EVIDENCE-BASED PROGRAMS TO IMPROVE THE WELLBEING OF PEOPLE WITH DEMENTIA AND THEIR CARERS: IMPLEMENTING COPE IN THE AUSTRALIAN HEALTH CONTEXT

THE COPE PROJECT

PROTOCOL

CONFIDENTIAL

STATEMENT OF COMPLIANCE

This document is a protocol for a clinical research study. The study will be conducted in compliance with all stipulations of this protocol, the conditions of 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)

PROTOCOL SYNOPSIS

Title	Evidence-based programs to improve the wellbeing of people with dementia and their carers: Implementing COPE in the Australian health context
Objectives	i. To identify the facilitators and barriers that will impact on uptake of COPE include organisational, social and professional factors. ii. Identify a team of change champions, including key senior OT and nurses who will help drive the implementation and determine how to mobilise this into a network of ongoing support and dissemination. iii. Understand the evidence-practice gap via a case note audit to determine current occupational therapy practice. iv. Understand current practice from professionals' perspective via interviews with health professionals and service managers. v. Understand the perspectives of people with dementia and their families and carers via interviews. vi. Examine the organisational context via content analysis of documented organisational procedures including referral mechanisms vii. Determine the effectiveness of the intervention as assessed by measures of engagement of people with dementia and caregiver wellbeing. viii. Determine the acceptability of the intervention through examination of the experience of integrating the intervention, the engagement of champions, carer attitudes to dose and engagement of participants. ix. Determine the degree of adoption of the intervention evident as measured by service provider staff satisfaction with the amount, content and format of training. x. Measure adherence and outcome indicators of fidelity. xi. To describe and compare organisational influences on uptake, integration and routinisation. xii. To determine through health-economic evaluation, the cost of providing the intervention and whether resource utilisation changes following intervention.
Study Design	Process evaluation. This translational implementation research project aims to understand what, why and how the COPE intervention will work in the Australian setting within existing programs and resources. See **Figure 1** for diagram of study.
Planned Sample Size	Phase 1: • Case note audit of 100 notes (20 each from 2 NSW sites and 30 each from two SA sites) to gauge current practice

	• Structured interview with up to 30 health professionals (occupational therapists, nurses, managers) employed at participating sites • Content analysis of current organisational structure of all participating sites Phase 2: • Up to 40 nominated therapists employed at participating organisation sites will undertake training and participate in mentoring and fidelity checks. Phase 3: • 103 dyads (person with dementia and care giver) will complete pre- and post-intervention questionnaires • 10 of these dyads (person with dementia and care giver) will be invited to participate in an interview regarding their experience of participating in the COPE program. • 15 participating therapists will be interviewed regarding their experience with COPE • All COPE therapists will complete an implementation determinants questionnaire
Selection Criteria	Phase 1: • De-identified client case notes will be provided by participating organisations. • Purposeful sampling will be used to recruit health professionals to be interviewed. All will be employed by participating organisations (including occupational therapists, nurses, and management staff). Phase 2: • COPE therapists will be nominated by their employing organisation and invited to participate. Eligible therapists are already employed to provide occupational therapy services to people living with dementia in the community. Phase 3: • Participant dyads will be clients of Occupational Therapists from various organisations recruited and trained by the COPE team. **See section 5.2** for eligibility criteria. • All potential participant dyads will be made aware that they can receive the COPE intervention from their Occupational Therapist without participating in the questionnaires or interview, and that this will in no way affect the service they receive from their Occupational Therapist.

	• 15 COPE therapists will be interviewed about their experience with COPE. Purposeful sampling will be used to recruit these therapists.
Study Procedures	This study consists of three main phases: 1. Planning and Preparation Phase This phase involves in-depth relationship building and exploration of preparation for change. The aim of this stage of the research is to identify the facilitators and barriers that will impact on uptake of COPE. This will include organisational, social and professional factors. Activities will commence with facilitated group discussions with the collaborators who will also act as the reference group for the project. 2. Implementation Phase We will work closely with Professor Laura Gitlin and her team, the primary developers of the COPE program, identifying the mutable and immutable aspects which are adaptable or not when implemented in varying contexts. Training and manuals will be refined for the Australian context and implemented with participating therapists. 3. Evaluation Phase Evaluation will be conducted using both a process evaluation and an economic evaluation. This will determine if we can deliver the COPE intervention as intended and identify differences between and similarities within the three delivery health contexts. We will evaluate the feasibility of implementing within the different contexts and the acceptability of the program to the consumer dyad, health professional and organisation. We will explore organisational challenges in enabling training and support as therapists gain mastery and new skills. We will determine the cost of implementing the program using therapist logs to cost service delivery.
Statistical Procedures	• Case Audit data will be entered into SPSS and summarised descriptively • The DIBQ will be coded in SPSS and summarised descriptively. • Responses to participant dyad survey data (pre and post measures) will be coded in SPSS, analysed descriptively and compared within and across groups. Data from the resource utilisation in dementia questionnaire (RUD Lite) will be used to

	cost both formal and informal services. • All interviews will be audio-recorded, transcribed verbatim and entered into QSR NVivo. Thematic analysis (developing codes) will identify patterns within the study group. A combination of inductive and deductive coding will be used.
Duration of the study	42 Months (January 2016-June 2019)

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1.3 Statistician (if applicable)

Statistical support is available at both the University of Sydney and Flinders University as required.

