face to face interview and will be piloted prior to the main study with a
4 small number of older people (n=10) to ensure that the task is easily understood and completion rates are
5 maximized. The optimal sample size for the BWS task is dependent upon the final number of attributes and
6 levels included within the descriptive system and will be determined by consideration of the requirements of
7 the BWS task and by the key objective of deriving older person-specific quality of life state values from a
8 large and inclusive sample of older people from a variety of care settings. For a descriptive system
9 comprising nine attributes with five levels assigned to each attribute a target sample size of N=500 older
10 people will ensure precise estimation of model parameters for development of the scoring algorithm, whilst
11 also protecting against any extremes of heterogeneity in preferences.^{18,19,23} A fractional factorial design will
12 be generated to reduce the number of quality of life states to a manageable number for the purposes of a face
13 to face interview whilst retaining statistical efficiency for the estimation of model parameters. For example, a
14 fractional factorial that permits the estimation of main effects for a DCE with 9 attributes each with 5 levels,
15 (whilst maintaining the design properties of efficiency and level balance) may be generated in 50 scenarios.
16 We propose to block the design into 5 versions so that each participant is presented with a maximum of 10
17 scenarios for the BWS task. This will promote participant completion rates and minimise error due to fatigue.
18 It has been demonstrated that large sample properties can be achieved with 50 respondents per block or
19 version.²³ The presentation of 5 versions with 50 respondents per version therefore requires a total minimum
20 sample size of 250 respondents. A sample size of 500 will therefore be sufficient to assess any differences in
21 preference structure between participant sub-groups (e.g. older people living with and without mild cognitive
22 impairment, older people living in rural or more remote vs urban areas, older people recruited from
23 community vs residential aged care settings).

54 Valuation Survey

55 The valuation survey will be comprised of three main sections. Firstly, participants will be asked to indicate
56 their level of agreement with a series of attitudinal statements relating to quality of life and it's description
57 and definition on a 5 point Likert scale (ranging from completely agree to completely disagree). The

attitudinal statements will be drawn from the findings of the initial qualitative interviews and will act as a warm up task to familiarize the participants with the topic and the descriptions to be included within the BWS task. Secondly, participants will be presented with a series of quality of life states presented one at a time and asked to indicate the best and worst attribute for each state. Each scenario will include a range of high, moderate and low levels for attributes rather than predominantly a consistently 'high' or 'low' selection of attribute levels. Each quality of life state description will consist of the common attributes of the new quality of life instrument with different levels for each of the states presented. Thirdly, socio-demographic information including age, gender, health status as measured by the EQ-5D²⁴ and the level of aged care services being received will be collected at the final phase of the survey to facilitate sub-group analyses. The length of time spent completing the survey will be measured for each participant and they will also be asked to indicate how difficult they found the task to complete.

Data Analysis

Paired and marginal models for the prediction of quality of life state values will be estimated using data from the BWS task. The BWS data will firstly be analysed using conditional logistic regression models. These will be used to estimate paired (maxdiff) models where the best-worst pair is the unit of analysis, and sequential best worst multinomial logit models where the attribute level is the unit of analysis.^{18,19} Preference heterogeneity will be investigated via covariate-adjusted regression as well as random parameter versions of these models and scale-adjusted latent class analyses. Values will be obtained for all possible states defined by the descriptive system using the marginal sequential or paired (maxdiff) model suggested by the BWS data. The explanatory power of the two BWS models is likely to be similar. The marginal sequential model will be utilised when investigating heterogeneity in preferences, given its support in major statistical packages including Stata and Latent Gold.^{18,19}

The estimates from the BWS task are initially anchored to the least valued attribute level. Since these estimates are on an interval scale, a linear transformation can be applied in order that the best state takes the value 1 and the 'PITS' state (the state comprising the lowest level on each of the attributes of the descriptive system) takes the value 0. However, in order for the estimates to have QALY properties for application

1 within economic evaluation 0 must represent the state 'dead', not the PITS state. One method of achieving
2 this involves administering a traditional DCE where length of life is included as an additional attribute. This
3 would necessarily involve the presentation of many states for valuation and a complex choice task, which is a
4 concern amongst an older population. An alternative method involves rescaling the estimates using the
5 results obtained from a second choice task. This can be achieved (mathematically and conceptually) by using
6 the most severe or PITS state value from a time trade off or standard gamble exercise to rescale the original
7 estimates to ensure that the 0 represents dead.^{19,24}

18 We will elicit a PITS state value for re-scaling, via a time trade off exercise. This will be undertaken with a
19 sub sample of older people without cognitive impairment (defined according to a MMSE score of 24 or
20 above) who consent to participate in a follow up study via an interview. Previous health state valuation
21 exercises have indicated a time trade off task is generally easier for respondents to understand and complete
22 than standard gamble and direct valuation by a sub sample of older people with good cognitive functioning
23 will be feasible.⁵ Previous research has also indicated that a relatively small sample size of n=40 will be
24 sufficient to ensure precise estimation of the PITS state value.^{19,24} The values elicited from the time trade off
25 task will be utilised to rescale the BWS estimates to ensure that the 0 represents dead, rather than the utility
26 of the most severe state. The resulting scoring algorithm will then be applicable to generate values for all
27 quality of life states defined by the new quality of life instrument.

43 ETHICS AND DISSEMINATION

46 A project steering committee, consisting of key stakeholders and including consumer representatives will
47 provide congruency across the project in relation to the development of the new quality of life instrument.
48 The steering committee will meet quarterly throughout the project's duration to advise on the development
49 of the new descriptive system, its practical implementation and provide feedback. This project will directly
50 address the limitations of existing instruments by incorporating the preferences and values of older people
51 into the first generic preference based instrument, developed exclusively from its inception with older
52 people, for the calculation of QALYs for economic evaluation. The new quality of life instrument will have

1 wide applicability in Australia and internationally for assessing the cost effectiveness of new service
2 innovations and for quality assessment across the spectrum of aging and aged care.
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7 Information about the project and its findings will be communicated to the aged care sector and the general
8 community via the participating organisations' external relations units targeting local, state and national
9 web, print and electronic media. In addition, the results of the project will be disseminated at international
10 conferences and published in academic journals. A website will be developed to facilitate access to the new
11 quality of life instrument and for publishing outcomes and key findings from the project for participants,
12 their families and the general public.
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24 to design of the research project. All authors contributed to reviewing the manuscript and approved the
25 final manuscript.
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Developing a new quality of life instrument with older people for economic evaluation in aged care: study protocol

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1 Developing a new quality of life instrument with older people for economic evaluation in aged care:
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3 study protocol
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Abstract

Introduction

The ageing of the population represents a significant challenge for aged care in Australia and in many other countries internationally. In an environment of increasing resource constraints, new methods, techniques and evaluative frameworks are needed to support resource allocation decisions that maximise the quality of life and wellbeing of older people. Economic evaluation offers a rigorous, systematic and transparent framework for measuring quality and efficiency, but there is currently no composite mechanism for incorporating older people's values into the measurement and valuation of quality of life for quality assessment and economic evaluation. In addition, to date relatively few economic evaluations have been conducted in aged care despite the large potential benefits associated with their application in this sector. This study will generate a new preference based older person specific quality of life instrument designed for application in economic evaluation and co-created from its inception with older people.

