**This protocol has regard for the HRA guidance and order of content**

**FULL/LONG TITLE OF THE STUDY**

**A**sian diagnosis **D**ementi**A** **P**a**T**hway - refining a package of intervention for people with dementia from South Asian communities

**SHORT STUDY TITLE / ACRONYM**

ADAPT

**PROTOCOL VERSION NUMBER AND DATE**

Version 1 27/11/2020

**RESEARCH REFERENCE NUMBERS**

|  |  |
| --- | --- |
| **IRAS ID Number:** | 289226 |
| **SPONSORS Number:** | HAS-HSS-18-084 |
| **FUNDERS Number:** | NIHR200736 |

# SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor’s SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

|  |  |  |
| --- | --- | --- |
| **For and on behalf of the Study Sponsor:** | | |
| Signature:  ...................................................................................................... |  | Date: ....../....../...... |
| Name (please print):  ...................................................................................................... |  |  |
| Position: ...................................................................................................... |  |  |
| **Co-Chief Investigator:** | | |
| Signature: ...................................................................................................... |  | Date: ....../....../...... |
| Name: (please print):  ...................................................................................................... |  |  |

# 

|  |  |  |
| --- | --- | --- |
| **Co-Chief Investigator:** | | |
| Signature: ...................................................................................................... |  | Date: ....../....../...... |
| Name: (please print):  ...................................................................................................... |  |  |

# LIST of CONTENTS

|  |  |
| --- | --- |
| **GENERAL INFORMATION** | **Page No.** |
| HRA PROTOCOL COMPLIANCE DECLARATION | i |
| TITLE PAGE | ii |
| RESEARCH REFERENCE NUMBERS | ii |
| SIGNATURE PAGE | iii |
| LIST OF CONTENTS | iv |
| KEY STUDY CONTACTS | v |
| STUDY SUMMARY | v |
| FUNDING | vi |
| ROLE OF SPONSOR AND FUNDER | vi |
| ROLES & RESPONSIBILITIES OF STUDY STEERING GROUPS AND INDIVIDUALS | vi |
| STUDY FLOW CHART | vii |
| SECTION | |
| 1. BACKGROUND | 1 |
| 2. RATIONALE | 3 |
| 3. RESEARCH QUESTION/AIM(S) | 4 |
| 4. STUDY DESIGN/METHODS | 5 |
| 5. STUDY SETTING | 18 |
| 6. SAMPLE AND RECRUITMENT | 18 |
| 7. ETHICAL AND REGULATORY COMPLIANCE | 20 |
| 8. DISSEMINATION POLICY | 24 |
| 9. REFERENCES | 25 |
| 10. APPENDICES | 26 |

# KEY STUDY CONTACTS

|  |  |
| --- | --- |
| Co-Chief Investigator  Co-Chief Investigator | Prof Richard Cheston  University of the West of England  Room 3A07, Frenchay Campus,  Coldharbour Lane  Bristol  BS16 1QY  [Richard.cheston@uwe.ac.uk](mailto:Richard.cheston@uwe.ac.uk)  0117 3288927  Dr Sahdia Parveen  University of Bradford  Centre for Applied Dementia Studies, Faculty of Health Studies  Bradford  West Yorkshire  BD7 1DP  [s.parveen27@bradford.ac.uk](mailto:s.parveen27@bradford.ac.uk)  01274 236089 |
| Study Co-ordinator | Dr Emily Dodd  Trial Manager  University of the West of England  Room 3L07, Frenchay Campus  Coldharbour Lane  Bristol  BS16 1QY  [Emily3.dodd@uwe.ac.uk](mailto:Emily3.dodd@uwe.ac.uk)  0117 3287496 |
| Other Protocol Contributors/  Co-applicants | Dr Karan Jutlla  University of Wolverhampton  Faculty of Education, Health and Wellbeing  University of Wolverhampton  Sister Dora Building WP138  Walsall Campus Gorway Road, Walsall WS1 3BD  [K.Jutlla@wlv.ac.uk](mailto:K.Jutlla@wlv.ac.uk)  01902 323309  Dr Paula Smith  The University of Bath  Department of Psychology, Centre for Death and Society  10 West 3.18  Claverton Down, Bath BA2 7AY  [P.C.Smith@bath.ac.uk](mailto:P.C.Smith@bath.ac.uk)  01225 384844  Mr David Truswell  Dementia Alliance for Culture and Ethnicity, London  [davidtruswell@icloud.com](mailto:davidtruswell@icloud.com)  Mr Jabeer Butt  Race Equality Foundation  Unit 17 & 22, Deane House Studios  27 Greenwood Place  London NW5 1LB  [jabeer@racefound.org.uk](mailto:jabeer@racefound.org.uk)  0207 428 1880 |
| Sponsor | Prof Olena Doran  Associate Dean (Research)  Faculty of Health and Applied Sciences  University of the West of England, Bristol  BS16 1QY  [Olena.doran@uwe.ac.uk](mailto:Olena.doran@uwe.ac.uk)  0117 3281670 |
| Funder | National Institute for Health Research – Research for Patient Benefit  Central Commissioning Facility  Grange House  15 Church Street  Twickenham TW1 3NL |
| Committees | Dept of Health and Social Sciences Faculty Research committee  c/o Leigh Taylor,  Senior Research Administrator,  University of the West of England,  Research Administration,  Northavon House,  Coldharbour Lane,  Bristol.  BS16 1QY.  Tel: 0117 328 1170  Email: [Leigh.Taylor@uwe.ac.uk](mailto:Leigh.Taylor@uwe.ac.uk) |

**STUDY SUMMARY**

|  |  |
| --- | --- |
| Study Title | Asian diagnosis DementiA PaThway - refining a package of intervention for people with dementia from South Asian communities (ADAPT) |
| Internal ref. no. (or short title) | HAS-HSS-18-084 |
| Study Design | Mixed methods across four sites |
| Study Participants | * People living with dementia from South Asian communities * Friends and family members of those living with dementia * Staff from Voluntary Community Sector Organisations, eg Alzheimer’ Society, Dhek Bhal * NHS Staff working with people living with dementia |
| Planned Size of Sample (if applicable) | Approx. 100 |
| Follow up duration (if applicable) | N/A |
| Planned Study Period | 12 months |
| Research Question/Aim(s) | The primary aim of this study is to identify the elements of an online toolkit that can be drawn on as necessary by commissioners, clinicians and care teams to meet the local needs of South Asians living with dementia. As there are many different South Asian communities and the profile of these communities varies across regions and cities, different services will draw on different elements of the toolkit in order to create bespoke versions of the pathway that meet local needs and priorities. |

**FUNDING AND SUPPORT**

|  |  |
| --- | --- |
| **FUNDER(S)** | National Institute for Health Research: Research for Patient Benefit  Central Commissioning Facility  Grange House  15 Church Street  Twickenham TW1 3NL |
| **FINANCIAL AND NON FINANCIALSUPPORT GIVEN** | Grant ref: NIHR200736  Amount:£156, 627.00 |
| **HOST** | Bristol North Somerset South Gloucestershire Clinical Commissioning Group |

**ROLE OF STUDY SPONSOR AND FUNDER**

The University of the West of England Bristol (UWE) is the Sponsor for this study. UWE Bristol takes responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting. UWE Bristol will ensure that all necessary approvals from an NHS research ethics committee are obtained before undertaking the study. Signed ethically approved informed consent and acknowledgement forms from any participants who will be involved in the project will be obtained.

The study is funded by the National Institute for Health Research – Research for Patient Benefit funding stream. The funder has not had any influence over the study design or analysis.

**ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS**

The Project Management Group will meet monthly via video conference for the duration of the study. This group will be led by the two co-chief investigators, Prof Richard Cheston and Dr Sahdia Parveen. Both CIs will oversee the management of the project as a whole. Prof Cheston will co-lead work package 2 and 4, Dr Parveen will co-lead work package 1.

The group will comprise the research team; Dr Emily Dodd, Trial Manager, UWE Bristol, (co-lead work package 4), Dr Karan Jutlla, Senior Lecturer, University of Wolverhampton (co-lead work package 1), Dr Paula Smith, Senior Lecturer, The University of Bath (co-lead of work package 2), Mr David Truswell, Dementia Alliance for Culture and Ethnicity (co-lead of work package 3), Mr Jabeer Butt, Race Equality Foundation (co-lead work package 3), Sharon Woma, Equality and Diversity Lead, Bristol North Somerset South Gloucestershire Clinical Commissioning Group and Manjit Nijjar, Public contributor.

A Study Steering Committee (SSC) will be established to monitor progress, advise the investigators in general scientific and management issues, and ensure that there are no major deviations from the study protocol. The SSC will meet at the start and end of the study via a video/teleconference and at the mid-point in person at the Race Equality Foundation Offices in London. In addition to the project management group members, the SSC will include an experienced independent chair (Professor Dawn Brooker, Director of the Association for Dementia Studies, University of Worcester), a clinician (Sarah Ghani, the diversity lead for the Faculty of Psychology of Older people), Dr Naheed Mukadam (Clinical Research Fellow at University College London), Subitha Baghirathan (independent dementia consultant) and an additional two carers of people living with dementia (Jag Kaur and Dalbinder Sanghera).

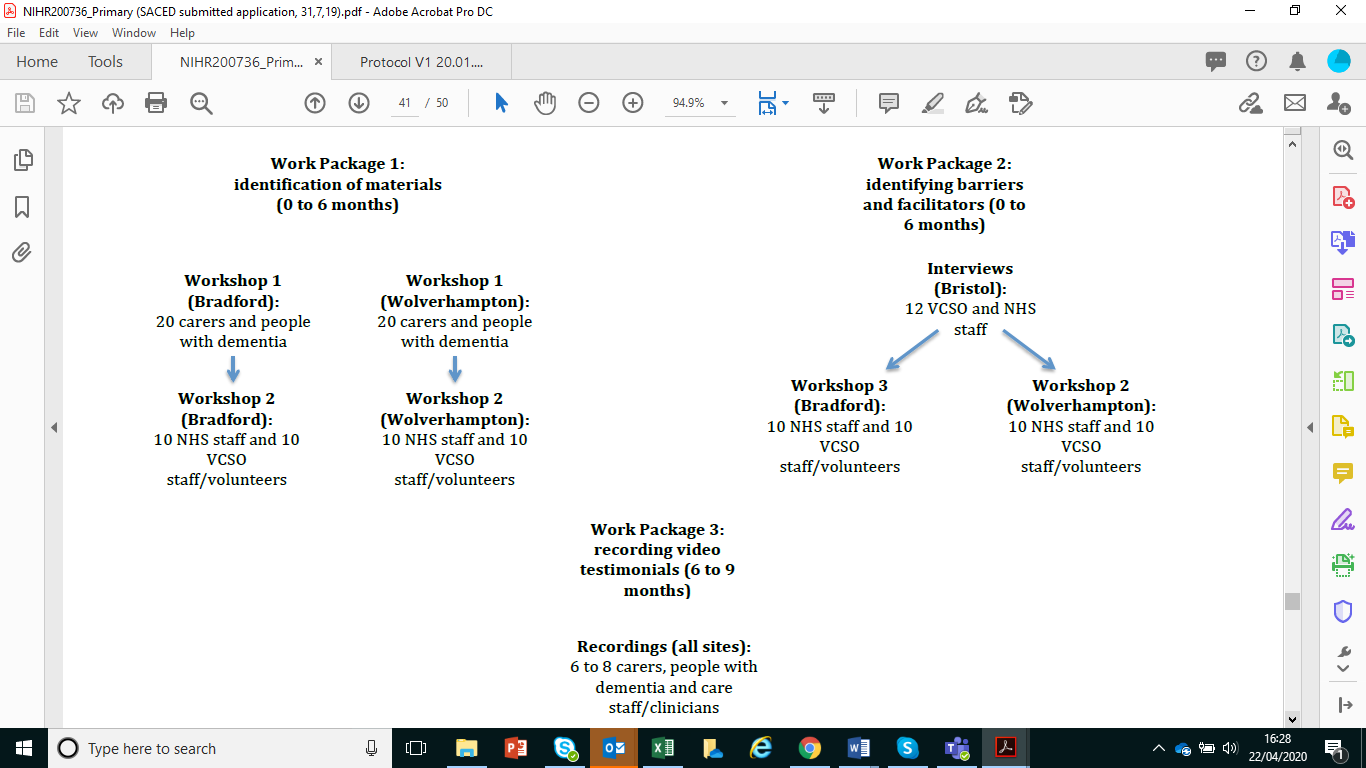
|  |  |
| --- | --- |
| **KEY WORDS:** | Dementia; South Asian communities; Enhanced Pathway; Toolkit; Engagement; Voluntary Community Sector Organisations |

# STUDY FLOW CHARTS

1. Gantt Chart

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | 2020 | 2021 | | | | | | | | | | | |
|  | June –  Dec | Jan | Feb | Mar | Apr | May | June | July | Aug | Sept | Oct | Nov | Dec |
| **Preliminary work** (e.g. establishing site permissions, recruitment, contracts, planning meetings with collaborators, scoping grey literature) |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Project Management Group |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Study Steering Committee |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Work Package 1: identification of materials** |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1a. Rapid review of literature, assessments and interventions |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1b. Workshops with different communities |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1c. Analysis |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Work Package 2: identifying barriers and facilitators to collaboration** |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 2a. Interviews to create vignettes for workshops |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 2b. Workshops to identify practical solutions |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 2c. Analysis |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Work Package 3: video testimonies** |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 3a. Gathering testimonies |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 3b. Editing and integration into toolkit |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Work package 4:Creation of toolkit** |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Work Package 5: Dissemination** |  |  |  |  |  |  |  |  |  |  |  |  |  |

**2.** study flow diagram



**STUDY PROTOCOL**

Asian diagnosis DementiA PaThway - refining a package of intervention for people with dementia from South Asian communities (ADAPT)

# 1 BACKGROUND

**1.1. What is the problem being addressed?**

Roughly 25,000 people from ethnic minority communities are living with dementia in the UK. Of these the largest, single grouping are people whose origins are from South Asian countries (1). However, South Asians living with dementia are less likely to access the dementia care pathway (2) or receive NICE-recommended treatments, including medication for Alzheimer’s disease, than are their white British counterparts (3, 4). Diagnosis of dementia is also more likely to occur at a later stage for South Asians (5), when the patient is often more severely impaired or in crisis (6, 7). People from South Asian communities who are living with dementia and their carers are more likely to evaluate NHS dementia services negatively (5, 6) and to be cared for at home, have a poorer quality of life and experience more complex transfers to residential care (6, 8).

