

PROTOCOL

Draw-Care: Using animation and digital technologies to support Culturally and Linguistically Diverse (CALD) family carers and people living with dementia

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Statement of Compliance

This document is a protocol for a research project. This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

Table of Contents

Study synopsis	3
Study sites	7
1 Introduction and background	8
1.1 Lay summary	8
1.2 Introduction	9
1.3 Background information	9
2 Study objectives	11
2.1 Project aims	11
2.2 Hypotheses	11
2.3 Theoretical framework	12
3 Project governance and steering group	0
4 Study 1 – Co-produce the Draw-Care Intervention	1
4.1 Co-production workshops	1
4.1.1 <i>Workshop participants and recruitment</i>	1
4.1.2 <i>Method</i>	2
4.1.3 <i>Workshop schedule</i>	2
4.2 Interviews with people with dementia	2
4.2.1 <i>Interview participants and recruitment</i>	3
4.2.2 <i>Method</i>	3
4.3 Creating Draw-Care	4
4.4 User-testing	4
4.4.1 <i>Member checking</i>	4
4.4.2 <i>User testing</i>	4
5 Study 2 – Trial the Draw-Care Intervention	0
5.1 Participants	0
5.2 Randomisation.....	1
5.3 Interventions.....	1
5.4 Outcome measures	1
5.5 Sample size and statistical analysis	2
5.6 Qualitative analysis	2
6 Study 3 – Evaluate the cost-effectiveness of the intervention	3
7 Participant Safety and Withdrawal	0

7.1	Consent.....	0
7.2	Risk management and safety.....	1
7.3	Handling of withdrawals.....	2
7.3.1	<i>People with dementia</i>	2
7.3.2	<i>Family carers</i>	2
7.3.3	<i>Clinicians and service providers</i>	2
7.4	Replacements.....	2
7.4.1	<i>Study 1</i>	2
7.4.2	<i>Study 2</i>	3
8	Data Security and Handling.....	4
8.1	Details of where records will be kept and how long will they be stored.....	4
8.2	Confidentiality and security.....	4
8.2.1	<i>Study 1</i>	4
8.2.2	<i>Study 2</i>	4
8.2.3	<i>Study 3</i>	5
8.2.4	<i>Ancillary data</i>	5
8.3	Public availability of data.....	5
9	References.....	6

Study synopsis

Title:	Draw-Care: Using animation and digital technologies to support Culturally and Linguistically Diverse (CALD) family carers and people living with dementia
Short title:	Draw-Care
Study centres:	National Ageing Research Institute
Study aim:	The Draw-Care study aims to improve the lives of culturally and linguistically diverse (CALD) family carers and people living with dementia using animations, digital fact sheets, and a multilingual chat-bot, collectively titled “The Draw-Care Intervention”.
Primary objectives:	<ol style="list-style-type: none">1. To co-produce with CALD carers, clinicians, service providers and people living with dementia, the Draw-Care Intervention in 9 CALD languages plus English.2. To undertake a Randomised Control Trial (RCT) with 194 CALD family carers to evaluate the clinical effectiveness of the Draw-Care Intervention in reducing burden experienced by CALD family carers up to 12 weeks after receipt of the resource, relative to active control.3. To evaluate the cost-effectiveness of the intervention from a societal perspective (as compared to a control condition approximating usual care).

Design:	<p>Using co-productions methods, we will conduct three studies as below:</p> <p><u>Study 1</u>: Culturally adapt i-Support Lite by working with CALD family carers, clinicians, service providers, and people living with dementia, as well as our partners WHO, Dementia Australia, and the Federation of Ethnic Communities Council of Australia (Objective 1).</p> <p><u>Study 2</u>: Evaluate the clinical effectiveness of the Draw-Care Intervention in reducing burden experienced by CALD family carers, by undertaking a Randomised Control Trial (RCT) with 194 Arabic, Cantonese, English, Greek, Hindi, Italian, Mandarin, Spanish, Tamil, and Vietnamese-speaking carers up to 12 weeks after receipt of the resource (Objective 2).</p> <p><u>Study 3</u>: Evaluate the cost-effectiveness of the intervention from a societal perspective (Objective 3).</p>
Outcomes:	<p>Our outcomes are significant and measurable:</p> <ol style="list-style-type: none"> 1. Reductions in care burden 2. Improvements in the family carer’s mood and quality of life 3. Improvements in the quality of life for the person with dementia.
Safety considerations:	<p>Informed consent required from all participants.</p>

Glossary of abbreviations and terms

Abbreviation/term	Description
AI	Associate Investigator
CALD	Culturally and Linguistically Diverse
CarerQOL-7D	Carer Quality Of Life Seven important burden Dimensions
CES-D	Center for Epidemiologic Studies Depression Scale
CI	Chief Investigator
ED-5Q-5L	The 5-level EQ-5D version to describe and value health
eHEALS	The eHealth Literacy Scale
FECCA	Federation of Ethnic Communities Council of Australia
HREC	Human Research Ethics Committee
MRFF	Medical Research Future Fund
NAATI	National Accreditation Authority for Translators & Interpreters
NARI	National Ageing Research Institute
NHMRC	National Health and Medical Research Council
PICF	Participant Information and Consent Form
PM	Project Manager
RA	Research Assistant
RCT	Randomised Control Trial
RUD	Resource Utilization in Dementia (RUD)
UTAUT	Unified Theory of Acceptance and Use of Technology (UTAUT) questionnaire (adapted for current study)
WHO	World Health Organization
WHOQOL-Bref	World Health Organization Quality of Life
WPAI:CG	Work Productivity and Activity Impairment questionnaire as adapted for caregiving
ZBI	Zarit Burden Interview

Study sites

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1 Introduction and background

1.1 Lay summary

Dementia is a global public health priority and negatively impacts individuals affected by this disorder and their families. These effects are felt more significant in Culturally and Linguistically Diverse (CALD) families, where the majority of dementia care is undertaken at home by family carers, especially women. Carers from a CALD background are likely to have higher risks of physical and psychological distress compared to the Australian born. Besides, they often experience loss of household productivity and income due to unpaid care. CALD family carers in our current research have voiced their need for practical assistance to support their care efforts.

This project will co-produce the Draw-Care Intervention with CALD family carers and people living with dementia. The intervention will use animations, digital fact sheets, and a multilingual chat-bot. Then, we will evaluate the clinical and cost effectiveness of the Draw-Care in reducing family carer's burden and improving their mood and quality of life, and the quality of life of the person living with dementia. The project consists of three studies, over three years.