Methods and analysis

A candidate descriptive system for the new instrument will be developed by synthesizing the findings from a series of in-depth qualitative interviews with 40 older people currently in receipt of aged care services about the salient factors which make up their quality of life. The candidate descriptive system will be tested for construct validity, practicality and reliability with a new independent sample of older people (n=100). Quality of life state valuation tasks using best worst scaling (a form of discrete choice experiment) will then be undertaken with a representative sample of older people currently receiving aged care services across five Australian states (n=500). A multinomial (conditional) logistic framework will be used to analyse responses and generate a scoring algorithm for the new preference-based instrument.

Ethics and dissemination

The new quality of life instrument will have wide potential applicability in assessing the cost effectiveness of new service innovations and for quality assessment across the spectrum of aging and aged care. Results will be disseminated in ageing, quality of life research and health economics journals and through professional conferences and policy forums. This study has been reviewed by the Human Research Ethics Committee of the University of South Australia and has ethics approval (Application ID: 201644).

Strengths and limitations of this study

- The new quality of life instrument developed will be co-created with older people and will provide a composite mechanism or incorporating older people's values into the measurement and valuation of quality of life for quality assessment and economic evaluation.
- Inclusivity will be enhanced by incorporating the preferences of older people from a variety of care settings (including those with mild cognitive impairment and mild dementia, previously excluded from research of this nature) in the development, validation and valuation of the new instrument.
- The study has a broad range of investigators with input into the study protocol from consumers, aged care practitioners and providers.
- The best worst scaling approach utilised for the valuation may not be easily understood by older people receiving aged care services and therefore this may limit their ability to value quality of life from their own perspective.
- The ability of the study to generate a new quality of life instrument which is co-developed with and representative of older people receiving aged care services may be compromised if older people from a variety of care settings do not elect to participate.

INTRODUCTION

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3 People, aged 65 years and over, represent a rapidly growing age group and are major users of health and aged
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5 care services. In 2013–14, recurrent Australian Government expenditure on aged care programs and services
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7 was \$14.8 billion and this is forecast to increase to \$80 billion by 2054–55.¹ Annual health system
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9 expenditures for older people are four to five times higher than those in their early teens and increase
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11 exponentially beyond 65 years of age.¹ Recently, a number of policy initiatives have been introduced to break
12
13 down boundaries in care settings and build partnerships between aged care organizations and the health care
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15 sector.^{2,3} Examples include the use of multi-disciplinary aged care teams and mechanisms to allow services
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17 traditionally provided in a hospital setting to be provided in the community, in an older person's home or
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19 within aged care facilities. These reforms have been designed to reduce fragmentation and to improve quality
20
21 and efficiency in the care provided to older people.^{2,3} Economic evaluation is a powerful tool that can help
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23 decision makers across health and aged care sectors to drive quality and efficiency improvements and
24
25 thereby make the most of limited resources. Economic evaluation offers a systematic and robust
26
27 methodological framework for comparing the costs and outcomes of new and existing services and
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29 programs.^{4,5}

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37 The measurement and valuation of quality of life represents the cornerstone of cost utility analysis, the most
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39 prevalent form of economic evaluation. Within cost utility analysis, outcomes are typically captured and
40
41 reported in terms of quality adjusted life years (QALYs). The QALY combines quality of life and length of life
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43 into a single index on a "0" to "1" (dead - full health) scale. As a generic measure, the QALY facilitates
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45 comparisons of the benefits generated from disparate interventions.⁵ Despite the label 'quality of life', to date
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47 QALY's have narrowly focused upon health status. This priority may be viewed as appropriate for curative
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49 interventions in the health care sector where the main objective is to improve health.⁵ However, the aged care
50
51 sector has broader and more inclusive goals, especially those that emphasize improvements to the quality of
52
53 life and wellbeing of older people.^{5,6} Prior research conducted by our team strongly indicates that quality of
54
55 life attributes that transcend health e.g. independence and control, social participation, safety and dignity are
56
57 highly valued by older people.^{7,8} Many innovations in aged care seek to improve the quality of life of older
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59 people by promoting these quality of life attributes. For example, consumer directed care (CDC) empowers
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1 older people to live independently through the ability to exercise autonomy and choice.⁹ Similarly emerging
2 models of reablement seek to maintain an older person's capacity to live as independently as possible and
3 actively participate in home-life, community and society.¹⁰ Whilst such models of care may not impact directly
4 upon the health status of an older person, they may result in cost savings to government and society whilst
5 delivering overall improvements in quality of life.
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14 Our team has successfully conducted two pilot studies highlighting the central importance of quality of life
15 attributes to older people. Our first pilot study employed a mixed methods (quantitative and qualitative)
16 design with two separately convened focus groups of older people (N=21) recovering from illness.⁷ Whilst
17 health status was valued as an important contributor to overall quality of life, other broader aspects of quality
18 of life including independence, control and social relationships were also consistently highly valued.⁷ Our
19 large-scale pilot study, recently published in the international journal *Quality of Life Research* compared the
20 preferences of younger adults aged 18 to 64 years (n=500) with those of older adults aged 65 years and
21 above (n=500) as to the relative importance of key quality of life attributes utilizing ranking and best worst
22 scaling (BWS-a form of discrete choice experiment or DCE).⁸ The findings from this study indicated that the
23 preferences of younger and older people in relation to the relative importance of the attributes of quality of
24 life embedded in health status and broader attributes of quality of life were not the same. The ability to be
25 independent, physically mobile and have control over their daily lives were found to be the most important
26 determinants of older people's quality of life. It is important to note that whilst existing preference based
27 instruments, including the EQ-5D and the ASCOT incorporate some of these elements, no currently existing
28 preference based instrument incorporates all three of these quality of life attributes for the calculation of
29 QALYs. Many recent innovations in service delivery targeted for older people including consumer directed
30 care, reablement and frailty interventions are designed to improve older peoples' ability to be independent,
31 physically mobile and have control over their daily lives.^{9,10} The new instrument will provide a robust
32 mechanism for capturing these attributes within quality adjusted life years for economic evaluation. New
33 methods, techniques and evaluative frameworks are needed to overcome resource constraints while
34 maximising the quality of life and wellbeing of older people.
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1 This project will fill this gap through the development of a new preference based older person specific quality
2 of life instrument designed for application in economic evaluation and co-created from its inception with older
3 people.
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9 AIMS