Within South Asian communities there is a greater reliance on support from community groups whose staff and volunteers are not dementia-trained. This impacts upon care in a number of ways: first, South Asians with dementia are less likely to have access to specialist care and support (2) thus reducing, for instance, their ability to plan for the future; secondly, symptoms that are potentially treatable may be missed as they are mistakenly attributed to dementia or to ageing. The cumulative effect of these differences in service uptake means that South Asians who are living with dementia and their families are socially and financially disadvantaged compared to their white British counterparts. A growing body of evidence points to the need for interventions at multiple levels of the dementia care pathway and for statutory and voluntary services to work together to implement an enhanced form of care if people from South Asian communities with dementia and their families are to have access to an equitable level (1). This includes education campaigns to improve levels of awareness about dementia in South Asian communities (9) so that symptoms of dementia are recognised as an illness (4, 6, 10, 11) rather than as normal ageing (12, 13). Additionally, as only a third of South Asians aged over 65 speak English and just a fifth can read or write in English (1), memory assessment services require skilled interpreters and culturally validated assessment tools (3, 14, 15). However, while it is clear that the dementia pathway needs to adapted to provide a better service for the South Asian community, it is not clear which interventions are acceptable or can be realistically implemented.

The purpose of this study is to create an online toolkit of culturally appropriate assessments and interventions that support people from South Asian communities across the dementia care pathway. This will be the Asian diagnosis DementiA PaThway or ADAPT. The online toolkit will be a resource for service commissioners and managers, clinicians and people who have been affected by or who are living with dementia.

**1.2. How does the existing literature support this research?**

Research consistently identifies that South Asian people living with dementia need better access to assessment and support services that meet their needs. For instance, diagnosis of dementia is more likely to occur at a later stage for people from South Asian communities (5) and, partly as a consequence of this, South Asians living with Alzheimer’s disease are less likely to receive NICE-recommended medication (3, 4). Similarly, in a national online survey carried out by a co-applicant (Truswell) of the dementia needs of ethnic minority communities (19) 89% of the South Asian respondents stated that they did not feel that they had enough information about dementia.

A series of reviews have brought together evidence about the impact of ethnicity (6) and religion (20) on dementia pathways, innovative practice amongst South Asian communities (10), facilitators and barriers to access (1, 21), use of interpreters (15), and the attitudes, experiences and needs of carers (22).

The evidence that these reviews summarise falls into two areas:

1) Factors that reduce access to the dementia care pathway for people from South Asian communities:

1a. Cultural-specific factors. These include lower levels of awareness about dementia (9); differing expectations about care (6, 7, 22); greater levels of stigma (10, 12); and previous negative experiences of healthcare services (4, 6). Differences in nationality, language, religion, social class and migration routes to the UK all potentially impact on how dementia is experienced across different South Asian communities.

1b. Health service delivery. This acts as a barrier to utilisation when dementia services are not culturally acceptable or inappropriate (6, 21) (for instance by being held on a Friday, or by serving food that is not prepared appropriately), or lack sufficient resources to overcome linguistic and cultural barriers (1, 12, 15).

1c. Health policy. This impacts on uptake through inadequate financing, a workforce that lacks appropriate skills or commissioning frameworks that do not account for diversity (14).

2) Factors that enhance access to the dementia care pathway:

2a. Education. Improving dementia knowledge, awareness and attitudes within South Asian communities (3, 6, 7) and improving the awareness of staff within specialist dementia services about the needs of South Asian communities (3) both lead to improved service utilisation.

2b. Collaboration. Equitable access to services relies on the NHS working collaboratively with South Asian community and religious organisations (4, 15) to train staff to meet cultural and generational needs (2, 12, 22), facilitate access (12, 22) and culturally tailor services (2, 22).

While the research strongly points towards the potential for a package of interventions at different levels adding value to a dementia care pathway for South Asian communities, to date no systematic study of an enhanced pathway or indeed any adaptation of a NICE recommended intervention or assessment has been carried out. Additionally a search of the ISRCTN national database of studies indicates that no trials are being planned.

# 2 RATIONALE

**2.1 Why is this research important in improving the health and wellbeing of patients and health and care services?**

Dementia is a key priority for the NHS in all four UK nations. The health needs of people living with dementia from South Asian communities is clearly defined, for instance a large-scale analysis of primary care data that found that despite there being a higher risk of dementia amongst South Asian communities, the incidence of a diagnosis of dementia was 18% lower for South Asian women and 12% lower for men compared to their white counterparts (16). The most likely cause of this difference is the under-diagnosis of dementia within Asian communities. This is consistent with both the findings of the All Party Parliamentary Group on dementia (2) and NHS policy documents (17) all of which have identified a low rate of dementia diagnosis amongst ethnic minority communities and the need for increased support. Most recently, the 2018 NICE dementia guidance states that health and social care services need to be adapted to ensure that people from every community should have equal access to care. The need for an enhanced dementia care pathway for people from South Asian communities will steadily increase.

While the total number of people living with dementia in the UK will double in the next forty years, the numbers of South Asians with this diagnosis will increase seven-fold (2). This is due both to a higher incidence of risk factors such as diabetes and hypertension amongst South Asians and the fact that the average age of South Asians is rapidly rising as those people who came to the UK between 1950 and 1970 now approach old age. By 2051 proportionately higher numbers of people from South Asian communities will be experiencing dementia than will their white counterparts (18).

**2.2. What do we anticipate the outcomes and impact of the research programme will be?**

The key outcome for an enhanced dementia care pathway for South Asian people will be to improve engagement with dementia services provided by either the NHS or by VCSOs. Increased engagement will result in three key outcomes: increased rates of dementia diagnosis; diagnosis occurring at an earlier stage of the illness; and greater access to NICE recommended treatments.

These outcomes will impact on the health of patients and their families. Earlier and more timely diagnosis will reduce caregiver strain, maximise opportunities to adjust to the illness and to plan ahead. As people living with dementia would be more likely to receive their diagnosis at an earlier stage of the condition, they could therefore start treatment earlier, meaning that they (and their carers) can stay in work for longer. Improved access to treatments, including medication, will also enhance quality of life and improve functioning, thereby potentially delaying institutionalisation and reducing care home costs. As, currently, diagnosis of people from South Asian communities is more likely to occur as a result of a crisis, enhancing the dementia pathway is likely to reduce emergency admissions.

# 3 RESEARCH QUESTION/AIM(S)

The primary aim of this study is to identify the elements of an online toolkit that can be drawn on as necessary by commissioners, clinicians and care teams to meet the local needs of South Asians living with dementia. As there are many different South Asian communities and the profile of these communities varies across regions and cities, different services will draw on different elements of the toolkit in order to create bespoke versions of the pathway that meet local needs and priorities.

**3.1 Objectives**

Objective 1: Creating the content of the toolkit. We will identify existing interventions that enhance recognition of dementia symptoms, enable assessment, facilitate the effective use of interpreters and promote support after diagnosis. We will consult with communities to establish the most appropriate elements of the toolkit.

Objective 2: Identifying the implementation process. We will identify potential barriers and facilitators to effective collaboration between South Asian VCSOs, dementia-specific VCSOs, the NHS, and statutory services.

Objective 3: Creating video testimonies. We will generate new material in the form of video testimonies of South Asians living with dementia and South Asian dementia care workers about best practice. These testimonies will set out the principles and key elements of ADAPT in an accessible manner.

Objective 4: Integrating feedback from the three different work packages to create the ADAPT online toolkit.

Objective 5: Dissemination. We will disseminate the results of the project to stakeholders through community and clinical networks. We will also seek to make materials from the ADAPT toolkit available as part of existing online CPD courses.