During the **first study**, we will co-design the Draw-Care Intervention, including 6 animated films, 6 digital fact sheets, and a chat-bot in 10 languages: Arabic, Cantonese, English, Greek, Hindi, Italian, Mandarin, Spanish, Tamil, and Vietnamese. The co-design process will be as follow:

1. We will develop 6 draft animation storyboards with their accompanying storyline based on the 6 components of the iSupport Lite program from WHO. This will be done via 6 online co-production workshops, 2-hour duration each, spread over 2 weeks; and qualitative interviews. Each workshop focuses on one storyboard/component of iSupport Lite. Workshops participants will be a mix of CALD carers, clinicians, and service providers from different language backgrounds. Between 7-10 people will participate in each co-production workshop (total 42-60 for 6 workshops). In addition we will interview people living with dementia (total 6-12 people). We will try to make sure that the workshops and interviews have interstate and language representation.
2. We will prepare 6 animation films, 2-3 minutes each with voiceover narration and subtitles in language. In addition, we will prepare digital factsheets synthesising the key points from each animation. Both animations and digital factsheets will be located on our website. Also, a multilingual interactive chat-bot will be integrated on the website, offering to help carers navigate to the animations, factsheets, and other resources they need.
3. Finally, we will conduct user testing of the developed Draw-Care intervention. To begin with, member-checking will be conducted with the original workshop and interview participants to ensure believability and trustworthiness. This will be done via asking participants to complete a short survey after viewing the animations. After that, the feedback from participants will be incorporated in the intervention.

The intervention will also be tested by users, including 27-45 CALD carers, using the thinking-aloud method. In this method, the carers will be asked to complete some short questionnaire online. Then they will be asked to complete tasks navigating through the Draw-Care's interface while thinking aloud to give researchers insight into their thought

processes in relation to the Draw-Care and any other feedback. In addition, carers' movements on the interface will be captured by Hotjar behaviour analytics to identify patterns of use and user behaviour. This process evaluation, in combination with the research team's observations, will be collated to finalise the Draw-Care Intervention for trial.

The **second study** will be a digital RCT (Randomized Control Trial) to evaluate our primary study aim – whether the Draw-Care Intervention reduces carer burden. The trial will involve two groups of 97 carers (194 in total), recruited through our national networks servicing Australia's CALD communities, and then randomly assigned to each group. The intervention group will access the Draw-Care Intervention for 12 weeks continuously. The control group will not access the intervention until after 12 weeks. Participants from both groups will be assessed online at three intervals, at the beginning of the trial (baseline), at 6, and 12 weeks. The assessment will involve completing questionnaires about carer burden, carer mood, quality of life of the carer and person with dementia, and productivity and activity impairment. We will then statistically analyse whether there is an improvement in performance after doing the intervention, as well as differences between the intervention and control groups. Besides, we will also interview 45-55 participants via video conferencing/phone to obtain carers' and service providers' views about the Draw-Care Intervention. The interviews will be audio-recorded, transcribed and then analysed.

In the **third study**, we will evaluate the cost-effectiveness of the intervention from a societal perspective. Apart from the questionnaires on carer burden, quality of life, we will also analyse direct costs of intervention's delivery.

1.2 Introduction

The Draw-Care project aims to improve the lives of culturally and linguistically diverse (CALD) family carers and people living with dementia using animations, digital fact sheets, and a multilingual chat-bot, collectively titled "The Draw-Care Intervention." The animated films and digital fact sheets will be based on our partner - the World Health Organization's - iSupport Lite programme.

Using co-production methods, first, we culturally adapt i-Support Lite by working with CALD family carers, clinicians, service providers, and people living with dementia, as well as our partners Dementia Australia and the Federation of Ethnic Communities Council of Australia. Then, the clinical and cost effectiveness of the Draw-Care Intervention will be evaluated in a trial with 194 Italian, Greek, Mandarin, Cantonese, Hindi, Tamil, Arabic, Vietnamese, and Spanish-speaking carers. These groups reflect Australia's top 10 established and emerging older CALD communities.

Our outcomes measurable are: (i) reductions in care burden, (ii) improvements in the family carer's mood and quality of life, and (iii) improvements in the quality of life for the person with dementia. The study's outcome will be directly disseminated to 12 Asia-Pacific nations, including India and China.

1.3 Background information

Dementia is a global public health priority World Health Organization (2012). Dementia's global prevalence grows exponentially, tripling from 46.8 million in 2015 to 131.5 million in 2050 (Prince et al., 2015). Dementia is among the leading causes of disability and dependency in older people, creating significant care needs for people with dementia, their families and carers, impacting social, health, well-being and economic dimensions (Prince et al., 2015;

World Health Organization, 2012). In 2018, dementia was estimated to cost US\$ 1 trillion worldwide, and the cost is predicted to rise to US\$ 2 trillion by 2030 (Prince et al., 2015). The catastrophic costs of long-term care drive many families of people with dementia into poverty, strain health and social systems, and are an impost on government budgets (World Health Organization, 2012).

These effects are more significant in CALD families, where the majority of dementia care is undertaken at home by family carers, especially women. Carers from a CALD background are likely to have higher risks of physical and psychological distress compared to the Australian born (Temple & Dow, 2018). Besides, they often experience loss of household productivity and income due to unpaid care (Prince et al., 2015). Supporting family and other informal carers of people with dementia to deliver and sustain high-quality, culturally appropriate care at home to improve the quality of life of people with dementia and their carers is a high priority for the Dementia, Ageing and Aged Care Mission (Dementia Australia, 2020). Over 300 CALD consumers in the NHMRC's National Institute of Dementia Research (NNIDR) CALD Research Action Plan (NHMRC National Institute for Dementia Research, 2020) and over 100 CALD family carers in our current research have voiced their need for practical assistance to support their care efforts (Brijnath et al., 2019).

Animation is a highly effective means of communicating health messages to multicultural populations (Leiner, Handal, & Williams, 2004). In our current *Moving Pictures* and *Animating for Dementia Prevention (ADAPT)* studies we use animation to convey information about dementia and the latest dementia science in an engaging, non-stigmatizing and aesthetically appealing way. These resources are targeted to CALD Australians who have difficulty accessing written information or in-person sessions because of low English proficiency, busy lives, difficulty travelling, and/or geographical isolation. Online animations overcome these barriers and capitalise on the high levels of digital inclusion in these communities (Thomas, 2019).

The 6 animated films and 6 factsheets in the Draw-Care Intervention will be based on the 6 components of the World Health Organization's (WHO) iSupport Lite practical support messages. iSupport Lite comprises easy-read tips that aim to prevent and/or decrease mental and physical health problems associated with caregiving and to improve the quality of life of those caring for people with dementia (WHO, 2021). Using iSupport Lite, carers should be able to quickly and easily avail of information they need.

iSupport Lite was developed in response to the COVID-19 pandemic and resulting breakdown of community-based care services, as well as feedback from trials of the full iSupport program in India (Baruah et al., 2021) and Australia (Xiao et al., 2021). Family carers in both trials valued the resources, but asked for shorter versions to help them quickly identify solutions for immediate problems in real time. Additionally, in the Australian pilot, 5 carers wanted iSupport to be available for CALD carers (Xiao et al., 2021). Thus, we will adapt, then animate for CALD carers the 6 key components of iSupport Lite: (1) providing everyday care, (2) ensuring continuity of care, (3) communicating effectively with the person with dementia, (4) responding to changes in the person with dementia, (5) reaching out for support, and (6) self-care (WHO, 2021). Systematic reviews have shown that culturally-adapted psychological interventions are more efficacious than non-adapted interventions (Standardised mean difference 0.72, 95% (CI), -0.94 to -0.49) (Chowdhary et al., 2014). Animations will be professionally narrated and with subtitles in 10 languages: English, Italian, Greek, Mandarin, Cantonese, Hindi, Tamil, Arabic, Vietnamese, and Spanish. These languages reflect the top 10 languages spoken by established and emerging CALD communities aged >65 in Australia (Australian Bureau of Statistics, 2016). These animations build on our established track record

of using film and digital media to raise awareness of dementia signs and symptoms, navigating the aged care system, and carers' emotional journeys in accepting dementia and their carer role.