10 This study has three main objectives:

- 11 • Identify the quality of life attributes relevant to older people in receipt of aged care, going beyond
12 those captured by existing instruments.
- 13 • Develop and validate the descriptive system for the new quality of life instrument to appropriately
14 capture those attributes.
- 15 • Engage older people with discrete choice experiments to produce a scoring system for the new
16 instrument that is compatible with the QALY scale and has wide applicability for economic
17 evaluation.
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32 METHODS AND ANALYSIS

33 This three-phase multimethod project will be conducted over a three year time frame (January 2019-
34 December 2021) and will utilise a qualitative and quantitative design including semi-structured interviews
35 and DCE's. We will build upon the methodological and project management approaches successfully
36 employed by our team in our previous ARC linkage project to develop a health economics model for the
37 development and evaluation of Consumer Directed Care in community aged care services.⁹ A particular
38 strength of our proposed project is its inclusivity. We will build on our collective research and practical
39 stakeholder experience to incorporate the preferences of older people from a variety of care settings
40 (including those with mild cognitive impairment and mild dementia, previously excluded from research of
41 this nature) in the development, validation and valuation of the new quality of life instrument. The research
42 team has extensive experience in recruitment and the conduct of research studies with older people
43 including those with cognitive impairment, the development of aged care services for older people and the
44 translation of research into practice.
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Consumer and Public Involvement

The research question and the need for a new older person specific quality of life instrument designed for economic evaluation and developed from its inception with older people in receipt of aged care was directly informed by our prior research working in partnership with older people in community settings.⁷⁻⁹ Our Chief Investigator Team and Project Advisory Group includes consumer representatives who have actively contributed to the study design. Older people (aged 65 years and above) will be integrally involved in all stages of the project via the client base of our partner organizations aged care services in South Australia (ECH and Helping Hand), Victoria (Uniting Age Well), Australian Capital Territory and New South Wales (Uniting ACT NSW and Presbyterian Aged Care). We will recruit participants with a range of cognitive abilities including older people living with mild cognitive impairment and mild dementia, (defined according to a mini-mental state examination (MMSE) score of 19-23) according to their prevalence amongst older people in receipt of aged care services.

Collectively, our team has extensive experience in incorporating the values and preferences of older people in all stages of study design and delivery, including those with mild cognitive impairment and mild dementia. We have demonstrated in several previously successful studies through the careful development and application of the methodological approaches adopted for this study (including discrete choice experiments) that older people with mild cognitive impairment and mild dementia are able to provide informed consent, fully participate and provide highly valuable insights in assessing their values and preferences in relation to quality of life and quality of care.¹¹⁻¹³ Individuals who are unable to communicate in English, with moderate or severe dementia and/or delirium will be excluded. Older people will be optimally supported to participate in all phases of the project by enabling participation from a variety of care settings including the older person's home, community centre, retirement village or aged care facility and at a time to suit their (and, if necessary, their family carers) needs.

Information about the project and its findings will be communicated to study participants, the aged care sector and the general community via our participating organisations' external relations units who target local, state and national web, print and electronic media. A website will also be developed for publishing

1 outcomes and key findings from the project for participants, their families and the general public, as well as
2 a final report on the conclusions of the project.
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9 **Phase 1: Development of the Descriptive System**

10 Research design

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12 The first phase of the project will address Aim 1. A descriptive system for the new instrument will be
13 developed which encapsulates the key attributes of quality of life from the perspective of older people.
14 Traditionally, descriptive systems for existing preference-based measures of quality of life have been
15 developed using top down methods whereby the content of descriptive systems has been derived from
16 existing measures and/or the literature. A contrasting approach is to employ a bottom up approach using
17 qualitative research methods which encompasses the views of older people themselves about the factors
18 which make up their quality of life. This approach will ensure the descriptive system has appropriate
19 language, facilitate content validity and responsiveness to change. Qualitative research methods have been
20 used successfully recently in the development of descriptive systems for several preference based
21 instruments and are recommended as best practice methods for guiding attribute selection.^{14,15}
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39 Data collection

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41 A series of qualitative semi-structured interviews will be conducted initially with older people who
42 consent to be interviewed. Participants will be purposively chosen to reflect a range of socio-demographic
43 characteristics including: age, gender, living situation (living alone or with family/carer or in the role of an
44 older family carer), location (urban vs country areas), physical functioning (absence or presence of
45 physical impairment), cognitive functioning (absence or presence of mild cognitive impairment and mild
46 dementia) the level of aged care services being received (home care package level). Our previous
47 experience and recommendations from the literature indicate that a maximum sample size of N=40 will be
48 sufficient to reach 'data saturation' (i.e. where no new views or themes are expressed).¹⁶ The qualitative
49 interviews will be semi-structured and designed to build upon our previous pilot studies to confirm the
50 content and interpretation of the key quality of life attributes for older people. The interviews will probe
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factors and issues relating to quality of life including:

- What does the term 'quality of life' mean to an older person?
- How does quality of life relate to health status?
- What are the defining characteristics or attributes that determine the quality of life of older people?

The interviews will also investigate the relationship between quality of life and the characteristics of the older person and/or their environment (e.g. older people living with mild cognitive impairment and mild dementia, older people living in country vs urban areas).

Data analysis

All interviews will be recorded and transcribed verbatim and data entered into the qualitative data analysis software package NVIVO to assist in the analysis. Thematic content analysis will be conducted involving three stages, according to established methods to provide a descriptive, or thematic, account.¹⁷ The first stage will involve detailed listening, reading and re-reading of each interview transcript, to allow for continual data immersion. The second stage will involve the process of coding parts of the interview transcripts, sorting and tagging data to develop a coding framework and the final stage will involve identifying links between codes and the creation of broader categories or over-riding themes in the data. A coding diary and coding map will be maintained to track the progression of the analysis until the research team has agreed the final themes for the descriptive system. The inductive analysis will be utilized together with the findings from our previous pilot studies and best practice guidance from the methodological literature to inform the development of the draft descriptive system.^{14,18} The qualitative interviews will be used to guide the wording of the attributes and the categorization and wording of the levels attached to each attribute to ensure that all language is clear, relevant and understandable to the intended population. Negatively worded questions will be avoided and the levels assigned to each attribute will be ordinal, with discrete responses for the instrument attributes.^{14,18,19}

Phase 2: Development and validation of the new descriptive system

Research design

The second phase of the project will address **Aim 2**. Psychometric testing will be employed to assess the

1 construct validity, practicality and reliability of the newly developed descriptive system.
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5 Data collection 6