1.4 Funding and resources

All funding is provided by a National Health and Medical Research Centre Cognitive Decline Partnership Centre (CDPC) research grant.

2. INTRODUCTION AND BACKGROUND

2.1 Background Information

Functional decline is one of the core features of dementia (1). As the disease progresses, the person with dementia becomes increasingly dependent and requires more assistance to perform activities of daily living. Functional decline is associated with reduced quality of life in the person with dementia, considerable impact on carers and the health and social care system, high health care costs and institutionalisation (2-4).

Most people with dementia live in the community and approximately 9 in 10 people rely on informal care from a family member, friend or neighbour. Caring for someone with dementia is often physically demanding and time consuming. Approximately 80% of carers report that they provide forty or more hours of care per week and

more than half (57%) report adverse effects such as feeling weary or worried (5). This is supported in recent work by Dr. Tracy Comans on the economic impact of 266 carers of people with dementia, showing that the cost of replacing informal care with equivalent services would cost on average $1,400 per week (unpublished data).

There is now strong evidence that non-pharmacological interventions that address functional capacity and carer impact are effective. There are currently more than forty non-pharmacological interventions that have been shown to have positive effects on functional outcomes for the person with dementia and improved carer outcomes.(6-8) These interventions have all demonstrated their effectiveness in randomised controlled trials.(6) Furthermore, non-pharmacological interventions have been shown to delay functional decline, reduce carer impact, improve carer knowledge, reduce carer anxiety, reduce carer depression and delay time to institutionalisation in systematic reviews (9). While intervention approaches within studies vary, the evidence suggests that interventions that involve tailored multiple components (e.g., carer education plus skills training plus engaging the person with dementia in activities) are most effective (9). A recent meta-analysis demonstrated that functional decline associated with dementia can be delayed through occupational therapy or multi-component interventions (7). Prominent were interventions designed to improve the home environment, the ability of the person with dementia and the skills of the carer. None were developed or tested in Australia.

Despite the strong body of evidence few people with dementia and their carers have access to evidence based interventions. The collective experience of researchers to date has been that once the research trial finishes, the knowledge and skills associated with delivering programs tends to remain with the researchers, organisations and clinicians involved in their development (10). The primary reason for this is that most interventions have been tested outside of existing care systems therefore the feasibility of providing the programs in everyday practice is unclear. In addition, there is little evidence regarding when and for whom which intervention should be used, and the associated cost if it were.

2.2 Research Question

- To what extent can the COPE intervention be translated into existing services for people with dementia within the Australian context?
- What are the costs associated with delivery of COPE? Is there an impact on resource utilisation as a consequence of the intervention?
- When implemented into existing services, is COPE as effective as when tested in a randomised controlled trial?

2.3 Rationale for Current Study

Implementation studies are increasing in the United States, but Australia is yet to follow. The purpose of implementation research is to determine whether evidence based treatments can be successfully implemented and result in similar outcomes when provided outside of a clinical trial (6). A number of interventions to support people with dementia have been shown to be effective in randomised controlled trials, but very few of these have been translated to a real-world setting (6). Of those that do exist, many translation studies tested a modified version of the original evidence based treatment suggesting that some adaptations are required to enhance feasibility in clinical practice. The majority of implementation work has occurred in the United States; a country with a significantly different health and social care system to Australia.

Current practice in Australia: Dementia care in Australia is fragmented and education and care are provided by a number of different health professionals and services. While policy makers, administrators, researchers, people with dementia and their families expect evidence based services, tailored, systematic and multi-component carer interventions are not yet readily accessible in Australia (11). Consumer consultations have revealed that consumers want a stronger focus on restorative care with support provided to maximise independence and that increased support is required to help carers support people with dementia to remain at home (12, 13). Therapists report an increasing focus on assessment at the expense of intervention and belief in a diminishing of skills in utilising a structured, evidence-based approach (14).

Current policy environment: The Living Longer, Living Better reforms introduced in 2013 and now being implemented under the Coalition Government's Healthy Life Better Ageing Program are intended to '…create a flexible and seamless system that provides older Australians with more choice, control and easier access to a full range of services, where they want it and when they need it' (15). One of the most innovative components of the new program is the Consumer Directed Care (CDC) Home Care Packages. The CDC framework provides individualised budgets and other measures that aim to maximise consumer choice and flexibility, rights and respect, participation, wellness and re-ablement, and transparency. All new home care packages from mid-2013 are being delivered as CDC packages, and all existing packages were converted to CDC by mid-2015. Underlying these new approaches is evidence-based and value-based recognition of the improvability of ageing experiences and the benefits of ageing well for older people, their families, and funders and providers of aged care services. CDC packages are delivered through aged care organisations, community health professionals engaged within state health service community services, and private groups or individuals who provide a user-pays or GP referral EPC (Enhanced Primary Care) items with partial user-pay.

This implementation research project will employ a mixed methods research design (16) to evaluate the process of implementation of the COPE project. COPE is a bio-behavioural multi-component non-pharmacological intervention program designed to

improve functioning in people with dementia. It has been proven to be effective in reducing dependency and increasing engagement of the person with dementia and improving carer wellbeing in a randomised trial in the US (17). Results (n=237 dyads) showed that at 4 months the persons with dementia were significantly less dependent and more engaged. In addition, carers reported significantly higher levels of wellbeing. Nine months after intervention carers in the intervention group reported a "great deal" of improvement in their lives overall, confidence managing behaviours of concern and improved ability to keep living at home.