2 Study objectives

2.1 Project aims

To improve the lives of culturally and linguistically diverse (CALD) family carers and people living with dementia using the Draw-Care or Draw-Care Intervention, which comprises animations, factsheets, and a multilingual chat-bot.

The specific study objectives are to:

- Co-produce with CALD family carers, clinicians, service providers, and people living with dementia, the Draw-Care Intervention comprising 6 animated films, 6 digital factsheets, and a chat-bot – in 10 languages providing culturally-tailored messages relating to key areas where family carers indicate they require greater information, strategies or support (Year1).
- Evaluate the clinical effectiveness of the Draw-Care Intervention in reducing burden experienced by CALD family carers (primary outcome) up to 12 weeks after receipt of the resource, relative to active control (Year 2-3).
- Evaluate the cost-effectiveness of the intervention (Year 3).

We will achieve our project aims by conducting three studies:

Study 1

Co-produce with CALD carers, clinicians, service providers and people living with dementia, the Draw-Care Intervention in 9 CALD languages plus English (Objective 1).

Study 2

Undertake a Randomised Control Trial (RCT) with 194 CALD family carers to evaluate the clinical effectiveness of the Draw-Care Intervention in reducing burden experienced by CALD family carers up to 12 weeks after receipt of the resource, relative to active control (Objective 2).

Study 3

Evaluate the cost-effectiveness of the intervention from a societal perspective (as compared to a control condition approximating usual care) (Objective 3).

2.2 Hypotheses

Our hypotheses are that:

Study 1

Dementia CALD carers, clinicians, service providers and people living with dementia will, together with the research team and industry partners, successfully co-design the Draw-Care Intervention in 9 CALD languages plus English.

Study 2

Dementia CALD family carers' burden will show a decrease at 6 weeks and 12 weeks after receiving the Draw-Care resource, when compared to active control (Access to PDF dementia information comic). This will be demonstrated by the improvement of following indicators:

- **The Zarit Burden Interview (ZBI)** (Zarit, Reever, & Bach-Peterson, 1980) (primary outcome)
- **The Center for Epidemiologic Studies Depression Scale (CES-D)** (Lewinsohn, Seeley, Allen, & Roberts, 1997) (secondary outcome)
- **The WHO Quality of Life Bref (WHOQOL-Bref)** (WHO, 1998) and the Carer Quality of Life 7 Dimension (CarerQoL-7D) (W. B. F. Brouwer, van Exel, van Gorp, & Redekop, 2006) (for a carer sub-group) (secondary outcome)
- **The Work Productivity and Activity Impairment scale (WPAI:CG)** (Giovannetti, Wolff, Frick, & Boult, 2009) (secondary outcome).

Study 3

The Draw-Care Intervention will be found to be cost-effectiveness from a societal perspective, comparing to a control condition approximating usual care (secondary outcomes).

2.3 Theoretical framework

Our intervention is guided by the stress-health model (R. Schulz, 2004), where the goal is to change the nature of specific stressors, its appraisal, and/or the carers' response. The stress-health model has been used in dementia care interventions targeted at CALD participants. It is an effective way to understand determinants and levers of change. Using this model, our intervention seeks to create change through cognitive reframing, problem solving, and emotional regulation (Richard Schulz, 2000). We will do this by ensuring the intervention focuses on imparting knowledge and skills on dementia care, problem-solving, and stress management (see Fig.1).

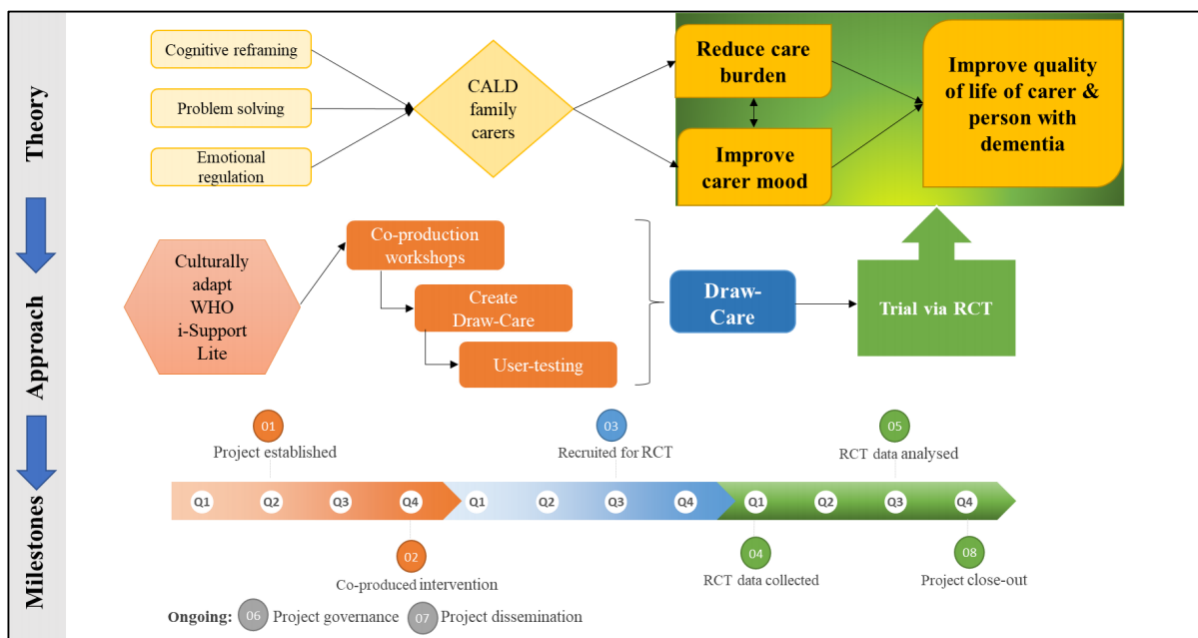


Figure1: Project theory, approach, and milestones.

3 Project governance and steering group

A project Executive Team will be formed, consisting of Chief Investigators (CIs), Associate Investigators (AIs) and Project Manager (PM). The Executive Team will be responsible for implementation of the project and all related activities. The Project Executive Team will meet every second month.