7 Psychometric testing will be undertaken with a new independent sample of older people recruited via our
8 partner organizations care networks previously specified. Our previous experience indicates that a sample
9 size of N=100 will be sufficient to adequately represent and evaluate the psychometric properties.^{5,16,17}
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12 Construct validity is defined as the extent to which the description comprehensively covers the different
13 attributes of quality of life, is sufficiently sensitive to change and the quality of life state descriptions
14 appears to be realistic. Participants will be asked to rank the levels of each attribute in order of their
15 severity, to complete the instrument and provide feedback on the descriptions of the attributes and levels.
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24 Data analysis 25

26 In addition to the participant feedback highlighted above, the level rankings will be analyzed empirically
27 using mean rankings and variation and by using Kendall's coefficient of concordance test statistic.
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30 Factor analysis will be undertaken to ensure the instrument uses the minimum number of items to represent
31 the attributes of quality of life included.¹⁴ The practicality of administering the new instrument depends upon
32 its acceptability to older people and the cost of administration (in terms of time).¹⁸⁻²⁰ This will be
33 investigated by assessing how long the instrument takes to administer in different populations (e.g.
34 differentiated according to the presence or absence of mild cognitive impairment), different modes of
35 administration (e.g. electronic or hard copy version), and settings and the proportion of completed responses.
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37 Our recent related research has found that with an appropriate level of support, many people classified with
38 mild or moderate cognitive impairment or dementia are able to provide a valid assessment of their own
39 quality of life.²¹ Our team will focus on the development of easy read resources and pictographs to assist in
40 effectively communicating the content of the new descriptive system and facilitating understanding for older
41 people with cognitive impairment and dementia.
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57 Reliability is the ability of a descriptive system to produce the same responses on two separate occasions
58 when there has been no change in quality of life.^{18,19} This will be assessed by a sub sample of participants
59 (N=40) who will complete the instrument on two separate occasions separated by an interval of one week.
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1 The results from each stage of the psychometric testing will be used to inform any refinement of the
2 descriptive system prior to valuation.
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7 **Phase 3: Determining weights for the descriptive system using DCE methodology**

8 Research design

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10 The third phase of the project will address **Aim 3**, determining the relative value or weight assigned to each
11 attribute defined by the descriptive system and to produce a preference based scoring algorithm for the
12 calculation of QALYs for economic evaluation.^{5,22,23} Our previous DCE studies with older people have
13 indicated that an interview mode of administration is preferable to self-completion postal or on-line surveys
14 as this helps to aid participant understanding and promotes completion rates.¹¹⁻¹³ The BWS task will be
15 developed for administration via a face to face interview and will be piloted prior to the main study with a
16 small number of older people (n=10) to ensure that the task is easily understood and completion rates are
17 maximized. The optimal sample size for the BWS task is dependent upon the final number of attributes and
18 levels included within the descriptive system and will be determined by consideration of the requirements of
19 the BWS task and by the key objective of deriving older person-specific quality of life state values from a
20 large and inclusive sample of older people from a variety of care settings.
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39 Data collection

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41 For a descriptive system comprising nine attributes with five levels assigned to each attribute a target sample
42 size of N=500 older people will ensure precise estimation of model parameters for development of the
43 scoring algorithm, whilst also protecting against any extremes of heterogeneity in preferences.^{22,23,24} A
44 fractional factorial design will be generated to reduce the number of quality of life states to a manageable
45 number for the purposes of a face to face interview whilst retaining statistical efficiency for the estimation of
46 model parameters. For example, a fractional factorial that permits the estimation of main effects for a DCE
47 with 9 attributes each with 5 levels, (whilst maintaining the design properties of efficiency and level balance)
48 may be generated in 50 scenarios. We propose to block the design into 5 versions so that each participant is
49 presented with a maximum of 10 scenarios for the BWS task. This will promote participant completion rates
50 and minimise error due to fatigue. It has been demonstrated that large sample properties can be achieved with
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1 50 respondents per block or version.²⁵ The presentation of 5 versions with 50 respondents per version
2 therefore requires a total minimum sample size of 250 respondents. A sample size of 500 will therefore be
3 sufficient to assess any differences in preference structure between participant sub-groups (e.g. older people
4 living with and without mild cognitive impairment, older people living in rural or more remote vs urban
5 areas, older people recruited from community vs residential aged care settings).
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14 The valuation survey will be comprised of three main sections. Firstly, participants will be asked to indicate
15 their level of agreement with a series of attitudinal statements relating to quality of life and its description
16 and definition on a 5 point Likert scale (ranging from completely agree to completely disagree). The
17 attitudinal statements will be drawn from the findings of the initial qualitative interviews and will act as a
18 warm up task to familiarize the participants with the topic and the descriptions to be included within the
19 BWS task. Secondly, participants will be presented with a series of quality of life states presented one at a
20 time and asked to indicate the best and worst attribute for each state. Each scenario will include a range of
21 high, moderate and low levels for attributes rather than predominantly a consistently 'high' or 'low'
22 selection of attribute levels. Each quality of life state description will consist of the common attributes of the
23 new quality of life instrument with different levels for each of the states presented. Thirdly, socio-
24 demographic information including age, gender, health status as measured by the EQ-5D^{26,27} and the level of
25 aged care services being received will be collected at the final phase of the survey to facilitate sub-group
26 analyses. The length of time spent completing the survey will be measured for each participant and they will
27 also be asked to indicate how difficult they found the task to complete.
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48 Data Analysis