Implementation research is particularly concerned with the users of the research and as such establishing the key stakeholders and developing effective collaborative relationships is key to successful implementation. We will build on these relationships to develop an implementation plan based on the facilitators and barriers identified at the commencement of the project. The evaluation will seek to understand how the intervention can be made workable and integrated into the organisational environment.

3. STUDY OBJECTIVES

3.1 Primary Objective

i. To identify the facilitators and barriers that will impact on uptake of COPE include organisational, social and professional factors

3.2 Secondary Objectives

ii. Identify a team of change champions, including key senior OT and nurses who will help drive the implementation and determine how to mobilise this into a network of ongoing support and dissemination.
iii. Understand the evidence-practice gap via a case note audit to determine current occupational therapy practice.
iv. Understand current practice from professionals' perspective via interviews with health professionals and service managers.
v. Understand the perspectives of people with dementia and their families and carers via interviews.
vi. Examine the organisational context via content analysis of documented organisational procedures including referral mechanisms
vii. Determine the effectiveness of the intervention as assessed by measures of engagement of people with dementia and caregiver wellbeing.
viii. Determine the acceptability of the intervention through examination of the experience of integrating the intervention, the engagement of champions, carer attitudes to dose and engagement of participants.

ix. Determine the degree of adoption of the intervention evident as measured by service provider staff satisfaction with the amount, content and format of training.
x. Measure adherence and outcome indicators of fidelity.
xi. To describe and compare organisational influences on uptake, integration and routinisation.
xii. To determine through health-economic evaluation the cost of providing the intervention and whether resource utilisation changes following intervention.

4. STUDY DESIGN

4.1 Type of Study

This study is a process evaluation to assess the success of efforts to translate the COPE project in the Australian setting within existing programs and resources. The mixed methods design (16) includes qualitative and quantitative methods, conducted across a number of phases (**see Figure 1**).

4.2 Study Design

This implementation research project seeks to understand what, why and how the COPE intervention will work in the Australian setting within existing programs and resources. The goal of implementation science is to understand how health interventions are made workable and integrated in context-specific ways into the organisational, social and policy environment (18). The mixed methods design (16) includes qualitative and quantitative components. We will use Normalisation Process Theory (NPT) (18), to identify and explain the factors that contribute to the translation, implementation and adoption of the COPE intervention, including organisational influences on uptake and integration. We will assess the acceptability, feasibility and efficacy of the COPE intervention. We will also examine the costs of delivering the intervention (therapist training, time spent providing the intervention and materials) as well as whether there are any reductions in the amount of formal or informal care after the dyad (person with dementia and carer) has received the intervention.

4.3 Study Procedures

This study consists of three main phases:

1. Planning and Preparation Phase
2. Implementation Phase

3. Evaluation Phase

4.3.1 Planning and Preparation Phase

This phase involves in-depth relationship building and exploration of preparation for change. The aim of this stage of the research is to identify the facilitators and barriers that will impact on uptake of COPE. This will include organisational, social and professional factors. Activities will commence with facilitated group discussions with the collaborators who will also act as the reference group for the project.

This phase will include:

1. *Understand the evidence-practice gap.* A case note audit of 100 client records will be conducted with representation from different service contexts. The client records will be reviewed against a set of pre-determined measurable criteria and will describe the interventions that are currently used to promote independence and manage behaviours of concern, the balance of assessment and intervention and the health professionals involved in providing the aforementioned interventions.

2. *Understand current practice from professionals' perspective.* We will conduct semi-structured interviews with up to 30 with occupational therapists, nurses and service managers to identify current practices, the rationale for current interventions, beliefs about their own capabilities, skills, and consequences of their actions, motivation, environments, social influences, emotion and professional role (19).

3. *Examine the organisational context.* A content analysis of documented organisational procedures including referral mechanisms and documentation will be undertaken during the semi-structured interviewers with participating organisation staff. We will construct a map of referral mechanisms, internal procedures, practices and documentation based on interviews with staff for each organisation. Notes and minutes of meetings and discussions during the recruitment of participating organisations and over the course of the project will also be used to inform this process. These notes will be de-identified and note taking is agreed as part of the research collaboration agreement signed by the organisation.

4. Understand the perspectives of community-dwelling people with dementia and their families and carers (called 'community dyads' from here). 10 semi-structured interviews will be conducted to explore perceptions of

community-dwelling dyad's expectations and experience of services and any health professional advice/services they have accessed in relation to managing behaviours of concern and promoting independence. Note: This is a discrete PhD project that will be conducted with separate ethics approval. Ethics for this portion of the project is not sought here, and further details are not included below.

4.3.2 Implementation Phase

Training and intervention manuals are currently being refined and tested in the US ready for implementation. We will work closely with Professor Laura Gitlin and her team, the primary developers of the COPE program, identifying the mutable and immutable aspects which are adaptable or not when implemented in varying contexts. Training and manuals will be refined for the Australian context. **See Figure 2** for overview of COPE program.