A project Stakeholder Advisory Group will be created to provide oversight of the research, offer guidance about the appropriateness and applicability of the interventions, and ensure that the intervention aligns with concurrent and planned policy and regulatory initiatives. The group will be co-chaired by CIs Hlis and Brijnath, and comprise representation from CALD carers, services, policy makers, peak bodies and the Project Manager. The Advisory Group will meet twice a year, including to ratify the Draw-Care Intervention pre-RCT and for a Stakeholder Forum towards the end of the project.

The Implementation Team, consisting of the Project Manager and the Research Assistant (RA) will meet monthly.

The project brings together an interdisciplinary team of recognised researchers, consumers, and clinical leaders who are highly regarded amongst their peers nationally and internationally. It has funding from the Medical Research Future Fund (MRFF) and in-kind support from the Department of Mental Health and Substance Use, WHO; Dementia Australia; and the Federation of Ethnic Communities Council of Australia (FECCA).

4 Study 1 – Co-produce the Draw-Care Intervention

Study 1 will use the 6 components of the iSupport Lite program and apply a co-produced approach to develop an evidence-based, co-developed and user-tested Draw-Care Intervention. The intervention includes 6 animated films, 6 digital fact sheets, and a chat-bot in 10 languages: Arabic, Cantonese, English, Greek, Hindi, Italian, Mandarin, Spanish, Tamil, and Vietnamese.

Study 1 will therefore involve the following stages:

- Co-production workshops
- Interviews with people with dementia
- Creating the Draw-Care intervention
- User-testing

4.1 Co-production workshops

This stage recognises the importance of working with CALD carers, clinicians, and service providers to better understand their mutual needs and expectations, and thereby develop an intervention that is accurate, effective and appropriate for the users. Co-design emphasises the importance of lived experience, collaboration, and participation of all stakeholders in the research (Borgstrom & Barclay, 2019). Using a co-design technique ensures that the Draw-Care Intervention will genuinely meet the needs of end-users, and the result will be an intervention more relevant to all stakeholder due to the fact that they have been involved in the design and evaluation of it.

Workshops will be conducted online (e.g. via MS Teams) to minimize the risk of the project being delayed by any COVID-19-related restrictions. Online workshops also overcome the need for participants to travel to a central location, which enables better access for some participants.

4.1.1 Workshop participants and recruitment

We will not segregate participants by CALD status. Rather, we will work with a heterogeneous mix of CALD carers, clinicians, and service providers to ensure the accuracy of information, effectiveness of the storyline, and appropriateness of the content. Between 7-10 people will participate in each co-production workshop (total 42-60 for 6 workshops). We will try to make sure that the workshops have interstate representation and a mix of CALD carers, clinicians, and service providers.

To participate in the co-production workshops, participants must:

- Be either CALD carers caring for a person with dementia or a clinician/service provider working with CALD carers;
- Be from a non-English speaking background and speak one of the following languages at home: Arabic, Cantonese, Greek, Hindi, Italian, Mandarin, Spanish, Tamil, and Vietnamese;
- Also speak English;
- Be able to provide consent and participate in workshops; and
- Have access to an internet connection and device such as PC, laptop or tablet/smartphone.

Participants will be recruited via convenience and snowball sampling by the NARI research team. NARI has contact with carers, clinicians, and service providers for people living with dementia from CALD communities, who were participants in the *Moving Pictures* project

(Curtin University HRE2017-0758). NARI researchers will approach some of these contacts directly and ask for referrals. We will also issue a call for expressions of interest through the regular *Moving Pictures* newsletter, on social media and via professional networks.

The PICFs (Participant Information and Consent Forms) will be developed in English. Any recruits will be required to review and complete a Draw-Care written consent form online prior to the workshops.

4.1.2 Method

Workshops will be facilitated using the nominal group technique, which is designed to democratically elicit ideas and widely used in health and education research (McMillan et al., 2014). The nominal group technique comprises group members first working alone, then sharing ideas, group discussion, voting, and ranking.

Use of the nominal group technique will minimise potential power differentials between carers and providers as each participant gets one vote, ensuring all voices count. To minimise burden, participants will be able to opt-in to workshops most relevant to them.

Participants will connect to the workshops online (e.g. via MS Teams). We will utilize the inbuilt recording function to record workshops. Research team members will also be present throughout the workshops, taking field notes of the conversations, and recording the outcomes of activities. Following the workshops, all records will be analysed by members of the research team for the purpose of designing the animations. Workshop recordings may be transcribed, depending on project resources, and requirements. All notes, recordings and transcriptions will be subject to the project's data security and handling policy.

4.1.3 Workshop schedule

The co-production will comprise six two-hour workshops, spread over 2 weeks. Each workshop focuses on one storyboard/component of iSupport Lite. The workshop agendas will be scheduled as follows:

Workshop 1: Reach out for support

Workshop 2: Take care of yourself

Workshop 3: Ensure continuity of care

Workshop 4: Respond to change

Workshop 5: Be flexible

Workshop 6: Communicate effectively

4.2 Interviews with people with dementia

The qualitative interviews aim to understand the specific needs of CALD people living with dementia to make sure the Draw-Care intervention is accurate, effective and appropriate for them. We will interview between 6-12 people living with dementia from CALD backgrounds about their feedback on the 6 components of the iSupport Lite program and expectation from the animations and chat-bot. We will try to make sure that the interviews have interstate and language representation. Interview data, together with co-design workshop data will be fed into our design of the Draw-Care intervention.

We will ensure meaningful inclusion of CALD people with dementia by recruiting participants who still have cognitive capacity and are able to consent, briefing them in advance, and giving them extra time to verify the final outputs. Our process for consenting people with dementia is outlined in Section 8.1.

4.2.1 Interview participants and recruitment

To participate in the qualitative interviews, participants must:

- Have been diagnosed with any type of dementia;
- Be from a non-English speaking background and speak one of the following languages at home: Arabic, Cantonese, Greek, Hindi, Italian, Mandarin, Spanish, Tamil, and Vietnamese;
- Also speak English;
- Be able to provide consent and participate in an interview (see section 7.1 for details); and
- If participating in online interview, the participant will need to have access to an internet connection and an appropriate device e.g. laptop, PC, tablet or smartphone.

Participants will be recruited via convenience and snowball sampling by the NARI research team. NARI has contact with carers and service providers for people living with dementia from CALD communities, who were participants in the *Moving Pictures* project (Curtin University HRE2017-0758). NARI researchers will approach some of these contacts directly and ask for referrals. We will also issue a call for expressions of interest through the regular *Moving Pictures* newsletter, on social media and via professional networks.

The PICFs will be developed in English. Any recruits will be required to review and complete a Draw-Care written consent form online prior to the interview.

4.2.2 Method

Once consent has been obtained, interviews will take place either in-person, over e.g. MS Teams, or over telephone and will be audio-recorded. The interviews will be short and flexible - up to 30 minutes in duration – and will take into the needs of the person with dementia and the availability of any support they require. People with dementia may choose to complete the interview with a family carer or support person present. However, they will not be required to have a carer or support person present if they do not wish to have one.