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50 Paired and marginal models for the prediction of quality of life state values will be estimated using data from
51 the BWS task. The BWS data will firstly be analysed using conditional logistic regression models. These will
52 be used to estimate paired (maxdiff) models where the best-worst pair is the unit of analysis, and sequential
53 best worst multinomial logit models where the attribute level is the unit of analysis.^{18,19} Preference
54 heterogeneity will be investigated via covariate-adjusted regression as well as random parameter versions of
55 these models and scale-adjusted latent class analyses. Values will be obtained for all possible states defined
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1 by the descriptive system using the marginal sequential or paired (maxdiff) model suggested by the BWS
2 data. The explanatory power of the two BWS models is likely to be similar. The marginal sequential model
3 will be utilised when investigating heterogeneity in preferences, given its support in major statistical
4 packages including Stata and Latent Gold.^{22,23}
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11 The estimates from the BWS task are initially anchored to the least valued attribute level. Since these
12 estimates are on an interval scale, a linear transformation can be applied in order that the best state takes the
13 value 1 and the 'PITS' state (the state comprising the lowest level on each of the attributes of the descriptive
14 system) takes the value 0. However, in order for the estimates to have QALY properties for application
15 within economic evaluation 0 must represent the state 'dead', not the PITS state. One method of achieving
16 this involves administering a traditional DCE where length of life is included as an additional attribute. This
17 would necessarily involve the presentation of many states for valuation and a complex choice task, which is a
18 concern amongst an older population. An alternative method involves rescaling the estimates using the
19 results obtained from a second choice task. This can be achieved (mathematically and conceptually) by using
20 the most severe or PITS state value from a time trade off or standard gamble exercise to rescale the original
21 estimates to ensure that the 0 represents dead.^{23,24}
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39 We will elicit a PITS state value for re-scaling, via a time trade off exercise. This will be undertaken with a
40 sub sample of older people without cognitive impairment (defined according to a MMSE score of 24 or
41 above) who consent to participate in a follow up study via an interview. Previous health state valuation
42 exercises have indicated a time trade off task is generally easier for respondents to understand and complete
43 than standard gamble and direct valuation by a sub sample of older people with good cognitive functioning
44 will be feasible.⁵ Previous research has also indicated that a relatively small sample size of n=40 will be
45 sufficient to ensure precise estimation of the PITS state value.^{23,24} The values elicited from the time trade off
46 task will be utilised to rescale the BWS estimates to ensure that the 0 represents dead, rather than the utility
47 of the most severe state. The resulting scoring algorithm will then be applicable to generate values for all
48 quality of life states defined by the new quality of life instrument.
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1 Following the development of the new quality of life instrument, the relationships between the new quality of
2 life instrument and the EQ-5D-3L and the EQ-5D-5L will be investigated.^{26,27} Mapping algorithm will also
3 be developed using recommended best practice methods²⁸ to facilitate the estimation of re-weighted utility
4 values from existing data-sets incorporating the EQ-5D-3L or the EQ-5D-5L.
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10 11 12 **ETHICS AND DISSEMINATION** 13

14 A project steering committee, consisting of key stakeholders and including consumer representatives will
15 provide congruency across the project in relation to the development of the new quality of life instrument.
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17 The steering committee will meet quarterly throughout the project's duration to advise on the development
18 of the new descriptive system, its practical implementation and provide feedback. This project will directly
19 address the limitations of existing instruments by incorporating the preferences and values of older people
20 into the first generic preference based instrument, developed exclusively from its inception with older
21 people, for the calculation of QALYs for economic evaluation. The new quality of life instrument will have
22 wide applicability in Australia and internationally for assessing the cost effectiveness of new service
23 innovations and for quality assessment across the spectrum of aging and aged care.
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37 Information about the project and its findings will be communicated to the aged care sector and the general
38 community via the participating organisations' external relations units targeting local, state and national
39 web, print and electronic media. In addition, the results of the project will be disseminated at international
40 conferences and published in academic journals. A website will be developed to facilitate access to the new
41 quality of life instrument and for publishing outcomes and key findings from the project for participants,
42 their families and the general public.
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53 **Authors Contributions:** JR, IC, EL, RW, RM conceived the study; JR, IC, EL, RW, RM, CH, KS, SP
54 contributed to the design of the study; JR drafted the manuscript. IC, EL, RW, RM, CH, KS, SP reviewed
55 the draft manuscript and approved the final manuscript.
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BMJ Open

Developing a new quality of life instrument with older people for economic evaluation in aged care: study protocol

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Keywords:	Quality of life, Utility, Instruments, Older people, Aged Care, Dementia < NEUROLOGY

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Manuscripts

1 Developing a new quality of life instrument with older people for economic evaluation in aged care:
2
3 study protocol
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Keywords Quality of life, Utility, Instruments, Older people, Aged Care, Dementia.

1 **Word count** 3609 words

2 **Abstract**

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4 **Introduction**

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6
7 The ageing of the population represents a significant challenge for aged care in Australia and in many other
8 countries internationally. In an environment of increasing resource constraints, new methods, techniques and
9 evaluative frameworks are needed to support resource allocation decisions that maximise the quality of life
10 and wellbeing of older people. Economic evaluation offers a rigorous, systematic and transparent framework
11 for measuring quality and efficiency, but there is currently no composite mechanism for incorporating older
12 people's values into the measurement and valuation of quality of life for quality assessment and economic
13 evaluation. In addition, to date relatively few economic evaluations have been conducted in aged care despite
14 the large potential benefits associated with their application in this sector. This study will generate a new
15 preference based older person specific quality of life instrument designed for application in economic
16 evaluation and co-created from its inception with older people.
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30 **Methods and analysis**

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32 A candidate descriptive system for the new instrument will be developed by synthesizing the findings from a
33 series of in-depth qualitative interviews with 40 older people currently in receipt of aged care services about
34 the salient factors which make up their quality of life. The candidate descriptive system will be tested for
35 construct validity, practicality and reliability with a new independent sample of older people (n=100). Quality
36 of life state valuation tasks using best worst scaling (a form of discrete choice experiment) will then be
37 undertaken with a representative sample of older people currently receiving aged care services across five
38 Australian states (n=500). A multinomial (conditional) logistic framework will be used to analyse responses
39 and generate a scoring algorithm for the new preference-based instrument.
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51 **Ethics and dissemination**

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53 The new quality of life instrument will have wide potential applicability in assessing the cost effectiveness of
54 new service innovations and for quality assessment across the spectrum of aging and aged care. Results will
55 be disseminated in ageing, quality of life research and health economics journals and through professional
56 conferences and policy forums. This study has been reviewed by the Human Research Ethics Committee of
57 the University of South Australia and has ethics approval (Application ID: 201644).
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Strengths and limitations of this study

- The new quality of life instrument developed will be co-created with older people and will provide a composite mechanism or incorporating older people's values into the measurement and valuation of quality of life for quality assessment and economic evaluation.
- Inclusivity will be enhanced by incorporating the preferences of older people from a variety of care settings (including those with mild cognitive impairment and mild dementia, previously excluded from research of this nature) in the development, validation and valuation of the new instrument.
- The study has a broad range of investigators with input into the study protocol from consumers, aged care practitioners and providers.
- The best worst scaling approach utilised for the valuation may not be easily understood by older people receiving aged care services and therefore this may limit their ability to value quality of life from their own perspective.
- The ability of the study to generate a new quality of life instrument which is co-developed with and representative of older people receiving aged care services may be compromised if older people from a variety of care settings do not elect to participate.