**3.2 Outcome**

The main outcome of this study is to create an online toolkit. It will consist of three, complementary elements: first a comprehensive list of materials and resources that can be utilized together with guidance about potential strengths and limitations; secondly, information for clinicians about how to work effectively with people from South Asian backgrounds, for instance guidance about use of interpreters; finally, it will address potential barriers and facilitators of system co-operation between statutory and voluntary sectors – in effect a troubleshooting guide. The online toolkit will include written materials, links to relevant website and other resources and video testimonies

# 4 STUDY DESIGN and METHODS of DATA COLLECTION and DATA ANALYSIS

This mixed methods study consists of five work packages and will follow best practice in increasing the involvement of participants from Black, Asian and Minority Ethnic communities in health research (23):

**4.1 Work package 1: Identifying elements of the online toolkit**

This work package will be co-led by Drs Parveen (SP) and Jutlla (KJ). The aim of this work package is to identify the components of the online toolkit. This will be conducted in two phases. In phase one a rapid review will be conducted to identify culturally adapted materials, tools and resources. In phase two people living with dementia and their carers, and staff and volunteers working in health and social care and/or voluntary sector organisations will be asked to evaluate the materials identified.

**4.1a Work package 1: Phase 1 – Rapid review (months 1-2)**

A rapid review is a type of knowledge synthesis in which components of the systematic review process are simplified or omitted to produce information in a short period of time (Tricco et al., 2015). This review of the available literature will be conducted by a Research Fellow at the University of Bradford.

The aim of the review is to identify culturally specific versions of evidenced based materials, resources and best practice relating to three key elements of the dementia pathway:

1. *diagnosing well* (e.g. enhancing recognition of dementia in South Asian communities within primary care, culturally validated and translated dementia assessments and best practice guidelines for the use of trained interpreters);
2. *living well* (e.g. interventions to promote independence, support for carers and provision of respite care); and
3. *supporting well* (e.g. translated and culturally appropriate NICE recommended treatments, management of non-cognitive symptoms and use of advocates).

The rapid review will identify the evidence base for these adaptations and any gaps in the literature. Where an adapted version does not exist, then the best available, culturally neutral alternative will be identified. The findings of the review will be used to develop the content of the ADAPT toolkit.

*4.1a.1 Review questions:*

1. What materials, resources and best practice have been developed or adapted to raise awareness and aid diagnosis of dementia in people from South Asian communities?
2. What materials, resources and best practice have been developed or adapted to enable people from South Asian communities to live well and be supported with a diagnosis of dementia?
3. What is the evidence base for these materials and processes?
4. What and where are the gaps in the provision of culturally adapted materials, resources and best practice for people living with dementia and their carers from South Asian Communities?

*4.1a.2 Search strategy:*

The review will look at all literature, including grey literature and other sources of non-peer reviewed publications as it is likely that some adaptations and resources may not have been published in peer review journals. The search will not be time or location limited but, due to the rapid nature of this review, will be limited to citations written in English only.

The following examples of academic databases (some of which that cover grey literature) will be searched:

* Allied and Complementary Medicine Database (AMED)
* The Cochrane Database of Systematic Reviews
* Cumulative Index to Nursing and Allied Health Literature plus (CINAHL)
* EMBASE
* Health Management Information Consortium (HMIC)
* KSR evidence
* Medline
* PSychINFO
* PsycEXTRA
* Social Policy and Practice
* TRIP database

The following examples of web-based catalogues of grey literature will be searched:

* Department of Health and Social Care Reviews Facility: <https://eppi.ioe.ac.uk>
* EThOS by the British Library: <http://ethos.bl.uk/Home.do>
* Explore at the British Library: <http://explore.bl.uk/primo_library/libweb/action/search.do?vid=BLVU1>
* OpenGrey: <http://www.opengrey.eu/>
* Public Health England Knowledge and Library Services: <https://phelibrary.koha-ptfs.co.uk/>
* West of England AHSN Evidence Repository

The following examples of websites, search engines and non-peer reviewed publications will be searched:

* Alzheimer’s Europe: <https://www.alzheimer-europe.org/>
* Search engines such as Google [www.google.co.uk](http://www.google.co.uk) and Google Scholar: <https://scholar.google.co.uk/>
* National Institute for Health and Care Excellence: [www.nice.org.uk](http://www.nice.org.uk)
* The British Psychological Society – Faculty for Older People <https://www.bps.org.uk/member-microsites/dcp-faculty-psychology-older-people>
* Journal of Dementia Care [www.journalofdementiacare.co.uk](http://www.journalofdementiacare.co.uk)

*4.1a.3 Search Terms:*

The following example electronic search strategy will be used when searching via academic databases with a combination of MeSH and full-text search terms developed in (tbc). This search strategy will be modified for different websites and web based catalogue searching.

* *Population 1 – dementia:* (dement\*.mp OR exp dementia) OR (Alzheimer\*.mp OR exp Alzheimer Disease) OR (fronto temporal dement\*.mp OR exp frontotemporal dementia) OR (vascular dement\* OR exp multiinfarct dementia) OR (“lewy bod\*”.mp OR exp Lewy body OR exp diffuse lewy body disease)
* *Population 2 – South Asian communities*: (cultural diversity OR cultur\* OR ethnic\*OR ethnic minority OR Black Asian Minority Ethnic OR Black Minority Ethnic OR BAME OR BME OR Asian OR south Asian OR Indian OR Pakistani OR Bangladeshi OR Gujarati OR Sikh OR Muslim OR Hindi OR Asian British OR Punjabi)
* *Outcomes*: (Diagnos\* OR Assess\* OR “Cognitive assessment” OR Process OR Resource OR Policy OR material OR “best practice” OR Adapt\* OR Guideline OR Servic\* OR Barrier\* OR Interpret\* OR Translat\* OR Care OR Support OR Intervent\* OR Tool OR “Primary care” OR “secondary care”.)

*4.1a.4 Eligibility criteria:*

The results of the search will be eligible for inclusion if they relate to either people living with dementia from South Asian and/or carers of people living with dementia from South Asian communities and/or health and social care professionals working with people living with dementia from South Asian communities. The countries considered to be within the South Asian area include Afghanistan, Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan and Sri Lanka. Eligible citations will discuss, and/or outline and/or propose processes, and/or tools, and/or materials, and/or service models, and/or guidelines that have been developed to assist and/or improve the diagnosis, and/or care and/or support for people living with dementia in community settings. This could be through the development of something new or through the cultural adaptation of existing processes, tools, materials, service models and/or guideline.

Citations will not be eligible for inclusion if they relate to non-dementia topics e.g. mild cognitive impairment, Korsakoff Syndrome, delirium, if they relate to residential or institutional settings, e.g. nursing homes and acute hospitals.

*5.1a.5 Data extraction*:

Citations generated from the search will be stored and managed in reference software e.g. Endnote web and duplicates will be removed. A research fellow (primary reviewer) based at the University of Bradford will conduct the initial screen of the titles and abstracts against the eligibility criteria with a second reviewer screening 10% of the titles and abstracts. Disagreement at this stage will be resolved through discussion and if required reading the full text and further discussion with a third reviewer if required. The primary reviewer will then conduct the full text screening and extract data using a pre-designed data extraction form. A second reviewer will check at least a 10% random sample of extractions for accuracy. Disagreements will be resolved through discussion. Extracted data will include title, author(s), date of publication, study design and methodology, number of participants, setting, intervention, outcome/results summary, recommendations for practice and/or policy.

In addition, clinicians and commissioners working in the field will be contacted through existing networks (e.g. FPOP, memory assessment services), for information on any known culturally adapted or developed materials in use. We will contact Voluntary Community Sector Organisations or VCSOs (e.g. Race Equality Foundation, TiDE, Alzheimer’s Society) for information on their use of material, resources and best practice. We will advertise our requests for information using social media such as Twitter and will place letters in professional journals, publications and newsletters requesting information on materials, resources and best practice being used in south Asian communities.