People with dementia will be given adequate time to review the 6 components of the iSupport Lite program before the interviews. Interviews will consist of questions about the participants' feedback on the 6 components of the iSupport Lite program and expectation from the animations and chat-bot, for example, what they like most from the 6 components and want to replicate in the animations, what further information or images they want to add in, and what they expect from the animations and chat-bot.

We recognize there is a potential difficulty for people living with dementia who are not able to speak English fluently. For this reason, participants can choose to complete the interview with a family carer or support person present who is good at English.

Following the interviews, all records will be analysed by members of the research team for the purpose of designing the animations. Interview recordings may be transcribed, depending on project resources, and requirements. All notes taken during the interviews, recordings and transcriptions will be subject to the project's data security and handling policy.

4.3 Creating Draw-Care

The research team will use ideas and feedback generated during the six co-design workshops and interviews to develop the Draw-Care intervention. Six animation films, 2-3 minutes each, will be prepared with our animation team – Curve Tomorrow. Curve Tomorrow has a strong history of solving healthcare problems using health technology and is experienced in working with clinical and research teams to validate, build, integrate and commercialise technology solutions.

Once the 6 animations have been created, voiceover narration and subtitles in language will then be inserted in the 9 languages (Hindi, Tamil, Cantonese, Mandarin, Arabic, Spanish, Greek, Italian, Spanish & Vietnamese) plus English. Digital factsheets synthesising the key points from each animation will also be developed. Animations and digital factsheets will be located on the Moving Pictures mobile-optimised website.

A multilingual, interactive chat-bot will also be integrated on the website, offering to help carers navigate to the animations, factsheets, and other resources they need. These chat-bots will be developed by CI Wickramasinghe’s team. In this way, our chat-bots will not only record and support the behavioural changes our intervention enables, they will also act as ‘virtual navigators’.

4.4 User-testing

4.4.1 Member checking

Once the Draw-Care Intervention is developed, it will be member-checked with the original workshop participants (42-60 people) and interviewees (6-12 people) to ensure believability and trustworthiness. Participants will be asked to complete a short survey after viewing the animations. Guided by the Unified Theory of Acceptance and Use of Technology (UTAUT) (Venkatesh, Morris, Davis, & Davis, 2003), the survey will assess direct determinants of intention such as performance expectancy (the degree to which using the animations will enhance care), effort expectancy (the degree of ease associated with accessing the animations), social influence on intervention uptake, and facilitating conditions. After that, the feedback from participants will be incorporated in the intervention.

The Draw-Care Intervention will also be user-tested by 27-45 CALD carers as part of a process evaluation.

4.4.2 User testing

4.4.2.1 Participants and recruitment

27-45 CALD carers (3-5 carers for each language) will be recruited for user testing via convenience and snowball sampling by the NARI research team. We will also issue a call for expressions of interest through the regular *Moving Pictures* newsletter, on social media and via professional networks.

To participate in the user testing, participants must:

- Be CALD carers of people with dementia;
- Be from a non-English speaking background and speak one of the following languages at home: Arabic, Cantonese, Greek, Hindi, Italian, Mandarin, Spanish, Tamil, and Vietnamese;
- Also speak English;

- Be able to provide consent and participate in user testing; and
- Have access to an internet connection and an appropriate device e.g. laptop, PC, tablet or smartphone.

The PICFs will be developed in English. All participants will be required to review and complete a Draw-Care written consent form online prior to participating in the user-testing. Participants will receive \$30 gift card for their participation.

4.4.2.2 Methods

The user-testing will be conducted online (eg. via MS Teams) using the testing methods described by (Joe, Chaudhuri, Le, Thompson, & Demiris, 2015) for use in older people and care givers. This method uses Instant Data Analysis (IDA) to identify and rank usability issues among health information technologies.

Participants will be invited to an online evaluation session with two researchers (a facilitator and an observer/note taker). Prior to the session, participants will be asked to complete a short questionnaire about demographics and the eHealth Literacy Scale (eHEALS) (Norman & Skinner, 2006) via an online survey.

At the session, the researcher will briefly introduce the Draw-Care resource and a second researcher will take notes during the user test. The participant will complete different representative tasks on the site, such as identify the animations and factsheets in the participant's language/culture with/out the chat-bot's help, identifying a material of interest with/out the chat-bot's help, and watching the animations and reading the factsheets of interest. The participant will be asked to share their screen and complete tasks navigating through the Draw-Care's interface while thinking-aloud. This will help researchers to gain insight into participants' thought processes in relation to the Draw-Care and any other feedback (Joe et al., 2015). During the session the movements on the site will be captured by Hotjar behavior analytics and user feedback service which allows to identify patterns of use and user behaviour on site. Each session will be of an estimated duration of 20-30 minutes and several sessions will be hosted across one day.

Sessions will be analysed via IDA by initial brainstorming occurring at the end of each day of testing to identify usability issues observed and the session data captured by Hotjar. Issue will be ranked as critical (unable to complete task), severe (significant delay or frustration in task completion), or cosmetic (minor issues). Once all sessions are completed, the issues will be inductively separated out and aggregated into larger themes using affinity mapping - a process in which ideas or insights are organised into overarching themes (Joe et al., 2015). At the end of this process, the major themes of the Draw-Care's usability issues will have been identified as well as users' suggestions on how to improve the site. Demographic data, eHEALS scores and technology specific scores will undergo data analysis to gain insights into e-health literacy levels of participants, technology usage and sample demographics. SPSS Ver. 27 will be employed to analyse quantitative data. The usability issues and major themes identified will be used by the animation team to refine the Draw-Care intervention for trial.

5 Study 2 – Trial the Draw-Care Intervention

Study 2 will be a digital Randomized Control Trial (RCT), conducted to evaluate whether the Draw-Care Intervention developed during Study 1 fulfils our primary project aim of improving the lives of CALD family carers and people living with dementia. The trial will be a 12-week wait-list RCT with a parallel design, conducted with a target of 194 carers in equal allocation (97 in the intervention group and 97 in the control group). We will endeavour to achieve a balanced sample of carers from different language backgrounds.

Outcomes will be assessed at baseline (t_0), 6 weeks (t_1) and 12 weeks after baseline (t_2). The baseline covariates will include characteristics of carers (age, sex, ethnicity, location, educational and economic attainments, country of birth, English proficiency, and relationship with the care recipient) and care recipients (age, sex, country of birth, English proficiency, dementia duration, type, and severity, and behavioural and psychological symptoms). Where relevant, we will also collect information on native language proficiency, years lived in Australia, and visa on entry to Australia (e.g. to distinguish economic from humanitarian migrants).

Participants will receive \$20 gift card for each complete assessment (\$60 in total).