This phase will include:

a. *Project piloting.* The project coordinator will pilot the modified 'Australianised' version of the program with five dyads who are clients of a non-government organisation at which she is recognised as an occupational therapy provider. These dyads will be invited to participate in the project as normal following the procedures below.

b. *Program development and therapist training.* We will adapt COPE materials for the Australian context and train, mentor and coach occupational therapists and nurses at the involved sites in the adapted program. Clinicians will be taught 'what to do' and 'how to do it'. We will address barriers identified in the above phase, and as they emerge throughout our process evaluation.

   Specific intervention strategies, informed by contemporary behaviour change techniques (based on the methods described by Michie and colleagues(20)) will be selected to address the identified barriers. The intervention strategies believed to be most effective in facilitating skill acquisition include: rehearsal of skills, modelling or demonstration of the skills by others, goal setting, monitoring and rewards (21). Strategies will be developed in how to package and market the intervention based on consumer needs and values and in-line with organisational reimbursement and user-pay structures. The nature of training and documentation may

include a variety of methods such as face-to-face training, modelling, and use of web-based tools.

c. *Fidelity checking.* We will include fidelity strategies to facilitate adherence to program integrity and key treatment principles. . We will monitor carefully any alteration to number and timing of sessions within the program and explore alternative methods of intervention delivery (e.g., homework tasks and telecare).

4.3.3 Evaluation Phase

Evaluation will be conducted using both a process evaluation and an economic evaluation. This will determine if we can deliver the COPE intervention as intended and identify differences between and similarities within the three delivery health contexts. We will evaluate the feasibility of implementing within the different contexts and the acceptability of the program to the consumer dyad, health professional and organisation. We will explore organisational challenges in enabling training and support as therapists gain mastery and new skills. We will determine the cost of implementing the program using therapist logs to cost service delivery.

This phase will include:

a. *Health professionals survey.* We will survey all COPE therapists 6 months after they have completed their training to further evaluate practice change. We will use the Determinants of Implementation Behaviour Questionnaire (DIBQ) (22). The DIBQ was developed to measure the behavioural determinants of implementation and was based on the Theoretical Domains Framework (23). It has established validity and reliability and was developed using confirmatory factor analysis (22).

b. *In depth interviews with COPE Therapists (n=15) after implementing COPE*. These interviews aim to understand their experience of COPE, perceptions of change (or not) and factors that may influence uptake.

c. *Effectiveness of outcomes for COPE dyads.* We will assess whether outcomes for the carer and person with dementia who received COPE are consistent with previous research and conduct a pragmatic pre-post intervention evaluation as a secondary analysis. We shall recruit COPE dyads (carer and person with dementia) in numbers relative to the size of

each organisation (and the number of participating therapists) sequentially (following the training period). We shall use a measure of engagement of the person with dementia (a validated five-item scale) and a measure of caregiver wellbeing. We will recruit a total of 103 to allow for drop out.

10 of these dyads will also be asked to sit down for an interview at a time and location that is convenient for them. These dyads will be chosen using purposeful sampling, designed to reduce selection bias and in keeping with the qualitative nature of the inquiry. During this interview, they will be asked a range of questions about how they are managing, how much help they need, and how confident the caregiver feels about providing that care. This interview may take up to 1 hour, but breaks can be taken whenever needed. The interview will be recorded.

d. *Economic evaluation: Measurement of resource utilisation pre and post intervention.* Finally, a partial economic evaluation of COPE will be conducted. Costs relating to the provision of the COPE intervention will be collected. Direct costs include staff time in delivering the interventions, travel costs, and the cost of any resources provided (e.g. leaflets, equipment). Resources will be costed at 2016 prices using actual cost of materials and current award wage rates. All dyads will be asked to complete the Resource Utilisation in Dementia (Lite) questionnaire (24). This will provide information on formal and informal care resources used which can be used to value the costs of care received.

4.4 Number of participants

- Phase 1:
  - 100 case notes will be audited from 4 participating organisations.
  - Structured interview with up to 30 health professionals (occupational therapists, nurses, managers) employed at participating sites
- Phase 2:
  - Up to 40 nominated therapists employed at participating organisation sites will attend training and undertake fidelity assessment.
- Phase 3:
  - Pre/post questionnaires will be conducted with 103 dyads (i.e. 103 people with dementia and 103 caregivers = 206 individual participants).
  - Qualitative Interviews will be conducted with 10 people with dementia and/or care givers, selected from the 103 dyads.

- 15 COPE therapists will be interviewed regarding their experience with COPE
- All COPE therapists will complete the DIBQ

4.5 Study sites

There are two nominated sites for this study. The study will be conducted simultaneously at each site with the same procedures.

- **Site 1** Occupational Therapy providers located across South Australia, Australia.
  - ACH Group
  - Alwyndor Aged Care Adelaide
  - AnglicareSA
  - Country Health
  - Griffith Hospital
  - Resthaven
  - Southern Adelaide Local Health Network
  - Southern Mental Health Services for Older People

- **Site 2** Occupational Therapy providers located across New South Wales, Australia.
  - HammondCare
  - Hornsby Ku-Ring-Gai Health Service
  - Nepean Blue Mountains Community Health
  - Sir Moses Montefiore Jewish Home

Occupational Therapists engaged with these services will be nominated by their organisation and invited to attend COPE training. Participating therapists will identify and recruit suitable participant dyads from their client base. The Therapists will administer the dyad pre and post study questionnaire, and invite a small subset of dyads for the qualitative interview (to be conducted by the research team). We will ask each Occupational Therapist to implement COPE with up to six dyads.