*4.1a.6 Quality Appraisal:*

The primary reviewer will conduct a quality assessment using the appropriate critical appraisal checklist from the Critical Appraisal Skills Programme (<https://casp-uk.net/>) for the study design.

*4.1a.7 Data synthesis:*

The purpose of this review is to identify material that can be shared within and aid discussion at subsequent workshops with people directly affected by dementia from South Asian communities. The material collected will be grouped around the three areas of the dementia pathway; diagnosing well, living well and supporting well.

In addition, the rapid review will be published in a peer-reviewed journal and a shorter more accessible article in a non-peer reviewed publication e.g., the *Journal of Dementia Care*. The data will be presented in a narrative synthesis. The report will be written following the PRISMA guidelines. Summary tables will be presented to show the results from the completed quality appraisal checklists and data extraction forms. In addition, this paper will provide recommendations from the review and will highlight the identified gaps in the provision of culturally adapted materials and resources for people living with dementia from south Asian communities in the UK.

**4.1b Work package 1: Phase 2 - Evaluating the results of the rapid review with stakeholders and identifying toolkit items (months 3-6)**

The aim of this second phase of work package 1 is to evaluate the materials, resources and best practice that were identified during the rapid review (phase 1) with two groups of stakeholders; people living with dementia and their carers and staff and volunteers working in VCSO and NHS organisations. Given the restrictions imposed as a response to the pandemic, recruitment and data collection for this work package will be conducted either through video or teleconferencing facilities. It is envisaged that face to face meetings and workshops will not be conducted during this project. The detailed contingency planning for Covid-19 restrictions is found in appendix XX.

*4.1b.1 Stakeholder group 1: People living with dementia and their carers*

*4.1b.1.1 Recruitment*

Potential participants will be recruited predominately via community groups and organisations such as VCSOs that are working directly with people living with dementia and their carers from South Asian communities. These organisations will be largely based in the West Yorkshire and Wolverhampton areas. They will promote the opportunity to take part in the study through their newsletters, mailing lists and social media platforms. If appropriate, members of the research team will attend any virtual group sessions run by the organisations to introduce the study and invite those in attendance to take part in the study. Potential participants can either express their interest in taking part directly to the research project team or via the community groups. In addition, we will also use our national research and clinical contacts to purposively select participants from a wider area who have relevant appropriate expertise. Social media including Twitter will be used to further promote the study. A minimum of thirty carers and people living with dementia across the two sites.

*4.1b.1.2 Data collection*

In our original proposal, it was planned to collect data via two workshops, one in the West Yorkshire area and one in the Wolverhampton area. Given the possible restrictions likely to be in place due to the pandemic, face-to-face workshops are no longer a feasible method of collecting this data with this stakeholder group. Methods of data collection will be flexible and participant-led. Potential participants will be provided with different options for taking part in this research depending on the ease to which they can access and use technology. If people are unable to use platforms such as Zoom and MS Teams or do not have access to the resources to use such platforms, they will be offered the option of being interviewed over the telephone. Consent will be collected verbally or through gestures (e.g. ‘*thumbs-up*’) and recorded.

To enable people to prepare for the interview/appointment and to be familiar with the data, participants will be provided with a summary of the findings of the rapid review, and if appropriate a guide to using the online technology. Interviews will last up to one hour and will be conducted by members of the research team including a public contributor. Participants will be provided with concrete examples to aid the conversations around their reflections of the findings from the review. A topic guide will be developed which will be used to guide the conversation with both stakeholder groups. Specifically, participants will be asked how the findings from the review can be used to adapt each of the three elements of the pathway. The central questions that we will ask participants to address are to identify what materials can be used to enhance each part of the pathway, how we can adapt what is currently available to make it suitable for use and the drawbacks and advantages of each. We will ask participants to make pragmatic recommendations about what, in their opinion constitutes best practice and why this is the case. They will be asked to review materials that have been translated and validated as well as linguistically and culturally neutral alternatives. At the end of the interview, participants will be asked if they would be interested in being part of the video recordings in Work Package 3. Interviews will be audio-recorded.

*4.1b.2 Stakeholder group 2: Staff and volunteers from VCSOs and NHS services*

*4.1b.2.1 Recruitment*

Up to thirty staff and volunteers working in both VCSO organisations and statutory NHS services supporting people living with dementia and their carers will be invited to take part in online workshops. A number of BAME-led VCSO organisations in the West Yorkshire and Wolverhampton areas have already agreed to support this research in both stakeholder groups. Other dementia-focused VCSOs such as the Alzheimer’s Society and Dementia Action Alliance will be approached to invite their staff and volunteers to take part in the online workshops. The opportunity will also be advertised on social media.

A number of methods to recruit participants from the statutory NHS stakeholder group such as NHS Trusts in the West Yorkshire and Wolverhampton areas, professional networks and bodies, and social media will be used. This includes asking memory clinics and dementia services to advertise the opportunity to staff with the support of the Research and Development departments of the local NHS Trusts.

We will purposively sample across this stakeholder group to ensure that we hear from a number of different people with varied experiences of delivering support and services to people affected by dementia from south Asian backgrounds. As with stakeholder group 1, if potential participants are unable to take part in an online workshop then they will be offered the opportunity to take part in a one to one video or telephone interview.

*4.1b.2.2 Data collection*

Online workshops will last around 90 minutes including regular comfort breaks. Participants will be divided into virtual breakout rooms with up to six participants in each group with a member of the research team as facilitator and an interpreter if required. As with stakeholder group 1, participants will be provided with a summary of the review findings prior to the workshop. For consistency across the different data collection methods, the topic guide developed for stakeholder group 1 will be used to generate the group discussions. In this instance, we will use a consensus-based approach (Susskind 1999; https://www.seedsforchange.org.uk/consensus.pdf) to identify best practice changes to the pathway that can be widely agreed on. At the end of the workshop, participants will be asked if they would be interested in being part of the video testimonies in work package 3. Workshop discussions will be audio-recorded.

*4.1b.2.3 Data analysis*

A detailed qualitative analysis of transcripts from the audio recordings from the interviews and workshops will not be conducted. The analysis of these data will focus primarily on identifying a consensus around items to be included in the toolkit, and the reasons behind decisions about the acceptance or rejection of an item.

**4.2 Work package 2: Identifying Barriers and Facilitators to Effective Collaboration**

This work package will be led by Prof Cheston (RC) and Dr Smith (PS) supported by Dr Dodd (ED). Given the pandemic situation, it is envisaged that all data collection will be conducted through either through telephone interview or online via MS Teams or Zoom.

The aim of this work package is to identify barriers, facilitators and the fundamental components to effective collaboration between different organisations that provide dementia services and support people from South Asian communities living with dementia. This will be achieved in two phases. Phase 1 involves interviewing staff and volunteers working in organisations mainly in the Bristol and south-west. Phase 2 involves workshops with similar staff and volunteers in mainly the Bradford and Wolverhampton areas. To avoid contamination, people who participate in phase 1 will not be eligible to take part in phase 2.

**4.2a Work package 2: Phase 1 - Vignette development (months 1-2)**

The aim of Phase 1 is to develop up to three vignettes from data collected from online interviews with around twelve participants working with those living with dementia from South Asian communities in the Bristol and South-West area. These vignettes will be used as the basis for discussion within phase 2. Interviews will follow a semi structured interview topic guide which will be based on the themes generated from our previous work (e.g. Parveen, Blakey and Oyebode 2015; Blakey, Parveen and Oyebode 2016).