5.1 Participants

194 carers will be recruited using the National Ageing Research Institute's CALD Research Engagement Network (CALD-REN), which is a database of >1000 CALD community groups across Australia. Recruitment is further ensured by existing relationships built during current and previous research in these CALD communities including with carer support groups run by Dementia Australia, So-Wai Seniors Wellness Centre, SEWA Australia Seniors Services, the Australian Vietnamese Women's Association, Multicultural Services Centre of Western Australia, Co.As.It Italian Aged Services and Community Care, and Pronia Greek Welfare. Collectively, these organisations constitute a national network servicing Australia's CALD communities. Potential participants will be sent an invitation letter by these partners. Those who are interested will be screened by the study Project Manager (CI Antoniadou)/study Research Assistant (RA1). Where relevant, a telephone interpreter accredited by the National Accreditation Authority for Translators & Interpreters (NAATI) will facilitate recruitment and screening.

To be eligible, carers must be:

- Be informal carer of person living with dementia from a CALD background, aged 18 and over;
- Be from a non-English speaking background and can speak one of the following languages: Arabic, Cantonese, Greek, Hindi, Italian, Mandarin, Spanish, Tamil, and Vietnamese;
- Also speak English;
- Be able to provide consent and participate in the trial;
- Have access to an internet connection and appropriate device such as laptop, PC, Tablet or Smartphone; and
- Not participated in study 1 (in either the workshops or the user-testing).

The PICFs (Participant Information and Consent Forms) will be developed in English. In the PICFs, we will mention that the trial includes two parts: quantitative assessments and qualitative interviews; and participants can voluntarily consent for their participations in the

quantitative assessments only or both quantitative assessments and qualitative interviews. All participants will be required to review and complete the Draw-Care PDCF online (via REDCap), or can return a signed consent form to the research team via email. If requested, the team can also dispatch a hardcopy of the PDCF and Reply-paid envelope and participant can return the consent form by mail. Written consent will be obtained prior to data collection.

5.2 Randomisation

After completion of baseline questionnaires, carers will be randomised separately for each Draw-Care language version to either intervention or waiting list control groups (1:1 ratio). This is done separately for each of the 9 CALD groups to assist with creating balance in the intervention/control arms. Block randomisation using blocks sized four will be performed to ensure equal allocation of participants into control and intervention groups throughout the recruitment period. A clinical trials service will undertake randomisation.

Carers will be randomised into:

- An intervention group (n=97) who will use the animations for 12 weeks immediately following the randomisation.
- A wait-list control group (n=97) who will receive access to the animations 12 weeks after randomisation.

To minimise performance bias, a benign deception will be applied: all participants will be informed that there are two components to the intervention they will receive, that the order in which they receive these interventions is randomised, and that we want to understand the effects of each component. They will receive the first component upon completion of baseline assessment (intervention/active control) but will not receive access to the second component until they have completed the 12-week assessment. During this time, participants will also be asked not to discuss the intervention with anyone. The assessor (RA2) will be also be blinded. After 12 weeks, all participants will be given access to the Draw-Care intervention and online comic on dementia.

5.3 Interventions

Following informed consent, carers in the intervention arm will receive a link to the Moving Pictures website and a username/password to access the Draw-Care Intervention, which they can access for 12 weeks immediately after randomisation. After logging in and prior to accessing the animations, the chat-bot can help them identify and prioritise their needs. Animations will then be presented to them in order of their priorities. This technique ensures the intervention is tailored to their needs. As a booster, all participants will also receive a monthly email/phone text from the team and a reminder call to complete their assessments to sustain intervention engagement, which is a risk to any digital trial.

During the 12 week assessment period, carers in the active waitlist control group will receive access to electronic dementia information comic in their language of choice. They will be informed that they will receive access to the second component of the intervention (Draw-Care) after they have completed the 12 week assessment. Following their assessment, all wait-list carers will have access to the Draw-Care intervention.

5.4 Outcome measures

- The primary outcome measure is carer burden as measured by the Zarit Burden Interview (ZBI).

- Secondary outcomes are:
 - Carer mood as measured by the CES-D (Lewinsohn et al., 1997),
 - Quality of life of the carer and the person with dementia as measured by the WHOQOL-Bref (WHOQOL Group, 1998) and of a sub-group of carers using the CarerQoL-7D (W. B. F. Brouwer et al., 2006), and
 - Productivity and activity impairment as measured by WPAI:CG (Giovannetti et al., 2009).
 - Resource Utilization in Dementia (RUD) (Wimo et al., 2013)

Validated, translated versions of the ZBI, CES-D, WHOQOL-Bref and WPAI are already available in all 9 languages and English. The CarerQoL is currently available in Italian and Spanish and will be collected only in these language groups to evaluate concordance between directly elicited CarerQoL utilities and EQ-5D-5L utilities mapped from WHOQOL-Bref data (Wee, Yeo, Chong, Khoo, & Cheung, 2018). We expect, however, that participants will complete outcome measures in English as English is an inclusion criteria. Should the need arise for materials to be provided in language, we will organise this with participant, and translated documents will be submitted for ethical approval.

These measures will be collected online (via REDCap) at baseline, 6 and 12 weeks.

5.5 Sample size and statistical analysis

ZBI is our primary outcome measure and is used for the power calculation. Based on the normative data from carers of people with dementia (Zarit et al., 1980), we expect an effect size (Cohen *d*) of 0.40 measured between baseline and the 12 week endpoint. Assuming an alpha of .05 and a statistical power (1-beta) of .80 in a one-tailed test, we will need 78 respondents in each of the conditions, resulting in a total of 156 participants. Calculation of the sample size was carried out with Stata V16. Assuming 25% attrition the total sample is 194 participants. To evaluate our primary outcome, we will use mixed effects generalised linear regression. Random effects will account for repeated measures from participating carers. Time-point (baseline, 6wks and 12wks) and intervention/control group will be specified as fixed. Other independent variables will be considered for inclusion in the model as they may influence the primary outcome and require adjustment for confounding (e.g. age, sex, ethnicity, location, country of birth, English proficiency, and relationship to person with dementia).

Fidelity/adherence data will be derived from analytics, which will examine participant's hours of viewing, completeness of viewing of animations, frequency/timing of viewing, and interactions with the chat-bot. Acceptability of the intervention is pre-specified as >70% of participants rating the intervention 'completely acceptable'.

5.6 Qualitative analysis

Diverse views about the Draw-Care intervention will be captured using a bespoke semi-structured questionnaire. A cross-section of 45-55 participants will be video/phone interviewed by CI Gilbert. Interviewees will include diverse study participants (intervention/comparator; not/completed; intervention un/acceptable; 5 people/language group). Interviews will be audio-recorded and professionally transcribed. Thematic analysis will be conducted by GI Gilbert, and data will be managed using NVivo 12. A preliminary coding schedule will be devised and then verified by other CIs. Emergent themes will be iteratively discussed by the research team, and a final determination of themes will be reached by team consensus. Interview data will help us understand differences between CALD groups and barriers/facilitators to uptake.