INTRODUCTION

People, aged 65 years and over, represent a rapidly growing age group and are major users of health and aged care services. In 2013–14, recurrent Australian Government expenditure on aged care programs and services was \$14.8 billion and this is forecast to increase to \$80 billion by 2054–55.¹ Annual health system expenditures for older people are four to five times higher than those in their early teens and increase exponentially beyond 65 years of age.¹ Recently, a number of policy initiatives have been introduced to break down boundaries in care settings and build partnerships between aged care organizations and the health care sector.^{2,3} Examples include the use of multi-disciplinary aged care teams and mechanisms to allow services traditionally provided in a hospital setting to be provided in the community, in an older person's home or within aged care facilities. These reforms have been designed to reduce fragmentation and to improve quality and efficiency in the care provided to older people.^{2,3} Economic evaluation is a powerful tool that can help decision makers across health and aged care sectors to drive quality and efficiency improvements and thereby make the most of limited resources. Economic evaluation offers a systematic and robust methodological framework for comparing the costs and outcomes of new and existing services and programs.^{4,5}

The measurement and valuation of quality of life represents the cornerstone of cost utility analysis, the most prevalent form of economic evaluation. Within cost utility analysis, outcomes are typically captured and reported in terms of quality adjusted life years (QALYs). The QALY combines quality of life and length of life into a single index on a “0” to “1” (dead - full health) scale. As a generic measure, the QALY facilitates comparisons of the benefits generated from disparate interventions.⁵ Despite the label ‘quality of life’, to date QALY's have narrowly focused upon health status. This priority may be viewed as appropriate for curative interventions in the health care sector where the main objective is to improve health.⁵ However, the aged care sector has broader and more inclusive goals, especially those that emphasize improvements to the quality of life and wellbeing of older people.^{5,6} Prior research conducted by our team strongly indicates that quality of life attributes that transcend health e.g. independence and control, social participation, safety and dignity are highly valued by older people.^{7,8} Many innovations in aged care seek to improve the quality of life of older

1 people by promoting these quality of life attributes. For example, consumer directed care (CDC) empowers
2 older people to live independently through the ability to exercise autonomy and choice.⁹ Similarly emerging
3 models of reablement seek to maintain an older person's capacity to live as independently as possible and
4 actively participate in home-life, community and society.¹⁰ Whilst such models of care may not impact directly
5 upon the health status of an older person, they may result in cost savings to government and society whilst
6 delivering overall improvements in quality of life.
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16 Our team has successfully conducted two pilot studies highlighting the central importance of quality of life
17 attributes to older people. Our first pilot study employed a mixed methods (quantitative and qualitative)
18 design with two separately convened focus groups of older people (N=21) recovering from illness.⁷ Whilst
19 health status was valued as an important contributor to overall quality of life, other broader aspects of quality
20 of life including independence, control and social relationships were also consistently highly valued.⁷ Our
21 large-scale pilot study, recently published in the international journal *Quality of Life Research* compared the
22 preferences of younger adults aged 18 to 64 years (n=500) with those of older adults aged 65 years and
23 above (n=500) as to the relative importance of key quality of life attributes utilizing ranking and best worst
24 scaling (BWS-a form of discrete choice experiment or DCE).⁸ The findings from this study indicated that the
25 preferences of younger and older people in relation to the relative importance of the attributes of quality of
26 life embedded in health status and broader attributes of quality of life were not the same. The ability to be
27 independent, physically mobile and have control over their daily lives were found to be the most important
28 determinants of older people's quality of life. It is important to note that whilst existing preference based
29 instruments, including the EQ-5D and the ASCOT incorporate some of these elements, no currently existing
30 preference based instrument incorporates all three of these quality of life attributes for the calculation of
31 QALYs. Many recent innovations in service delivery targeted for older people including consumer directed
32 care, reablement and frailty interventions are designed to improve older peoples' ability to be independent,
33 physically mobile and have control over their daily lives.^{9,10} The new instrument will provide a robust
34 mechanism for capturing these attributes within quality adjusted life years for economic evaluation. New
35 methods, techniques and evaluative frameworks are needed to overcome resource constraints while
36 maximising the quality of life and wellbeing of older people.
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3 This project will fill this gap through the development of a new preference based older person specific quality
4 of life instrument designed for application in economic evaluation and co-created from its inception with older
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7 people.
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10 11 **AIMS**

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14 This study has three main objectives:

- 15
16 • Identify the quality of life attributes relevant to older people in receipt of aged care, going beyond
17 those captured by existing instruments.
- 18
19 • Develop and validate the descriptive system for the new quality of life instrument to appropriately
20 capture those attributes.
- 21
22 • Engage older people with discrete choice experiments to produce a scoring system for the new
23 instrument that is compatible with the QALY scale and has wide applicability for economic
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evaluation.

35 **METHODS AND ANALYSIS**

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37 This three-phase multimethod project will be conducted over a three year time frame (January 2019-
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39 December 2021) and will utilise a qualitative and quantitative design including semi-structured interviews
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41 and DCE's. We will build upon the methodological and project management approaches successfully
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43 employed by our team in our previous ARC linkage project to develop a health economics model for the
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45 development and evaluation of Consumer Directed Care in community aged care services.⁹ A particular
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47 strength of our proposed project is its inclusivity. We will build on our collective research and practical
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49 stakeholder experience to incorporate the preferences of older people from a variety of care settings
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51 (including those with mild cognitive impairment and mild dementia, previously excluded from research of
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53 this nature) in the development, validation and valuation of the new quality of life instrument. The research
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55 team has extensive experience in recruitment and the conduct of research studies with older people
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57 including those with cognitive impairment, the development of aged care services for older people and the
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60 translation of research into practice.

Patient and Public Involvement

The research question and the need for a new older person specific quality of life instrument designed for economic evaluation and developed from its inception with older people in receipt of aged care was directly informed by our prior research working in partnership with older people in community settings.⁷⁻⁹ Our Chief Investigator Team and Project Advisory Group includes consumer representatives who have actively contributed to the study design. Older people (aged 65 years and above) will be integrally involved in all stages of the project via the client base of our partner organizations aged care services in South Australia (ECH and Helping Hand), Victoria (Uniting Age Well), Australian Capital Territory and New South Wales (Uniting ACT NSW and Presbyterian Aged Care). We will recruit participants with a range of cognitive abilities including older people living with mild cognitive impairment and mild dementia, (defined according to a mini-mental state examination (MMSE) score of 19-23) according to their prevalence amongst older people in receipt of aged care services.

Collectively, our team has extensive experience in incorporating the values and preferences of older people in all stages of study design and delivery, including those with mild cognitive impairment and mild dementia. We have demonstrated in several previously successful studies through the careful development and application of the methodological approaches adopted for this study (including discrete choice experiments) that older people with mild cognitive impairment and mild dementia are able to provide informed consent, fully participate and provide highly valuable insights in assessing their values and preferences in relation to quality of life and quality of care.¹¹⁻¹³ Individuals who are unable to communicate in English, with moderate or severe dementia and/or delirium will be excluded. Older people will be optimally supported to participate in all phases of the project by enabling participation from a variety of care settings including the older person's home, community centre, retirement village or aged care facility and at a time to suit their (and, if necessary, their family carers) needs.