*4.2a.1 Recruitment*

Staff and volunteers working in BAME-led Voluntary and Community Sector Organisations (VCSOs; e.g. Dhek Bhal, and the Asian day centre) in the city of Bristol and across the south-west that support people living and caring for people with dementia from South Asian communities will be invited to take part in the interviews. Staff and volunteers from the local NHS provided service (Bristol Dementia Wellbeing Service and Avon and Wiltshire Mental Health Partnership NHS Trust) and from the local Dementia Action Alliance and Alzheimer’s Society will also be invited to be interviewed. The interviews will be promoted through email flyers and at team meetings, social media and snow-balling. We will purposively sample organisations and staff to ensure that we hear from a range of different voices at all levels of the included organisations. A member of the research team will attend the organisations’ team meetings virtually to introduce and explain the purpose of the study and the procedure. Potential participants will be invited to contact the researcher either via email or phone for more information if they chose to be interviewed for the study. Up to twelve participants will be recruited in this phase.

*4.2a.2 Data collection*

The focus of the interviews will be on barriers and facilitators to communication and joint working that can emerge at different interfaces between VSCOs and the NHS. These may arise as a result of organisations having different priorities, different levels of resources to draw on or different working practices. Consequently, problems may arise in working with families and individuals or in co-operating as organisations. Interviews, lasting up to an hour, will be conducted by ED, PS and RC. An interview topic guide that draws on the themes in this area from previous work by the project team will be further developed in collaboration with the PPI project partners. Interviews will either be face-to-face (if permitted by local and national guidelines) or more likely via video platforms (MS Teams) or telephone, dependent on the preference of the participant. Interviews will be audio-recorded and then transcribed using a transcription company that is compliant under the General Data Protection Regulations.

*4.2a.3 Data analysis*

Data from the interviews together with information from previous work by the team will be used as the basis for the development of up to three vignettes by PS, ED and RC. These will then be checked and modified where appropriate by the wider team including PPI partners and then used in Phase 2 as the basis for discussion. Evans et al. (2015) have produced a list of fifteen recommendations for generating vignettes (see table 1). To ensure good construct validity, we will follow these recommendations when developing the vignettes for this study.

Table 1 (taken from Evans et al. (2015), p. 165) - Vignettes should:

1. Derive from the literature and/or clinical experience
2. Be clear, well-written, and carefully edited
3. Not be longer than necessary (typically between 50 and 500 words)
4. Follow a narrative, story-like progression
5. Follow a similar structure and style for all vignettes in the study
6. Use present tense (past tense only for history and background information)
7. Avoid placing the participant ‘‘in the vignette’’ (e.g., as first- or third-person character)
8. Balance gender and age across vignettes\*
9. Be as neutral as possible with respect to cultural and socio-economic factors\*
10. Resemble real people, not a personification of a list of symptoms or behaviours
11. Be relatable, relevant, and plausible to participants
12. Avoid ‘‘red herrings’’, misleading details, and bizarre content
13. Highlight the key variables of interest, facilitating experimental effects
14. Facilitate participant engagement and thinking by including vague or ambiguous elements
15. Cover all pertinent variables (or omit selected variables for specific purposes)

\* Exceptions may apply if these factors are included among the experimental variables

The vignettes will focus on the broad issues and cross cutting themes across the different organisations, for example communication, access and culture. We aim to deliver the vignettes creatively such as through a storyboard or through short video clips. Time allowing, we will validate and further refine our vignettes with a small number of participants that were previously interviewed before using them in phase 2. The vignettes will be used as a means to generate discussion in workshops in phase 2.

**4.2b Work package 2: Phase 2 - Workshops to identify best practice (months 3-6)**

The vignettes generated during phase 1 will be used to generate discussions within an online workshop setting. They will focus on the fundamental issues of barriers and facilitators faced by both voluntary and statutory organisations when trying to work together to ensure people affected by dementia are being provided a high-quality service. Examples of such barriers include issues around different priorities and different level of resources available. Up to twenty-four participants in the focus groups will be drawn largely from people working with those living with dementia from South Asian communities in mainly the West Yorkshire and Wolverhampton areas. The vignettes will detail the fundamental components of barriers and facilitators to joint working to be further explored with workshop participants.

*4.2b.1 Recruitment*

To ensure that no contamination takes place between phase 1 and phase 2, participants for phase 2 will not be recruited in the Bristol/South-West area. Staff and volunteers from VCSOs and NHS Trusts in the Bradford and Wolverhampton areas providing dementia services in predominately the Bradford and Wolverhampton areas will be invited to take part in phase 2. We aim to recruit up to twenty-four participants in this phase (twelve from each geographical area). Participants will be invited to take part through a number of channels including advertising through posters, email, internal newsletters, social media. A member of the research team will also attend a team meeting at each of the identified stakeholder organisations, most probably virtually in each area to introduce and explain the purpose of the study and the workshop. Potential participants will be invited to contact the research team to sign up to the workshop.

*4.2b.2 Data collection*

Online workshops will last up to 90 minutes. The vignettes developed in phase 1 will be sent to participants prior to the workshop. An interpreter will be present if required (although members of the project team may be able to act as interpreters). Participants will be divided up into small groups between four to six people to discuss each of the vignettes. Areas of discussion will include their initial responses to the vignettes, whether these are plausible scenarios, whether there are ways of preventing such scenarios from occurring and the potential responses that might aggravate or ameliorate any challenges to joint working. Participants will be asked to problem-solve and find solutions that would enable their organisations to overcome the obstacles presented in the vignettes.

Workshops will be conducted online via a suitable platform such as MS Teams or Zoom. We will use the breakout room facilities on these platforms to divide the session up into the smaller working groups. Each smaller group will have a researcher facilitator and if required, an interpreter and will be homogenous groups e.g. NHS staff, BAME-led VCSOs, and dementia-specific VCSOs. The breakout groups will reconvene to share learning across the different organisations in the final session of the workshop. The workshops will be recorded on the platform and partial transcription conducted to aid data analysis.

We do not wish to exclude people who are unable to take part online but who would otherwise have taken part in a face-to-face workshop. In this instance, participants will be offered the option of a teleconference or an interview on the phone. Verbal consent will be obtained, and this will be recorded. The vignettes will be provided prior to the teleconference/phone interview.

*4.2b.3 Data analysis*

The data from the workshops and interviews will be analysed using thematic analysis (Braun and Clarke 2008) by RC, PS, and ED initially, taking this initial analysis back to the wider research team, including the public contributor for further discussion. The agreed themes from this analysis will be used to develop illustrative examples of best practice and innovative methods of overcoming barriers to joint working across organisations. These examples will be incorporated into the online toolkit either as written or video case studies. The vignettes developed to generate discussion in phase 2 will also be available on the online toolkit.

**4.3 Work Package 3: Video Testimonies About Best Practice – (months 7-9)**

This package will be led by Truswell and Butt. We intend to use video testimonies to facilitate communication with as wide a range of people from different South Asian communities as possible to illustrate and enhance the online toolkit. All activities related to filming including travel will adhere to Covid-19 guidelines in place at that time. Should national and local guidelines preclude filming contributors face-to-face, then we will film contributors online in consultation with the media company contracted to create the videos, Flexible Films.

*4.3.1 Recruitment*

Up to eight people will be invited to provide video testimonies from people living with dementia, their carers from South Asian communities and staff and volunteers who have experience of working in dementia care. Participants will be identified from existing contacts that the Race Equality Foundation (REF) and Dementia Alliance for Culture and Ethnicity (DACE) have within South Asian communities, and from people who have already participated in WP 1 & 2.