4.6 Expected duration of study

Total Duration: 42 Months
Commencement: 1-January-2016
Completion: 30-June-2019

Phase 1 (Planning & Training): 6 Months

- Key Activities:
  - Identification of project partners – "early adopters" of program
  - Recruitment of Occupational Therapists
  - Case note audit
  - Health professional interviews
  - PhD sub-study

Phase 2 (Implementation): 8 Months

- Key Activities:
  - Training of clinicians: 'what to do' and 'how to do it'
  - Mentoring and use of fidelity strategies to promote adherence to the intervention.

Phase 3 (Evaluation; during continued implementation): ~10-22 Months

- Key Activities:
  - Pre and post-test of patient and caregiver outcomes
  - Economic evaluation
  - Qualitative interviews with patient/caregiver dyads
  - Qualitative interviews with health professionals
  - COPE therapist Determinants of Implementation Behaviour Questionnaire (DIBQ)

Follow up phase (analysis and Publication): ~6 Months

- Key Activities:
  - Dissemination of results and development of Implementation Strategy Document
  - Development of business case for, and set up of, ongoing health professional training.

4.7 Primary and Secondary Outcome Measures

Primary objectives:

- Phase 1
  - Case note audit:
    - Audit data extraction tool (attached)
  - Health professional pre-interview:
    - Structured interview guide (attached)
- Phase 2
  - No primary outcome measures for this stage
- Phase 3
  - Pre- and post-intervention questionnaires:

        - Activity engagement of the person with dementia: measured using a 5-item scale (17) in which caregivers are asked to rate the person's engagement in activities from 1 (never) to 3 (often).
        - Caregiver wellbeing: measured using the 13 item Perceived Change Index (17). Caregivers are asked to rate changes in their wellbeing and coping over the last month using items such as "Have your feelings of being calm and relaxed…" with a Likert-style scale of responses from 1 (Gotten much worse) to 5 (Improved a lot).
    - Participant dyad structured qualitative interviews:
        - Structured interview guide (attached)
    - Health professional structured interviews:
        - Structured interview guide (attached)
    - Health professional implementation determinants:
        - Determinants of Implementation Behaviour tool, a 93-item questionnaire in which COPE therapists are ask to rate the acceptability of COPE from 1 (Strongly disagree) to 7 (Strongly agree). This will include basic demographic information.

Secondary outcomes:

- Phase 1
    - No secondary outcome measures
- Phase 2
    - Fidelity to intervention
        - Fidelity assessment tool (attached)
- Phase 3
    - Participant dyad pre- and post-intervention questionnaire :
        - Resource utilisation: measured using the Resources Utilisation in Dementia-Lite (RUD-Lite) questionnaire (24). Caregivers are asked to report how many hours in the past month they had provided informal care to the person with dementia, including:
            - personal activities of daily living including dressing, eating, toileting etc.;
            - instrumental activities of daily living including driving, shopping, managing finances etc.; and
            - supervision.

      Participants with dementia are asked to report how often they had accessed a range of formal services in the previous month.
    - Participant dyad structured qualitative interviews:
        - Adverse events
    - Health professional interviews:
        - Adverse events

5. PARTICIPANT ENROLLMENT AND RANDOMISATION

5.1 Recruitment

Preliminary work to establish partnerships with organisations who have affirmed their support to implement COPE within their existing services has been undertaken. Potential partner organisations for this project value innovation, are early adopters of innovative approaches, have good local connections, and are embedded in excellent health service delivery, policy and consumer networks. The partners share a common goal of providing restorative and evidence-based interventions with specific consumer benefit, in a cost-effective manner and in a sustainable manner. Partner organisations will nominate suitable therapists who will be invited to complete COPE training and become *'COPE trained therapists'*, delivering the program to clients.

The partner organisations will identify their own clients/patients (and their caregiver) who are eligible for and would benefit from the COPE program. They will then discuss the study and ask whether the dyad consents to participate in the study (predominantly by completing the questionnaires). If the dyad chooses to participate they will receive the COPE intervention and complete the study measures. If they choose not to participate they will receive usual occupational therapy care and will not complete questionnaires.

A small sub-set of participating dyads will also be invited by their COPE therapist to be contacted by the research team for a structure qualitative interview.

5.2 Eligibility Criteria

5.2.1 Inclusion Criteria

Case notes for auditing:

- Case notes will be reviewed in order of recent discharge. Notes will be included in auditing if the client has dementia, is living at home, had a regular caregiver living nearby, and has received occupational therapy.

Health professionals:

- Inclusion criteria for the interview components are: participants will be occupational therapists, nurses and managers employed at participating organisations
- Inclusion criteria for the training and questionnaire components of the study are: participants will be occupational therapists already employed by

participating organisations to provide occupational therapy services to people living with dementia in the community

Participant dyads:

- Inclusion criteria for the questionnaire and interview components of the study are: participants will:
  - have a diagnosis of probable dementia, or a Mini-Mental State Examination (MMSE) score less than 24 (or equivalent score on a comparable tool such as the MOCA);
  - have received the COPE intervention; and
  - live in the community with or nearby a family caregiver.
- Eligible caregivers:
  - provide regular oversight or care to a person with dementia; and
  - have received the COPE intervention.