Information about the project and its findings will be communicated to study participants, the aged care sector and the general community via our participating organisations' external relations units who target

1 local, state and national web, print and electronic media.. A website will also be developed for publishing
2 outcomes and key findings from the project for participants, their families and the general public, as well as
3 a final report on the conclusions of the project.
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11 **Phase 1: Development of the Descriptive System**

12 Research design

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16 The first phase of the project will address Aim 1. A descriptive system for the new instrument will be
17 developed which encapsulates the key attributes of quality of life from the perspective of older people.
18 Traditionally, descriptive systems for existing preference-based measures of quality of life have been
19 developed using top down methods whereby the content of descriptive systems has been derived from
20 existing measures and/or the literature. A contrasting approach is to employ a bottom up approach using
21 qualitative research methods which encompasses the views of older people themselves about the factors
22 which make up their quality of life. This approach will ensure the descriptive system has appropriate
23 language, facilitate content validity and responsiveness to change. Qualitative research methods have been
24 used successfully recently in the development of descriptive systems for several preference based
25 instruments and are recommended as best practice methods for guiding attribute selection.^{14,15}
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41 Data collection

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43 A series of qualitative semi-structured interviews will be conducted initially with older people who
44 consent to be interviewed. Participants will be purposively chosen to reflect a range of socio-demographic
45 characteristics including: age, gender, living situation (living alone or with family/carer or in the role of an
46 older family carer), location (urban vs country areas), physical functioning (absence or presence of
47 physical impairment), cognitive functioning (absence or presence of mild cognitive impairment and mild
48 dementia) the level of aged care services being received (home care package level). Our previous
49 experience and recommendations from the literature indicate that a maximum sample size of N=40 will be
50 sufficient to reach 'data saturation' (i.e. where no new views or themes are expressed).¹⁶ The qualitative
51 interviews will be semi-structured and designed to build upon our previous pilot studies to confirm the
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1 content and interpretation of the key quality of life attributes for older people. The interviews will probe
2 factors and issues relating to quality of life including:

- 3 • What does the term 'quality of life' mean to an older person?
- 4
- 5 • How does quality of life relate to health status?
- 6
- 7 • What are the defining characteristics or attributes that determine the quality of life of older people?
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10 The interviews will also investigate the relationship between quality of life and the characteristics of the
11 older person and/or their environment (e.g. older people living with mild cognitive impairment and mild
12 dementia, older people living in country vs urban areas).
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21 Data analysis

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23 All interviews will be recorded and transcribed verbatim and data entered into the qualitative data analysis
24 software package NVIVO to assist in the analysis. Thematic content analysis will be conducted involving
25 three stages, according to established methods to provide a descriptive, or thematic, account.¹⁷ The first
26 stage will involve detailed listening, reading and re-reading of each interview transcript, to allow for
27 continual data immersion. The second stage will involve the process of coding parts of the interview
28 transcripts, sorting and tagging data to develop a coding framework and the final stage will involve
29 identifying links between codes and the creation of broader categories or over-riding themes in the data. A
30 coding diary and coding map will be maintained to track the progression of the analysis until the research
31 team has agreed the final themes for the descriptive system. The inductive analysis will be utilized together
32 with the findings from our previous pilot studies and best practice guidance from the methodological
33 literature to inform the development of the draft descriptive system.^{14,18} The qualitative interviews will be
34 used to guide the wording of the attributes and the categorization and wording of the levels attached to each
35 attribute to ensure that all language is clear, relevant and understandable to the intended population.
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Negatively worded questions will be avoided and the levels assigned to each attribute will be ordinal, with
discrete responses for the instrument attributes.^{14,18,19}

Phase 2: Development and validation of the new descriptive system

Research design

1 The second phase of the project will address **Aim 2**. Psychometric testing will be employed to assess the
2 construct validity, practicality and reliability of the newly developed descriptive system.
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9 Data collection

10 Psychometric testing will be undertaken with a new independent sample of older people recruited via our
11 partner organizations care networks previously specified. Our previous experience indicates that a sample
12 size of N=100 will be sufficient to adequately represent and evaluate the psychometric properties.^{5,16,17}
13 Construct validity is defined as the extent to which the description comprehensively covers the different
14 attributes of quality of life, is sufficiently sensitive to change and the quality of life state descriptions
15 appears to be realistic. Participants will be asked to rank the levels of each attribute in order of their
16 severity, to complete the instrument and provide feedback on the descriptions of the attributes and levels.
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30 Data analysis

31 In addition to the participant feedback highlighted above, the level rankings will be analyzed empirically
32 using mean rankings and variation and by using Kendall's coefficient of concordance test statistic.
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34 Factor analysis will be undertaken to ensure the instrument uses the minimum number of items to represent
35 the attributes of quality of life included.¹⁴ The practicality of administering the new instrument depends upon
36 its acceptability to older people and the cost of administration (in terms of time).¹⁸⁻²⁰ This will be
37 investigated by assessing how long the instrument takes to administer in different populations (e.g.
38 differentiated according to the presence or absence of mild cognitive impairment), different modes of
39 administration (e.g. electronic or hard copy version), and settings and the proportion of completed responses.
40
41 Our recent related research has found that with an appropriate level of support, many people classified with
42 mild or moderate cognitive impairment or dementia are able to provide a valid assessment of their own
43 quality of life.²¹ Our team will focus on the development of easy read resources and pictographs to assist in
44 effectively communicating the content of the new descriptive system and facilitating understanding for older
45 people with cognitive impairment and dementia.
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Reliability is the ability of a descriptive system to produce the same responses on two separate occasions

1 when there has been no change in quality of life.^{18,19} This will be assessed by a sub sample of participants
2 (N=40) who will complete the instrument on two separate occasions separated by an interval of one week.
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4 The results from each stage of the psychometric testing will be used to inform any refinement of the
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6 descriptive system prior to valuation.
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11 **Phase 3: Determining weights for the descriptive system using DCE methodology**

12 Research design

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14 The third phase of the project will address **Aim 3**, determining the relative value or weight assigned to each
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16 attribute defined by the descriptive system and to produce a preference based scoring algorithm for the
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18 calculation of QALYs for economic evaluation.^{5,22,23} Our previous DCE studies with older people have
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20 indicated that an interview mode of administration is preferable to self-completion postal or on-line surveys
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22 as this helps to aid participant understanding and promotes completion rates.¹¹⁻¹³ The BWS task will be
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24 developed for administration via a face to face interview and will be piloted prior to the main study with a
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26 small number of older people (n=10) to ensure that the task is easily understood and completion rates are
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28 maximized. The optimal sample size for the BWS task is dependent upon the final number of attributes and
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30 levels included within the descriptive system and will be determined by consideration of the requirements of
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32 the BWS task and by the key objective of deriving older person-specific quality of life state values from a
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34 large and inclusive sample of older people from a variety of care settings.
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44 Data collection