*4.3.2 Video content*

The company Flexible Films will carry out the filming under the guidance of Truswell and Butt. The video testimonies will relate directly to issues that have been identified in the research and will illustrate best practice (e.g. around the use of translators, and how to be culturally respectful). Where required we will fund interpreters in the main South Asian languages and use subtitles. Four sets of testimonies, lasting around five minutes, will be recorded and will illustrate each of the areas of the toolkit. These videos will complement the written materials available on the toolkit. Shorter version of the video testimonies will be created to allow for sharing on social media.

**4.4 Work Package 4: Drafting The Toolkit (months 10-11)**

This WP will be led by Cheston and Dodd. The analyses conducted following the workshops in WP2 will identify the core materials and processes to be included in the toolkit. These findings will be reviewed by the study steering committee. The written materials identified from the rapid review will then be combined with the process learning from the workshops and the video testimonies to create the online ADAPT toolkit on a bespoke project website hosted at the Race Equality Foundation. The toolkit will primarily be aimed at dementia clinicians, managers and commissioners. However, there will also be a section that is aimed at people affected by dementia.

The ADAPT toolkit will address three levels of the dementia care pathway: diagnosing well, living well and supporting well. While it is likely that for some communities aspects of the pathway will be covered more comprehensively than others, the ADAPT toolkit will represent a range of care options that services can choose from to meet local needs. As well as the specific materials identified in WP1, each level will also include generic guidance about best practice (as identified by workshop participants), for instance how to be culturally respectful. This will ensure that material for each level of the pathway is suitable for South Asian people from different nationalities and religions. Where it is not possible to identify culturally specific material, then culturally neutral alternatives will be recommended.

**4.5 Work Package 5: Toolkit dissemination (month 12)**

Main findings will be published in high impact, peer-reviewed, open access journals (e.g. International Journal of Geriatric Psychiatry). Findings will also be presented to clinicians at relevant national meetings (e.g. UK Dementia Congress) and International Conferences (e.g. Alzheimer’s Europe) and by disseminating them through clinical networks (e.g. the RCP’s Memory Services National Accreditation Programme network).

If permitted, a roadshow will be held in Bristol, West Yorkshire and Wolverhampton to present the findings and promote the toolkit to those who participated in the research and the wider community. If such an event is unable to go ahead due to the pandemic, then this will be held as an online seminar. Other areas of promotion include through press releases, institution websites and the media including community radio. Woma (Equalities and Diversity Lead for BNSSG CCG) will assist in disseminating ADAPT to commissioners.

# 5 STUDY SETTING

Information detailing the study settings is found in the work packages in section four.

**6 SAMPLE AND RECRUITMENT**

The development of our methodology is informed by two key considerations: firstly South Asian communities are characterised by a diversity of cultures, religions and languages. Consequently, this study is based in three different areas (Bradford/West Yorkshire, Wolverhampton and Bristol/the South West) which each has a different profile of South Asian communities. According to the 2011 census, 20% of the people living in Bradford have their origins in Pakistan. There are a smaller number of people with their origins in India (2.5% of the overall population) and Bangladesh (1.9% of the populace). Similarly, a quarter of the population in Bradford identify themselves as Muslim, with just 1% being Sikh. Wolverhampton, in contrast, has the second largest Sikh population residing in the UK (9% of the population) with 3.7% of the city being Hindus. In Bristol, there are roughly equal (but lower) numbers of people from Pakistan (1.6%) and India (1.5%).

**6.1 Eligibility Criteria**

*6.1.1 Inclusion criteria*

A number of different populations will be recruited for this study. Participants will be eligible if:

* They live with a form of dementia (e.g. Alzheimer’s disease, vascular or mixed dementia) from a south Asian community (i.e. a family background from India, Afghanistan, Pakistan, Bangladesh, Nepal, Bhutan, the Maldives and Sri Lanka) - WP1, phase 2 only
* They have experience of providing informal care to a family member or close friend who falls into the first category - WP1, phase 2 only
* They work for an organisation (either community based or a statutory service) which cares for and supports people in the first two categories - WP1, phase 2; WP2, phase 1 & 2

Given that data collection will most likely be via online or telephone methods, participants will need to have access to either a phone and/or the technology to connect through MS Teams or Zoom.

There is no criteria around gender or age but by using purposive sampling the aim is to recruit a sample across the gender and age spectrums. Participants from WP1 and 2 will be invited to take part in WP3.

*6.1.2 Exclusion criteria*

Participants who lack capacity to consent to the study will not be eligible for recruitment.

**6.2 Sampling**

6.2.1 Size of sample

Table two shows the breakdown of minimum recruitment target within each work package.

|  |  |  |
| --- | --- | --- |
|  | People living with dementia and informal carers | Staff and volunteers working for organisations supporting PLWD |
| WP1 Phase 2 | 30 | 30 |
| WP2 Phase 1 | N/A | 12 |
| WP2 Phase 2 | N/A | 24 |
| WP3 | Up to eight participants will be recruitment across the two populations for this work package | |

6.2.2 Sampling technique

A purposive sampling technique will be used to ensure a range of experiences and voices are heard. The team have good existing relationships with the VCSOs that have agreed to identify participants and be part of this project and so will be aware of the population they support.

**6.3 Recruitment**

6.3.1 Sample identification

Sample identification has been described in detail in section five under the work packages. Participants will be identified through community groups and organisations in predominately the Bristol/South West, West Yorkshire and Wolverhampton areas. Previous experience suggests that personal contacts are critical when engaging with people from South Asian communities around what can be a sensitive issue, we will work with Subitha Baghirathan to facilitate recruitment in the Bristol area and Manjit Nijjar in the Wolverhampton Area.

6.3.2 Consent

# 7 ETHICAL AND REGULATORY CONSIDERATIONS

## **7.1 Assessment and management of risk**

There are a number of risks associated with this project. We have carried out a full risk assessment (see appendix XX) and a risk and mitigation document (appendix XX) particularly related to Covid-19 that details how we set out to manage that particular risk. In summary:

Exposure to Covid-19. We have moved to online data collection supplemented by telephone calls where participants prefer this. We will provide participants with the option of borrowing a tablet if they do not otherwise have access to the internet. Research practice will follow local and national guidance around social distancing and use of PPE.

Risk of distress. Discussing the process of assessment, diagnosis and treatment can be distressing for people whose lives have been affected by dementia. This risk is aggravated by the possibility that participants have experienced discrimination or racial abuse during this process. The distress protocol found in appendix XX provides more details on managing such risk.

**7.2 Research Ethics Committee (REC) and other Regulatory review & reports**

Before the start of the study, a favourable opinion will be sought from the University Ethics committee REC for the study protocol, informed consent forms and other relevant documents e.g. advertisements. Health Research Authority approvals to conduct the research with NHS staff and volunteers will be applied for using the Integrated Research Application System (IRAS).

*7.2.1 Regulatory Review & Compliance*

Appropriate site specific approvals will be in place prior to any recruitment to the study. Specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance. It is envisaged that governance for non-NHS sites will be carried out under the University ethics committee guidance.

For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as [amended](http://www.hra.nhs.uk/resources/after-you-apply/amendments/).

*7.2.2 Amendments*

Amendments will decided amongst the project management team. Any amendments will be notified at the steering group committee. The University ethics amendment process will be adhered to if an amendment is warranted for this study. The IRAS system will be used to notify any amendments relating to participating NHS sites. HRA processes will be followed to ensure that all sites work to the most recent version of the protocol.

**7.3 Patient & Public Involvement**

*7.3.1 Management of the research*

To ensure diversity within the study’s management, three PPI representatives who are all carers for people with dementia (Manjit Nijjar, Dalbinder Sanghera and Jag Kaur) have all agreed to be part of the steering group. Along with Dr Naheed Mukadam (Clinical Research Fellow at University College London) and Subitha Baghirathan (independent dementia consultant), their involvement in the steering group in this way will enable us to encompass generational, religious and cultural heterogeneity.