5.2.2 Exclusion Criteria

- Caregivers who are under 18 years of age will be excluded from the dyad questionnaire and interview components of the study.

6. INFORMED CONSENT PROCESS

Consent will not be collected for case note files for auditing. We have requested for consent to be waived given that 1) involvement in the research is of negligible risk, 2) it is impracticable to obtain consent given the records are of a previous contact and that sending out a letter regarding the audit may cause unnecessary worry, 3) there is no known reason why participants would not have consented if asked, and 4) confidentiality will be ensured as all data will be de-identified.

Health professionals suitable for the COPE project will be nominated by their organisation. They will meet with a member of the study team who will discuss the research project, will explain what would be involved for them and will provide them with a Participant Information and Consent Form. Whether or not the health professional chooses to participate in the research (i.e. questionnaires and interviews) will not impact on their ability to access the COPE training and deliver COPE to their clients with dementia, nor will it impact on their relationship with the University of Sydney, Flinders University or their employing organisation. Participants will have the opportunity to discuss the study and clarify any concerns before completing the consent form.

In order to ensure the COPE program is delivered in the most naturalistic way, the client's own therapist will seek the consent of clients and care givers to participate in the research study as part of the client's identified therapeutic needs. Whether or not the client and care giver choose to participate in the research will not impact on their ability to access the COPE program as part of their usual Occupational Therapy treatment.

Potential participant dyads will be initially approached by their Occupational Therapist about the study, who will explain what would be involved for them and provide them with a Participant Information and Consent Form. Obtaining consent face-to-face with the participant dyads enables the therapist to talk through the purpose of the study with the participants to facilitate and evaluate their understanding of the research (25). Potential dyads will be provided with contact numbers for the Occupational Therapist and study team so they can discuss the study, clarify any concerns and, if amenable, arrange an appointment for the process of written informed consent to be completed and the questionnaires provided/interview completed.

For participants deemed unable to consent due to cognitive impairment, verbal assent will be obtained for participation in the study, if they are capable (26, 27). Proxy consent will also be obtained for these participants from their appointed Guardian (as appropriate according to NSW and SA legislation).

Participants will be made aware that they are under no obligation to participate and that refusal to participate will in no way jeopardise the participant's existing relationship with their Occupational Therapist or treatment which in future may be provided to them. Participants will be advised that they are free to withdraw from the research at any time.

6.1 Participant Withdrawal

6.1.1 Reasons for withdrawal

All participation is fully voluntary and this will be emphasised at all stages of the project.

Withdrawal from the research by health professionals will not have specific consequences. Furthermore, all participants can choose to withdraw from some components of the research but not others with one exception. Therapists that choose to withdraw from delivering the intervention to community dyads will no longer be involved in other aspects of the research. Participant data can be withdrawn from the research study at their request.

Withdrawal from the research by dyads will not have specific consequences, or affect the care they receive from their Occupational Therapist. If a dyad chooses to participate, it is not anticipated that there will be early termination of this study.

7. STUDY VISITS AND PROCEDURES SCHEDULE

An overview of the study procedure is displayed in the **project flow chart in Figure 3.** To summarise:

For health professionals:

- Following organisation agreement, interviews will be conducted with up to 30 occupational therapists, nurses and managers prior to COPE training being offered to an organisation
- Meetings and discussions with participating organisations will be minuted throughout the project.
- Nominated occupational therapists will undertake COPE training
- Occupational therapists will implement COPE with up to six participant dyads, receiving mentoring and fidelity strategies to support adherence to the intervention
- Occupational therapists will complete Determinants of Implementation Behaviour Questionnaire (DIBQ) 6 months after completion of training
- Re-interview of 15 COPE health professionals following implementation of at least 3 COPE programs

For participant dyads:

- Participating organisations will identify suitable participant dyads to receive COPE, COPE therapists will invite them to participate
- If consenting, COPE therapists will ask dyads to complete pre-intervention questionnaires prior to commencing the program with person with dementia and care givers.
- Post-intervention questionnaires will be conducted with person with dementia and caregivers by the Occupational Therapist following conclusion of the program.
- Interviews will be conducted with 10 people with dementia and/or care givers following return of the pre/post questionnaire.

8. ADVERSE EVENT REPORTING

Therapists delivering the program are treating their own clients and would adhere to usual protocols for their organisation should an adverse event occur. The therapists will be asked to report any adverse events to the research team.

People with dementia and their caregivers may become tired during the pre- and post-interviews. However, interviewers will be alert to signs of fatigue and take breaks where necessary or cease and reschedule the interview if needed. Counselling services (via Alzheimer's Australia) will be recommended in the case of distress.

9. STATISTICAL METHODS

9.1 Sample Size Estimation

- Case note audit data and post-training questionnaires (DIBQ) will only be used for descriptive analyses and therefore no power estimation is required.