6 Study 3 – Evaluate the cost-effectiveness of the intervention

In Study 3, we will conduct trial-based economic evaluations of the cost-effectiveness of the intervention from a societal perspective (as compared to a control condition approximating usual care). In line with the main analysis, the primary outcome for the trial-based analysis will be carer burden as measured by the ZBI at 6- and 12-weeks. The secondary outcome for the economic evaluation will be quality-adjusted life-years (QALYs) in both carers and patients, calculated based on baseline, 6 week and 12 week data using EQ-5D-5L utilities mapped from WHOQOL-Bref data (Wee et al., 2018). Supplementary analyses will be conducted in the subgroup for which we have CarerQoL (W. B. F. Brouwer et al., 2006) utilities, calculating patient QALYs using mapped EQ-5D-5L utilities and calculating carer QALYs using CarerQoL utilities. Treatment effects with respect to the ZBI will be estimated as per the main effectiveness analysis. Treatment effects with respect to total QALYs to 12 week follow-up will be estimated using one-part generalized linear models (GLM); controlling for carer and patient WHOQoL-Bref scores at baseline and specifying appropriate variance and link functions (Glick, Doshi, Sonnad, & Polsky, 2014).

Direct costs of delivering the intervention and control conditions will be calculated based on administrative records and fidelity/adherence data - Resource Utilization in Dementia (RUD) (Wimo et al., 2013). Health service utilisation for both the carer and patient within the trial period will be calculated based on carer self-report at 6 and 12 weeks. Productivity gains/losses will be calculated using the friction cost approach (Werner B. F. Brouwer & Koopmanschap, 2005) based on WPAI:CG data for each carer at baseline, 6 and 12 weeks. Base-case analyses will exclude productivity gains/losses due to the risk of double-counting (Shiroiwa, Fukuda, Ikeda, & Shimozuma, 2013) but we will conduct supplementary analyses to evaluate the potential for bias due to separate inclusion/exclusion of productivity gains/losses. Given the likely structure of our data and the advice of Buntin and Zaslavsky (Buntin & Zaslavsky, 2004), treatment effects with respect to total cost will be estimated using a one-part GLM models with gamma variance function and a log link (rather than transformed OLS or two-part models); controlling for patient and carer characteristics at baseline. Results will be expressed as (i) cost per point improvement on the ZBI at trial end, and (ii) cost per QALY gained. We will summarise sampling error and parameter uncertainty using the bootstrap acceptability method to calculate confidence intervals and generate cost-effectiveness acceptability curves (Glick et al., 2014).

7 Participant Safety and Withdrawal

7.1 Consent

Consent

Individual consent will be required from all participants. Consent from third parties and waiver of consent will not be sought.

Gathering consent from participants living with dementia

Consistent with NHMRC's ethical guideline 4.5.3 'Justice' (NHMRC, 2018), NARI respects "the right of people with a cognitive impairment, an intellectual disability, or a mental illness ... to participate in research, and to do so for altruistic reasons."

The research staff who makes initial contact with participants during recruitment will be trained to recognise signs that the person does not fully understand the implications of participating in research. For example, the potential participant may think they are receiving a service from NARI or they may not be able to sufficiently orient themselves to time and place when discussing study procedures.

Capacity to provide informed consent will be determined by whether the potential participant:

- Understands the nature of the research and their participation in the research.
- Appreciates the consequence of their participation.
- Shows the ability to consider alternatives including the option to not participate; and
- Shows the ability to make a reasoned choice.

Written and verbal techniques will be used to communicate the details of the research, and the potential participant will be asked to explain the details back to the researcher. This approach is recommended by the Dementia Collaborative Research Centres as cognitive decline can be specific to one or more cognitive processes and a general cognitive screen may not be the best way to judge a person's capacity to give consent to participate in research.

Researchers will follow the 'Decision Tree for Respecting Dissent and Seeking Assent for Dementia Research' (Figure 2) (Black, Rabins, Sugarman, & Karlawish, 2010) throughout recruitment and interviews with participants living with dementia (Decision tree available online: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2811536/figure/F1/>).

If the researcher thinks that capacity is impaired and informed consent is not valid, then the potential participant will be politely dissuaded from participating in the study and offered instead to be put on the NARI mailing list to receive a quarterly newsletter. This approach is considered less invasive than conducting a formal cognitive test with someone who may not have capacity to consent to the test, or involving the potential participant's medical practitioner.