*7.3.2 Data collection*

Manjit Nijjar and Dalbinder Sanghera will be part of the data collection process as peer researchers. They will receive training from Jutlla and will be supported by People in Research South-west.

*7.3.3 Dissemination*

Manjit Nijjar and Dalbinder Sanghera will also take part in the online video ‘roadshows’ that we will hold to disseminate the results of the research. Additionally, a key feature of our study will be the collection on video testimonies from south Asians in which they will describe what they consider to be the most important aspects of good practice for practitioners. More generally, members of the research team have an established track record in working with South Asian people living with dementia and their families to bring about service change. SP was the lead author in a paper describing the role of experts by experience in the Caregiving HOPE study. DT is the Executive Director of the Dementia Alliance for Culture and Ethnicity (DACE), an alliance of groups providing information and support to people living with dementia from Black, Asian and minority ethnic communities in the UK. DACE carries out a range of activities to boost awareness of dementia within BAME communities. Jutlla was a co-author of a toolkit setting out best practice around increasing engagement and recruitment of people from BAME communities in mental health research.

**7.4 Protocol compliance**

Protocol deviations will be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

### 

**7.5 Data protection and patient confidentiality**

Participants will be provided with a data privacy notice which outlines how we intend to use and store their data and that their data will be used for the stated purposes of the study. Only members of the research team will have access to the data. Data minimisation will be achieved by collecting minimal personal data. Personal data collected which include name and a contact number.

Online meeting using Microsoft teams will be recorded using the facilities provided on Teams. This includes the automatic transcription option. These recordings are saved to Microsoft Stream (a secure cloud-based service). Following the meeting, the transcript will be checked for accuracy (and where necessary translated, see below) and anonymised through the removal of people’s names and other personal information. Where necessary non-identifiable terms or pseudonyms will be used instead. Transcript data will be anonymised through the use of unique participant identification codes, which will be used in all data storage files; these will not contain names or any other means of personal identification. Following checking, the data recording on Microsoft Stream will be deleted.

The transcripts will be stored electronically on computers and access will be controlled via passwords and

permissions to dedicated study folders. Where it is necessary to create hard copies of transcripts or other data, then these will be securely stored in locked filing cabinets that are accessible only to research staff. Participants’ personal details (including their names and addresses) will only be used to maintain contact with participants. This will be stored separately from transcriptions and will be kept in a separate file on a password protected computer at the relevant study site. Access to data will be limited to quality control, audit, and analyses. Data shared between sponsor and coinvestigators will be de-identified to minimise breach of confidentiality.

7.5.1 Home working.

We anticipate that members of the research team will work from their University offices and store electronic data on either secure one drives, or on a hard drive on their office computer. Should guidance around the pandemic prohibit this and make it necessary to work from home, then we will store electronic data using a University OneDrive, following the relevant university guidelines for home working during the pandemic. Electronic data will not be stored using home computers. Hard (paper) copies of personal data will not be kept at home.

7.5.2 Sharing of data.

As part of the checking of transcripts, it may be necessary to share recordings on Microsoft Stream between researchers or between the research team and translators. Recordings are cloud based and can only be accessed using a secure, password-based process. Recordings will not be downloaded and will be deleted once the checking and transcribing process has been completed.

7.5.3 Translation of recordings.

Members of the study team are fluent in some south Asian languages and previously have not required to use translators. However, if this does prove necessary, then we will use a translation services approved by the relevant university. They will access the recordings on Microsoft Stream and notify the lead for the work package when they have completed the transcription. Copies of the translated transcript will be in password protected forms and shared via Microsoft Teams.

7.5.4 Reporting of data.

In reports of the work, where excerpts are quoted from interviews, any information that might lead to the identity of participants, other people or organisations being inferred will be disguised.

7.5.5 Data disposal.

Recordings of meetings including focus groups and online interviews will be deleted once a transcription of the meeting has been checked and agreed. Personal details will be securely deleted at the end of the study. Anonymised data in the form of interview transcripts will be transferred to XXXX data repository at the end of the research and stored for up to XX years before being destroyed. Further information on data management can be found in the data management plan in appendix XX

7.6 Indemnity

The University of the West of England, Bristol (“UWE”) insurance arrangement for employees and for students working under the supervision of a UWE employee and where the project is included on an authorised UWE research register.

For research which is not deemed a clinical trial (i.e. not on UWE’s clinical trials register) UWE’s Professional Indemnity policy provides insurance cover for indemnity against legal liability for damages and claimant’s costs and expenses arising out of any act, neglect, error or omission (i.e.. wrongful advice given in good faith).

UWE’s Employers Liability Insurance is in place to protect UWE’s employees if they are harmed whilst engaged on UWE business, should UWE be held legally liable.

UWE’s Public Liability insurance policy covers legal liability for third party personal injury, death, disease or illness to any person or loss or damage to third party property. Details of the Employers / Public and Professional Indemnity policy covers are attached.

**7.7 Access to the final study dataset**

The co-applicants of this project detailed at the outset of the protocol will have access to the full dataset. The co-applicants with input from the steering group will work together to identify at what points study progress can be promoted e.g. through social media and the ADAPT study website. Any secondary analysis of the data will be permitted with consent from participants.

### 8 DISSEMINIATION POLICY

### 8.1 Dissemination policy

*8.1.1 Background IP*

The online toolkit will utilise third party materials. The decision of which specific materials to use in the online toolkit, will be arrived at during the first stages of the project. Then relevant third parties will be contacted to ask for permission to use their materials. It is likely that there will be benefits for copyright holders to licence their material to us on a royalty free basis and consequently we do not envisage significant hurdles in obtaining such permissions. However, if some organisations are looking for a royalty-bearing, copyright licence, in the first instance we will seek to negotiate the appropriate, cost-reasonable terms. Alternatively we may signpost to conventional subscription based resources, for example as is the case with some PROM and similar health-assessment protocols.

*8.1.2 Foreground IP*

The research data and research materials (e.g. digital recordings, transcripts) will be owned by the Sponsor, the University of the West of England, Bristol (UWE). UWE Bristol will own these materials to ensure and enable their management of data archiving in line with their obligations as Sponsor to the research.

The online toolkit as a whole will be owned by the grant Host, NHS Bristol, North Somerset and South Gloucestershire CCG on behalf of the NHS. Licences will be granted to all collaborating parties (within the collaboration agreement) for use of the Foreground IP for non-commercial charitable, academic and teaching purposes

*8.1.3 Study reporting*

On completion of the study, the data will be analysed and tabulated and a final study report will be prepared. This will be published and accessed on the ADAPT website. The funder will be acknowledged in the study report.

Participants will be informed of the findings through a virtual roadshow event and through a newsletter summary of the final report.

**8.2 Authorship eligibility guidelines and any intended use of professional writers**

There is no intention to use professional writers to write the final study report or the published papers arising from this project. It is envisaged that all co-applicants will be involved in the authorship of the final study report and at least one paper arising from the project. The International Committee of Medical Journal Editors criteria for defining authorship will be followed when submitting manuscripts to journals.

### 9 REFERENCES

### 10. APPENDICIES

**10.1 Appendix 1- Required documentation**

List here all the local documentation you require prior to initiating a participating site (e.g. CVs of the research team, Patient Information Sheet (PIS) on headed paper etc.).

**10.2 Appendix 2 – Schedule of Procedures**

**10.3 Appendix 3 – Amendment History**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Amendment No.** | **Protocol version no.** | **Date issued** | **Author(s) of changes** | **Details of changes made** |
|  |  |  |  |  |