- The pre-and-post-intervention dyad questionnaires include a measure of engagement of the person with dementia (a validated five-item scale which demonstrated an effect size of 0.26 (Cohen d) in the earlier trial (17) and a measure of carer wellbeing, the Perceived Change Index (17), which had an effect size of 0.30. We calculate the estimated effect size of 0.26 will give a power of 80% (alpha error probability of.05) testing mean differences of time points using G-power (version 3) software which gave a sample of 93 dyads (before adding the dropout estimate). This is sufficient as the estimate for the 0.30 effect size is 71 dyads. We will recruit a total of 103 to allow for drop out.

- 30 qualitative interviews with health professionals and 10 qualitative interviews with participant dyads will allow for adequate saturation for qualitative analyses.

9.2 Statistical Analysis Plan

- Case Audit data will be entered into SPSS. Socio-demographic data will be summarised descriptively (e.g. mean, range, percentage). We will also summarise service characteristics descriptively. In regards to the intervention approaches used, we will describe how commonly these approaches are used (e.g. percentage of cases where a particular approach was used) and also

describe the average number of approaches (and range) used across clients (eg. 'therapists used an average of intervention approaches with clients').

- The DIBQ responses will be coded in SPSS. As the sample will be too small for statistical analysis, the information gathered will be used as indicative and descriptive information to inform the development and outcomes of the intervention.

- Responses to participant dyad survey data (pre and post measures) will be coded in SPSS, analysed descriptively and compared within and across groups. Data from the resource utilisation in dementia questionnaire (RUD Lite) will be used to cost both formal and informal services.

- All interviews will be audio-recorded, transcribed verbatim and entered into QSR NVivo. Thematic analysis (developing codes) will identify patterns within the study group. A combination of inductive and deductive coding will be used. F or participant dyads coding will commence with experience of COPE program and perceptions of change, but will be open to unexpected findings that may contribute to these. For health professionals the four NPT constructs will inform analysis of data gathered in order to build a comprehensive assessment of the barriers and facilitators; and thus informing implementation.

9.3 Interim Analyses (if applicable)

N/A

10. DATA MANAGEMENT

10.1 Data Collection

Case note audit data will be extracted from the case notes using the data extraction tool included in this application. Methods of extraction will be consistent but the person extracting the data will be guided by each organisation's individual policies and processes. These processes will be detailed in site specific assessments where applicable. At some organisations we will employ a staff member from that organisation to extract the data for us and provide it to us in de-identified form. At another organisation a member of the research team may complete the data extraction.

Fidelity assessment tools will be collected in-person or by mail by the research team from participating organisations.

Pre- and post-intervention participant dyad questionnaires will be collected by the therapists at each organisation and provided in-person to the research team for collation, de-identification and evaluation. Therapists will also report details of their interaction with the dyad (including time spent, materials provided).

DIBQ questionnaires will be collected in-person or by mail by the research team from participating organisations.

Interviews with health professionals will be conducted by the research team at a time and place that is convenient for the health professional. They will be audio-recorded, transcribed verbatim and entered into QSR NVivo. Thematic analysis (developing codes) will identify patterns within and across the study groups. A combination of inductive and deductive coding will be used – coding will commence with examination of barriers and facilitators, but will be open to unexpected findings that may contribute to these. Data analysis will examine similarities and differences within and between three organisational/service delivery contexts and changes evident at different time points in the intervention. Follow-up interviews will examine health professionals experience of COPE, perceptions of change (or not) and factors that may influence uptake.

Interviews with dyads will be conducted by the research team at a time and place that is convenient for the dyad. They will be audio-recorded, transcribed verbatim and entered into QSR NVivo. Thematic analysis (developing codes) will identify patterns within and across the study groups. A combination of inductive and deductive coding will be used – coding will commence with examination of perceptions of the person's expectations and experience of the service and any health professional advice/services they have accessed in relation to dementia/managing behaviours of concern and promoting independence, identifying any factors that may influence program uptake, but will be open to unexpected findings that may contribute to these.

Documentation relating to field notes of meetings and observations (e.g., minutes of meetings, discussions with stakeholders) will be collected by the study team on a rolling basis and examined using content analysis. Analysis will focus on the 'work of the implementation' – who is doing the work, concerns raised about the work, and how responsibility for aspects of uptake, marketing, embedded structures and the intervention itself are distributed.

10.2 Data Storage

Questionnaire responses and other paper files, including case note audit record forms, will be entered into an electronic database and the paper files will be scanned electronically and shredded. Interviews will be audio recorded and transcribed into electronic documents. All electronic data will be securely stored on a secure University of Sydney-managed storage platform.

Participant data will be filed using re-identifiable ID codes. As data collected from the case note audit will be de-identified at point of collection, it will not be issued with a re-identifiable ID code. Computers will be password protected. Only the research team will have access to the records and then only under the Study Manager and PIs direction. Any paper files will be stored in locked cabinets until they are electronically scanned and shredded.

10.3 Data confidentiality

All participants will be assigned a unique code to identify and link data across the study. It will be necessary for the research team to keep (securely and confidentially) a document with participant codes and personal contact details in order to conduct the data collection phase of the study (e.g. scheduling interviews), hence the data will be potentially re-identifiable. Personal identifying information will not be available at data analysis and only group level (population) results will be published/disseminated. Re-identifiable data for this purpose will only be sought after receiving consent from participants.

For the case note audit, only de-identified data will be extracted from the medical records.

Only the researchers listed on this application and additional research staff to be employed will have access to study information and this will be controlled/monitored by the first two Principal Investigators in consultation with other PIs.