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46 For a descriptive system comprising nine attributes with five levels assigned to each attribute a target sample
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48 size of N=500 older people will ensure precise estimation of model parameters for development of the
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50 scoring algorithm, whilst also protecting against any extremes of heterogeneity in preferences.^{22,23,24} A
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52 fractional factorial design will be generated to reduce the number of quality of life states to a manageable
53
54 number for the purposes of a face to face interview whilst retaining statistical efficiency for the estimation of
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56 model parameters. For example, a fractional factorial that permits the estimation of main effects for a DCE
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58 with 9 attributes each with 5 levels, (whilst maintaining the design properties of efficiency and level balance)
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60 may be generated in 50 scenarios. We propose to block the design into 5 versions so that each participant is

1 presented with a maximum of 10 scenarios for the BWS task. This will promote participant completion rates
2 and minimise error due to fatigue. It has been demonstrated that large sample properties can be achieved with
3 50 respondents per block or version.²⁵ The presentation of 5 versions with 50 respondents per version
4 therefore requires a total minimum sample size of 250 respondents. A sample size of 500 will therefore be
5 sufficient to assess any differences in preference structure between participant sub-groups (e.g. older people
6 living with and without mild cognitive impairment, older people living in rural or more remote vs urban
7 areas, older people recruited from community vs residential aged care settings).

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19 The valuation survey will be comprised of three main sections. Firstly, participants will be asked to indicate
20 their level of agreement with a series of attitudinal statements relating to quality of life and it's description
21 and definition on a 5 point Likert scale (ranging from completely agree to completely disagree). The
22 attitudinal statements will be drawn from the findings of the initial qualitative interviews and will act as a
23 warm up task to familiarize the participants with the topic and the descriptions to be included within the
24 BWS task. Secondly, participants will be presented with a series of quality of life states presented one at a
25 time and asked to indicate the best and worst attribute for each state. Each scenario will include a range of
26 high, moderate and low levels for attributes rather than predominantly a consistently 'high' or 'low'
27 selection of attribute levels. Each quality of life state description will consist of the common attributes of the
28 new quality of life instrument with different levels for each of the states presented. Thirdly, socio-
29 demographic information including age, gender, health status as measured by the EQ-5D^{26,27} and the level of
30 aged care services being received will be collected at the final phase of the survey to facilitate sub-group
31 analyses. The length of time spent completing the survey will be measured for each participant and they will
32 also be asked to indicate how difficult they found the task to complete.
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51 52 53 Data Analysis

54 Paired and marginal models for the prediction of quality of life state values will be estimated using data from
55 the BWS task. The BWS data will firstly be analysed using conditional logistic regression models. These will
56 be used to estimate paired (maxdiff) models where the best-worst pair is the unit of analysis, and sequential
57 best worst multinomial logit models where the attribute level is the unit of analysis.^{18,19} Preference

1 heterogeneity will be investigated via covariate-adjusted regression as well as random parameter versions of
2 these models and scale-adjusted latent class analyses. Values will be obtained for all possible states defined
3 by the descriptive system using the marginal sequential or paired (maxdiff) model suggested by the BWS
4 data. The explanatory power of the two BWS models is likely to be similar. The marginal sequential model
5 will be utilised when investigating heterogeneity in preferences, given its support in major statistical
6 packages including Stata and Latent Gold.^{22,23}

16 The estimates from the BWS task are initially anchored to the least valued attribute level. Since these
17 estimates are on an interval scale, a linear transformation can be applied in order that the best state takes the
18 value 1 and the 'PITS' state (the state comprising the lowest level on each of the attributes of the descriptive
19 system) takes the value 0. However, in order for the estimates to have QALY properties for application
20 within economic evaluation 0 must represent the state 'dead', not the PITS state. One method of achieving
21 this involves administering a traditional DCE where length of life is included as an additional attribute. This
22 would necessarily involve the presentation of many states for valuation and a complex choice task, which is a
23 concern amongst an older population. An alternative method involves rescaling the estimates using the
24 results obtained from a second choice task. This can be achieved (mathematically and conceptually) by using
25 the most severe or PITS state value from a time trade off or standard gamble exercise to rescale the original
26 estimates to ensure that the 0 represents dead.^{23,24}

43 We will elicit a PITS state value for re-scaling, via a time trade off exercise. This will be undertaken with a
44 sub sample of older people without cognitive impairment (defined according to a MMSE score of 24 or
45 above) who consent to participate in a follow up study via an interview. Previous health state valuation
46 exercises have indicated a time trade off task is generally easier for respondents to understand and complete
47 than standard gamble and direct valuation by a sub sample of older people with good cognitive functioning
48 will be feasible.⁵ Previous research has also indicated that a relatively small sample size of n=40 will be
49 sufficient to ensure precise estimation of the PITS state value.^{23,24} The values elicited from the time trade off
50 task will be utilised to rescale the BWS estimates to ensure that the 0 represents dead, rather than the utility
51 of the most severe state. The resulting scoring algorithm will then be applicable to generate values for all

1 quality of life states defined by the new quality of life instrument.
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5 Following the development of the new quality of life instrument, the relationships between the new quality of
6 life instrument and the EQ-5D-3L and the EQ-5D-5L will be investigated.^{26,27} Mapping algorithm will also
7 be developed using recommended best practice methods²⁸ to facilitate the estimation of re-weighted utility
8 values from existing data-sets incorporating the EQ-5D-3L or the EQ-5D-5L.
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17 **ETHICS AND DISSEMINATION**

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19 This study has been reviewed by the Human Research Ethics Committee of the University of South Australia
20 and has ethics approval (Application ID: 201644). A project steering committee, consisting of key
21 stakeholders and including consumer representatives will provide congruency across the project in relation to
22 the development of the new quality of life instrument. The steering committee will meet quarterly
23 throughout the project's duration to advise on the development of the new descriptive system, its practical
24 implementation and provide feedback. This project will directly address the limitations of existing
25 instruments by incorporating the preferences and values of older people into the first generic preference
26 based instrument, developed exclusively from its inception with older people, for the calculation of QALYs
27 for economic evaluation. The new quality of life instrument will have wide applicability in Australia and
28 internationally for assessing the cost effectiveness of new service innovations and for quality assessment
29 across the spectrum of aging and aged care.
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47 Information about the project and its findings will be communicated to the aged care sector and the general
48 community via the participating organisations' external relations units targeting local, state and national
49 web, print and electronic media. In addition, the results of the project will be disseminated at international
50 conferences and published in academic journals. A website will be developed to facilitate access to the new
51 quality of life instrument and for publishing outcomes and key findings from the project for participants,
52 their families and the general public.
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2 **Authors Contributions:** JR, IC, EL, RW, RM conceived the study; JR, IC, EL, RW, RM, CH, KS, SP
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4 contributed to the design of the study; JR drafted the manuscript. IC, EL, RW, RM, CH, KS, SP reviewed
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6 the draft manuscript and approved the final manuscript.
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