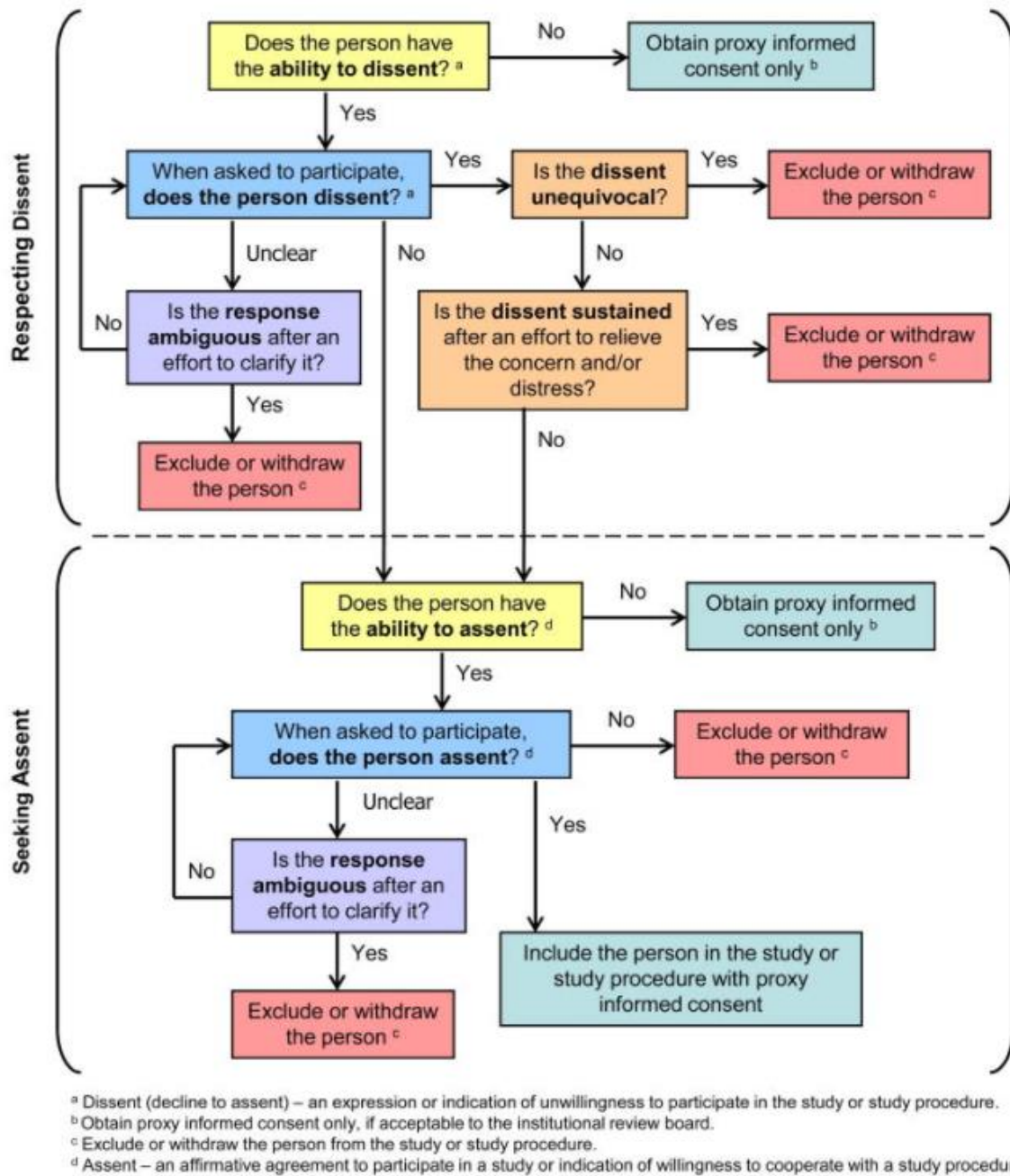


Figure 2. Decision Tree for respecting dissent and seeking assent for dementia research (Black et al., 2010)

7.2 Risk management and safety

There are no obvious disadvantages or risks associated with the participation of subjects in this study. However, participants with cognitive impairment may have increased susceptibility to some forms of discomfort or distress. The research team have experience in working with people with cognitive impairment on previous research projects. Every effort will be taken to ensure these risks are mitigated as much as is possible. The research staff will be observant to the impact of information on the potential participant during interviews, providing appropriate

rests, involving people familiar to the potential participant and ceasing any subjectively distressing interaction in a timely manner.

The potential risks will be reduced by the research team stressing that participation is strictly voluntary, and the participant can withdraw at any time without negative repercussions. The informed consent process will also highlight the nature of the study and the types of questions that will be asked.

If by taking part in this project, the participants suffer any injuries (including but not limited to physical or psychological distress) or complications as a result of this research project, the participants will be encouraged to contact the study team as soon as possible and they will be assisted with arranging appropriate treatment. If they are eligible for Medicare, they can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital. Participants may also be provided with information and contact details for free mental health services such as Beyond Blue or Lifeline.

Whether clients, family carers, clinicians, or interpreters take part in this research project, or not, will not have any bearing on their current or future relationship with service providers, the research team or any of the participating or supporting organisations.

7.3 Handling of withdrawals

For participants who wish to withdraw after data has been collected, the data collected up to that time will form part of the research project results. Participants will be informed of this at the time of consent, on their PICFs.

7.3.1 People with dementia

Participants may withdraw from the interviews at any time. If they consent to participate but change their mind and do not wish to continue their involvement, the decision will be respected, and a replacement sought. People with dementia are not part of study 2 or 3.

7.3.2 Family carers

Participants may withdraw from the workshops, member checking, user testing, RCT and interviews at any time. If they consent to participate but change their mind and do not wish to continue their involvement, the decision will be respected and a replacement sought, if no data has been collected.

7.3.3 Clinicians and service providers

Participants are free with withdraw at any time from Study 1, with no effect on their relationships with the researchers or their employers. If they consent but then change their mind, the decision will be respected, and a replacement sought, if no data has been collected. Clinicians and service providers are not part of Study 2 and 3.

7.4 Replacements

7.4.1 Study 1

If there is time to organize a replacement, then the withdrawn participant will be replaced. If workshop participants withdraw on the day of the workshop, then no replacement will be made.

7.4.2 *Study 2*

If there is time to organise a replacement then the withdrawn participant will be replaced, up until the end of the first data collection point (baseline). As our study design requires 194 (97/97) participants to power study, our target of 156 (78/78) allows for some drop-out. However, if we anticipate that the target of 156 will not be reached, we may continue recruiting participants after the end of the first data collection point.

8 Data Security and Handling

8.1 Details of where records will be kept and how long will they be stored

Any information obtained for the purpose of this research project that can identify participants will be treated as confidential and securely stored. It will be disclosed only with the participant's permission, or as permitted by law. Only members of the research team will have access to potentially identifying information. Industry partners or funding partners will only have access to de-identified aggregate project data.

The Project Lead Investigator A/Prof Brijnath has a conjoint position at Curtin University and NARI. All digital data will be stored in a password-protected folder located on a secure file server, which is located at the NARI premises, and will also be securely stored on Curtin University drives. A database of information will be created that will be used for this project only. The data will be kept securely at these locations for seven (7) years from the date of the last publication after which it will be destroyed.

8.2 Confidentiality and security

Participant confidentiality will be maintained along with the principles of Good Clinical Practice Guidelines (GCRP). No participant will be identifiable by name in any publications/presentations arising from the study. Data entry will be undertaken using a unique code number to identify participants. The code number key will be stored separately and only be accessible to the investigators of this study. Data collected will be entered directly into a secure electronic database and will be considered as source data. In any publication and/or presentation and data transferred overseas, information will be provided in such a way that participants cannot be identified. Hard copy data will be stored in locked filing cabinets at NARI. Electronic backups and all other electronic data will be stored in password protected electronic database in a de-identified format at Curtin University and NARI. Note that we may not be able to guarantee confidentiality in workshop discussions, due to the nature of group work.

8.2.1 Study 1

Interviews and workshops will be recorded using online platform, e.g. MS Teams's inbuilt recording function or audio-recorders. Recordings will be transcribed, and then checked and de-identified by the research team. All recordings and transcripts will be stored electronically at NARI and Curtin University. If any notes taken by researchers during the workshops contain identifying information about participants, they will be stored in locked filing cabinet on NARI premises. Only de-identified data will be reported on.

8.2.2 Study 2

Participant details and covariates, including characteristics of carers (age, sex, ethnicity, location, educational and economic attainments, country of birth, English proficiency, and relationship with the care recipient) and care recipients (age, sex, country of birth, English proficiency, dementia duration, type, and severity, and behavioural and psychological symptoms), will be gathered directly from participants by the research team. Individual assessments scores will be collected electronically and stored at NARI and Curtin University. These files will be password protected. Participants will be provided access to electronic versions of data collection tools to complete at each time points via REDcap. NARI researchers will check data to ensure participants are not personally identifiable. This de-identified data

will then be made available to other project partners for analysis and also saved on Curtin University drives.

8.2.3 *Study 3*

The same process for Study 2 will apply to Study 3.

8.2.4 *Ancillary data*

Audio and video data (e.g. workshops) will be stored on NARI's and Curtin University's secure, password-protected server. Confidentiality of audio data will be assured as each audio file will be labelled with a unique code number.

8.3 **Public availability of data**

Only aggregate and/or de-identified data will be publicly available on request. Only aggregate and/or de-identified data will be published.

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