Further identifiable information will only be accessible by members of the research team working directly with participants, and this access will be limited to information needed to conduct their study duties. Updates of the project to HRECs and funding bodies will use aggregate data.

10.4 Study Record Retention

Information will be stored electronically for a minimum of seven years in accordance with storage and retention of data recommendations from the Australian Code for Responsible Conduct of Research (28).

11. ADMINISTRATIVE ASPECTS

11.1 Independent HREC approval

This study has been approved by the Northern Sydney Local Health District HREC (RESP/16/188) and by the University of Sydney HREC (2016/292).

11.2 Amendments to the protocol

Any amendments will be submitted to the HREC for review prior to implementation as per HREC guidelines.

11.3 Participant reimbursement

Participating organisations and therapists will not be paid for their participation. COPE training will be provided at no cost.

Participant dyads that complete the pre- and post-questionnaires will not receive any reimbursement. Participant dyads who participate in a qualitative interview will receive a $50 gift card to thank them for their time.

11.4 Financial disclosure and conflicts of interest

N/A

12. USE OF DATA AND PUBLICATIONS POLICY

The results of the project will be disseminated in two PhD theses, a report for stakeholders, a 'one page summary' for policy makers and consumers and multiple conference presentations and journal publications.

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Figure 1. Overview of study design

Figure 2: Overview of COPE program

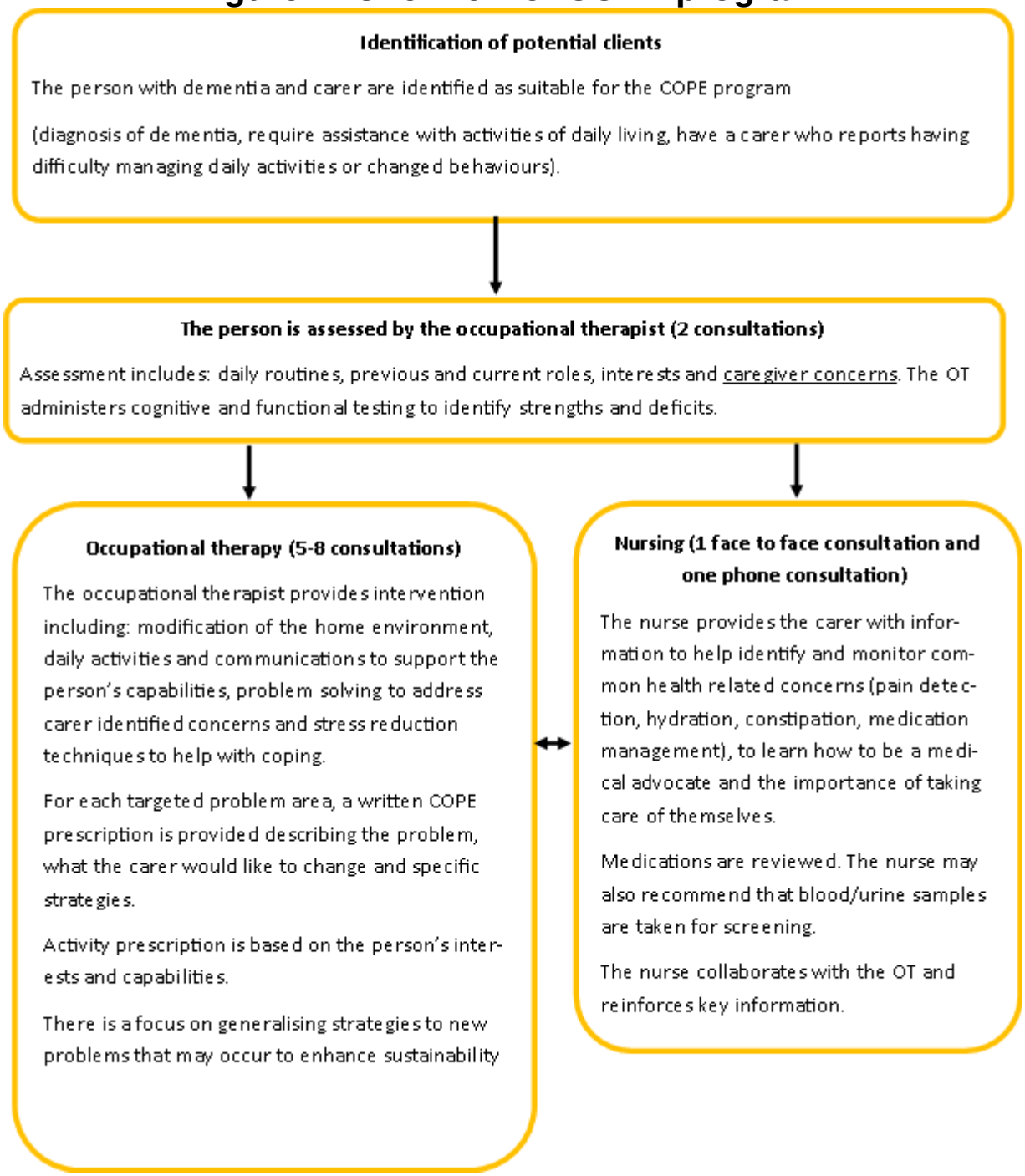

Figure 3: Flow chart of COPE procedure